PUBLIC PACKET

OREGON BOARD OF DENTISTRY

BOARD MEETING
JUNE 17, 2016

APPROVAL OF MINUTES

OREGON BOARD OF DENTISTRY
MINUTES
April 22, 2016

MEMBERS PRESENT:
Alton Harvey Sr., President
Julie Ann Smith, D.D.S., M.D., M.C.R., Vice-President
Todd Beck, D.M.D.
Amy B. Fine, D.M.D.
Jonna E. Hongo, D.M.D.
Yadira Martinez, R.D.H.
James Morris
Alicia Riedman, R.D.H.
Brandon Schwindt, D.M.D.
Gary Underhill, D.M.D.

STAFF PRESENT:
Stephen Prisby, Executive Director
Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator
Daryll Ross, Investigator (portion of meeting)
Harvey Wayson, Investigator (portion of meeting)
Daniel Blickenstaff, D.M.D., Investigator (portion of meeting)
Teresa Haynes, Exam and Licensing Manager (portion of meeting)
Ingrid Nye, Office Specialist (portion of meeting)
Mary Campbell, Office Support (portion of meeting)

ALSO PRESENT:
Lori Lindley, Sr. Assistant Attorney General
Sue Diciple, Strategic Planning Facilitator (portion of meeting)

VISITORS PRESENT:
Christina Swartz Bodamer, ODA; Pamela Lynch, R.D.H.; Bruce Burton, D.M.D., ODA; Lynn Ironside, R.D.H., ODHA; Mary Harrison, ODAA; Heidi Jo Grubbs, R.D.H.; John Terpening, LFO; Christopher Hamilton, RBH/HPSP; Anthony Medina, DAS; David Lambert; Harold Hickok

Call to Order: The meeting was called to order by the President at 7:38 a.m. at the Board office; 1500 SW 1st Ave., Suite 770, Portland, Oregon.

NEW BUSINESS

MINUTES

Dr. Smith moved and Dr. Hongo seconded that the minutes of the February 19, 2016 Board meeting be approved as presented. The motion passed with Dr. Beck, Dr. Fine, Dr. Hongo, Mr. Morris, Dr. Smith, Dr. Schwindt, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

ASSOCIATION REPORTS

Oregon Dental Association
Dr. Bruce Burton reported that the ODA appreciated the Board's assistance with their annual educational meeting. Dr. Burton reported it was a successful meeting with 6,609 attendees; of these, 5,542 were dental professionals. Dr. Burton also reported that the ODA peer review continues to work with consumers, with the ODA assisting when they can and referring most to the OBD.

Oregon Dental Hygienists' Association
Lynn Ironside reported that the ODHA would be having their annual EPDH conference May 20, 2016 – May 21, 2016 at the Holiday Inn in Springfield and would include two days of continuing education, which would include training to obtain and use Epi-Pen and Glucagon. The speaker will be William Laird. Dr. Jonna Hongo recognized Lynn Ironside for her many years as a great representative for Dental Hygiene.

Oregon Dental Assistants Association
Mary Harrison reported that the ODAA appreciates being included as a part of the Board's proceedings and on committees.

COMMITTEE AND LIAISON REPORTS

WREB Liaison Report
Dr. Jonna Hongo had nothing to report at this time. Yadira Martinez reported on a recent meeting of the Hygiene Exam review board. The next meeting is scheduled for June 8, 2016 and will be held in Austin, Texas.

AADB Liaison Report
Dr. Amy Fine had nothing to report at this time. Dr. Beck reported on his recent attendance at the AADB's mid-year meeting held in April in Chicago. He expressed interest in the continuing discussion on license portability and enjoyed the meeting.

ADEX Liaison Report
Dr. Jonna Hongo had nothing to report at this time. Dr. Amy Fine has agreed to be the OBD's ADEX dental liaison with Dr. Hongo leaving the Board.

CDCA Liaison Report
Dr. Amy Fine had nothing to report at this time. Stephen Prisby recognized Mr. James Morris, who has accepted a public position on the CDCA's public advocacy committee.

Board Committee Report
The Board has three committee meetings scheduled: Enforcement and Discipline Committee is scheduled to meet on May 17th, the Licensing, Standards and Competency Committee meeting is scheduled to meet on May 19th and the Anesthesia Committee is scheduled to meet on July 26th. The Rules Oversight Committee meeting has yet to be scheduled.

EXECUTIVE DIRECTOR'S REPORT

Board Member & Staff Updates

Mr. Prisby stated that he received interest forms from the governor's office for the upcoming Board vacancy with Dr. Jonna Hongo's term expiring in April. He thought a replacement would be announced by the Governor's Office in May. The office manager position was posted on the state's employment website through April 18th, as Mr. Prisby chose to end the Trial Service of the former office manager. The OBD has hired a temporary office support person to assist while the position is filled. Mr. Prisby reported that 94 people applied for the office manager position and that someone should be hired in May.

Legislation & Executive Order Updates

Mr. Prisby reported that the short legislative session started February 1st and ended March 6th. Mr. Prisby stated that he attached proposed legislation that will have a direct impact on the Board.

Budget Status Report

Mr. Prisby reviewed the latest budget report for the 2015 - 2017 Biennium. This report, which is from July 1, 2015 through February 29, 2016, shows revenue of $1,233,679.42 and expenditures of $801,888.28. Board members were asked if they had any questions regarding the budget.

Customer Service Survey Report

Mr. Prisby discussed the legislatively mandated survey results from July 1, 2015 – March 31, 2016, and comments received. The results of the survey show that the OBD continues to receive positive ratings from the majority of those that submit a survey.

Board and Staff Speaking Engagements

Mr. Prisby stated that he and Dr. Paul Kleinstub made a presentation to the third year Dental Students at the OHSU School of Dentistry in Portland on Wednesday, February 24, 2016.

Mr. Prisby stated that he and Teresa Haynes made a License Application Presentation the Dental Hygiene students at ODS/OIT in La Grande on Monday, February 29, 2016. We were also joined by Dr. Gary Underhill who shared some words of wisdom from a Board member's perspective.

The Oregon Dental Conference was held at the Oregon Convention Center in Portland, April 7-9, 2016. The OBD had a table outside the Exhibit Hall with staff available to answer questions. Dr. Paul Kleinstub and Mr. Prisby made presentations on Thursday, April 7th covering an overview of the Board, the complaint process and a review of the "must knows." As part of the DBIC Risk Management Seminar on Thursday, Mr. Prisby and Dr. Kleinstub presented on the investigative process as well.

2016 Dental License Renewal

Mr. Prisby reported that the following are the final numbers for the March 2016 Dental Renewal: 1966 – Renewed as of April 4, 2016; 1788 – Expired (84 Out of State, 58 in Oregon); 35 – Retired; 1 – Resigned

AADA & AADB Midyear Meetings
Mr. Prisby reported on his meetings with the AADA & AADB Mid-year meeting held in Chicago April 10-11. Dr. Beck also attended the AADB & National Dental Examiners Advisory Forum (NDAEF). Sr. AAG, Lori Lindley attended and participated in the Attorney's Roundtable discussions.

Proposed DANB Meetings
Mr. Prisby reported that he and Teresa Haynes had been working with DANB to facilitate the July 1, 2016 change over, regarding DANB issuing all dental assisting certifications on behalf of the OBD, as voted on by the Board at the December 18, 2015 Board meeting. He proposed a visit to DANB headquarters in Chicago to review the final documents, meet with their leadership and work out the final details of this arrangement. He asked that the Board approve his travel to Chicago, IL in June.

Dr. Fine moved and Ms. Martinez seconded that Mr. Prisby meet with DANB in Chicago in June. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2017 OBD Meeting Dates
Mr. Prisby asked the Board to review and approve the proposed 2017 OBD meeting dates. Dr. Smith moved and Dr. Fine seconded that the 2017 OBD meeting dates be accepted as presented. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Oregon Employees Charitable Fund Drive Results
Mr. Prisby reported the final results for the Charitable Fund drive.

Citizen Advocacy Center
Mr. Prisby reported that here is an opportunity to support the Citizen Advocacy Center (CAC) in September when their annual meeting is held in Portland. The Oregon Medical Board's Executive Director, Kathleen Haley, is helping coordinate with the CAC and asked the other health regulatory boards for support as well. Sponsorship for a coffee break runs $500.00. Mr. Prisby asked that the Board consider sponsoring a coffee break which would give the OBD mention in their meeting materials and discounts on attending the meeting.

Dr. Hongo moved and Ms. Martinez seconded that the Board approve sponsoring a coffee break at the Citizen Advocacy Center's annual meeting being held in Portland in September. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Strategic Planning Session
Mr. Prisby stated that the Strategic Planning Session materials had been disseminated as a separate public document with information for the session on Saturday, April 23rd.

Newsletter
Mr. Prisby stated that the last newsletter was published in December. He anticipates the next edition going out later in the year, which will incorporate the Board's Strategic Plan along with other important news and updates relevant to our Licensees.

UNFINISHED BUSINESS & RULES

Diagnostic Records Rule
Dr. Schwindt moved and Dr. Smith seconded that a proposed new rule regarding diagnostic records be referred to the Licensing and Standards Committee for further discussion. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Refer Rule Changes to Appropriate Committees
Dr. Beck moved and Dr. Fine seconded that the rules in Tab 5 of the Board book be referred to the appropriate committees for further review. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Refer Rule Changes to Public Rulemaking Hearings
Dr. Smith moved and Dr. Hongo seconded that the rules in Tab 5 of the Board book that have already been reviewed by the appropriate committees be referred to a public rulemaking hearing in October 2016. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

CORRESPONDENCE

Ethics and Boundaries Assessment Services Workshop
RPS Lead Apron Letter
Sleep Apnea Appliance – Email Dr. Dietrich and discussion
Dr. Underhill moved and Dr. Beck seconded that the Board reaffirm its policy regarding sleep apnea devices as expressed in October 2012. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.
Dr. James Miller regarding the use of 3DCBCt technology
Mr. Morris moved and Dr. Beck seconded that OBD staff research other state boards' positions on implant placement by general dentists. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

OTHER BUSINESS

Report on HPSP from Dr. Christopher Hamilton
Dr. Christopher Hamilton, the monitoring programs director for Reliant Behavioral Health Monitoring, updated the Board on the HPSP program. Effective July 2017, the program will be moving to be contracted directly by participating boards, with the contract administered by staff of the Oregon Medical Board. To date, Dr. Hamilton reports 750 licensees have entered into the HPSP program; 34 of these licensees were from the OBD, and 12 of these licensees are still in the program.

The Board Reviewed a Request for approval of a Soft Reline Course by Crystal Patton-Doherty and Melissa J. Barfuss. The course would be provided so the EFDA Dental Assistants

could qualify to apply soft relines in accordance with OAR 818-042-0090. Dr. Smith moved and Dr. Beck seconded that the Board approve the soft reline course as presented in Tab 7. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Recognition of Service
The Board recognized Alton Harvey, Sr. for his year of service as President of the Board. The Board also recognized Dr. Jonna Hongo for her eight years of service on the Board.

ARTICLES AND NEWS OF INTEREST (no action necessary)

CODA Winter 2016 Accreditation Actions
New 2016 AHA BLS Provider Cards
Reducing Opioid Overdose and Misuse
SERV OR information
Wilsonville dentist uses history to address rampant tooth decay

ELECTION OF OFFICERS

Election of President
Dr. Beck moved and Dr. Fine seconded that the Board elect Julie Ann Smith, DDS, MD, MCR to the office of President. The motion passed with Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Election of Vice-President
Mr. Morris moved and Dr. Schwindt seconded that the Board elect Todd Beck, DMD to the office of Vice-President. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

EXECUTIVE SESSION: The Board entered into Executive Session pursuant to ORS 192.606 (1)(f), (h) and (k); ORS 676.165; ORS 676.175 (1), and ORS 679.320 to review records exempt from public disclosure, to review confidential investigatory materials and investigatory information, and to consult with counsel.

OPEN SESSION: The Board returned to Open Session.

CONSENT AGENDA

2016-0130, 2016-0163 and **2016-0167** Dr. Smith moved and Dr. Hongo seconded that the above referenced cases be closed with a finding of No Violation of the Dental Practice Act per the staff's recommendations. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Schwindt and Dr. Beck recused on case 2016-0167.

COMPLETED CASES

2015-0199, 2016-0136, 2014-0239, 2015-0081, 2015-0168, 2015-0128, and 2015-0212 Dr. Smith moved and Dr. Beck seconded that the above referenced cases be closed with a finding of No Violation of the Dental Practice Act per the Board's recommendations. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Beck recused himself on case 2015-0199 and case 2015-0128. Dr. Smith recused herself on case 2015-0128.

2014-0183
Dr. Beck moved and Mr. Morris seconded that the Board close the matter with No Further Action per the Board's recommendation. The motion passed with Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Smith recused herself.

2016-0077
Mr. Morris moved and Dr. Hongo seconded that the Board close the matter with a Letter of Concern addressing the issue of ensuring that current CDC guidelines are followed to maintain dental unit water quality. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Beck recused himself.

2015-0202 Garcia, Peter, D.M.D.
Dr. Schwindt moved and Dr. Smith seconded that the Board issue a Notice of Proposed Disciplinary Action and offer Licensee a Consent Order incorporating a reprimand, a $3,000.00 civil penalty, 20 hours of Board approved community service, monthly submission of spore testing results for a period of one year, and complete 3 hours of Board approved continuing education on record keeping within six months. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Hongo recused herself.

2015-0174
Ms. Riedman moved and Dr. Underhill seconded that the Board close with a Letter of Concern reminding Licensee to assure that PARQ or its equivalent is always documented and that all materials used are documented. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0068 Gvozden, Jovan M., D.M.D
Dr. Fine moved and Dr. Hongo seconded that the Board issue a Notice of Proposed Disciplinary Action and offer the Licensee a Consent Order in which the Licensee would agree to be reprimanded and complete at least three hours of Board approved continuing education in record keeping within six months. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Beck recused himself.

2015-0160
Dr. Beck moved and Dr. Schwindt seconded that the Board close the matter with a STRONGLY worded Letter of Concern addressing the issue of ensuring that the licensee makes every effort to keep accurate and complete chart notes, makes adequate arrangements of after-hours emergency care for all patients, and provides prompt recognition and proper management of oral infections. The motion passed with Dr. Beck, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms.

Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Smith voted no. Dr. Fine recused herself.

2015-0021
Dr. Schwindt moved and Dr. Hongo seconded that for **Respondent #1**, the Board close the case with a Letter of Concern addressing the issues of ensuring that all diagnostic findings, including impaction risks and ectopic eruption risks, are accurately documented when an exam and treatment plan is done, that a discussion regarding the impact that the lack of extractions would have on achieving the treatment goals is documented, and that testing of heat sterilizers is done on a weekly basis; and for **Respondent #2**, move to close the case with a Letter of Concern addressing the issues of ensuring that when a patient's treatment is transferred from another practitioner, that all diagnostic findings at the time of transfer are documented prior to assuming treatment, that significant negative compromises to advance treatment progress, such as increased proclination, are documented, and that a complete copy of records are sent upon written request of the patient.. The motion passed with Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Smith recused herself.

2014-0148
Dr. Hongo moved and Dr. Beck seconded that the Board close the matter against all three Respondents with no further action. The motion passed with Dr. Beck, Dr. Hongo, Dr. Fine, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Smith recused herself.

2015-0172
Dr. Underhill moved and Dr. Hongo seconded that the Board close the matter with a Letter of Concern reminding Licensee to assure that all of the autoclaves that her instruments are sterilized in are being spore tested on a weekly basis, and for the Board to open an investigation on the responsible dentist Kaiser Permanente's Sunset Dental Clinic, due to the number of weekly biological spore tests missing at that clinic. The motion passed with Dr. Smith, Dr. Beck, Dr. Hongo, Dr. Fine, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0165
Dr. Beck moved and Dr. Hongo seconded that the Board close the matter with a STRONGLY worded Letter of Concern addressing the issue of ensuring that treatment notes accurately document treatment that was provided, that a diagnosis is documented as a justification to providing dental treatment, and that when there is dental pathology evident on radiographs, every effort is made to diagnose that pathology and plan for its treatment. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0161
Mr. Morris moved and Dr. Hongo seconded that the Board close the matter with a Letter of Concern reminding Licensee to assure that the instruments she uses have been sterilized in an autoclave that has been tested on a weekly basis. The motion passed with Dr. Smith, Dr. Hongo, Dr. Beck, Dr. Fine, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0169 Niles, David G., D.D.S.
Dr. Schwindt moved and Dr. Hongo seconded that the Board issue a Notice of Proposed Disciplinary Action and offer Licensee a Consent Order incorporating a reprimand; a civil penalty of $3,000.00, 20 hours of Board approved community service and monthly submission of spore testing results for both sterilizers for one year. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2016-0032
Ms. Riedman moved and Dr. Smith seconded that the Board close the case with a Strongly Worded Letter of Concern addressing the issues of ensuring that after delivering a removable prosthesis to a patient, every effort is made to address the patient's concerns and complaints regarding lack of function and pain produced by the prosthesis. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0194
Dr. Fine moved and Dr. Hongo seconded that the Board close with a Letter of Concern reminding Licensee to assure that it is thoroughly documented when the patient's esthetic demands may compromise the longevity of a restoration. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0188
Ms. Martinez moved and Dr. Underhill seconded that the Board close the matter with a Letter of Concern reminding Licensee to assure that his autoclave is tested weekly to assure sterilization of instruments. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0134
Dr. Underhill moved and Dr. Beck seconded that the Board close with a Letter of Concern reminding Licensee to assure that dental diagnoses are documented for all treatment provided, all medicaments administered are correctly documented and that all sterilization units are spore tested on a weekly basis. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Hongo recused herself.

2016-0043
Dr. Beck moved and Dr. Smith seconded that the Board close the matter with a Letter of Concern reminding Licensee to assure that he document diagnoses for treatment more thoroughly, and to remind him to test his autoclaves on a weekly basis. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

PREVIOUS CASES

2013-0116
Dr. Schwindt moved and Dr. Underhill seconded that the Board close the case with a finding of No Further Action per the staff recommendation. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0101 Carothers, David N., D.D.S.
Mr. Morris moved and Dr. Smith seconded that the Board endorse the signed Consent Order incorporating a reprimand, three hours of continuing education in record keeping, eight hours of continuing education in maintaining periodontal health around implants, and a $25,916.00 refund to patient TG. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Dr. Beck, Ms. Martinez and Dr. Underhill voting aye.

2014-0173
Dr. Schwindt moved and Dr. Hongo seconded that the Board issue an Order of Dismissal dismissing the Notice of Proposed License Suspension, dated 9/3/15, and close the case with No Further Action. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Dr. Beck, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0138
Ms. Riedman moved and Dr. Smith seconded that the Board deny Licensee's request, affirm the Board's decision of 2/19/16, and refer the case to hearing. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0221, 2015-0222, 2015-0223, 2015-0224 Haymore, Thomas L., D.M.D.
Dr. Fine moved and Dr. Underhill seconded that the Board issue an Order of Dismissal dismissing two allegations in the Amended Notice of Proposed License Suspension, dated 11/13/15, those being "Between July 8, 2015 and August 28, 2015 you failed to comply with a written request for an investigative interview in case 2015-0224" and "Between October 15, 2015 and November 12, 2015, you failed to comply with a written request for an investigative interview in case 2015-0221" and direct Counsel to request the Office of Administrative Hearings to issue a proposed order on the Board's Motion of Summary Determination. The motion passed with Dr. Fine, Dr. Hongo, Mr. Morris, Ms. Riedman, Dr. Smith, Ms. Martinez and Dr. Underhill voting aye. Dr. Schwindt and Dr. Beck recused themselves.

2014-0190 Ludwick, Michelle A., D.D.S.
Ms. Martinez moved and Dr. Hongo seconded that the Board issue an Amended Default Order incorporating a reprimand; 50 hours of community service, to be completed within nine months; and a $1,000.00 civil penalty. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0102 Olson, John L., D.M.D.
Dr. Hongo moved and Ms. Riedman seconded that the Board issue a Final Default Order incorporating a reprimand; a $1,260.00 refund to patient MG; a $3,000.00 civil penalty; 20 hours of community service; and, for a period of one year, shall submit results of the weekly biological monitoring testing of sterilization devices on a monthly basis. The motion passed with Dr. Smith,

Dr. Fine, Dr. Hongo, Dr. Beck, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2014-0033
Dr. Underhill moved and Dr. Hongo seconded that the Board affirm the Board's action of December 19, 2014 and close with No Further Action. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Beck, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

2015-0158
Mr. Morris moved and Ms. Riedman seconded that the Board affirm the Board's February 19, 2016 decision and refer the matter to hearing. The motion passed with Dr. Smith, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye. Dr. Beck recused himself.

LICENSURE AND EXAMINATION

Request for Non-resident Permit: David Resnick, D.D.S.
Dr. Underhill moved and Dr. Hongo seconded that the Board grant the non-resident permit to Dr. David Resnick. The motion passed with Dr. Smith, Dr. Beck, Ms. Martinez, Dr. Fine, Dr. Hongo, Mr. Morris, Ms. Riedman, Dr. Underhill and Dr. Schwindt voting aye.

Case Summary 2012-0208 & 2007-0033
Dr. Beck moved and Dr. Smith seconded that the Board release summaries of the investigations to the California Dental. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

Ratification of Licenses Issued
As authorized by the Board, licenses to practice dentistry and dental hygiene were issued to applicants who fulfilled all routine licensure requirements. It is recommended the Board ratify issuance of the following licenses. Complete application files will be available for review during the Board meeting. Mr. Morris moved and Dr. Smith seconded that the issuance of the following licenses be ratified by the Board. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Dr. Hongo, Dr. Schwindt, Mr. Morris, Ms. Riedman, Ms. Martinez and Dr. Underhill voting aye.

DENTAL HYGIENISTS

H7144	WENDY JEAN FOXE, R.D.H.	2/12/2016
H7145	MAKAHLA ROSE HUFF, R.D.H.	2/12/2016
H7146	KELSEY DAWN WHITAKER, R.D.H.	2/25/2016
H7147	NICOLE LYNN TIFFANY, R.D.H.	2/26/2016
H7148	CARISSA MARIE HOPPIE, R.D.H.	2/26/2016
H7149	BRIANNE TRACI ELLIOTT, R.D.H.	3/2/2016
H7150	JOHN ROSS EDWARD ERICKSON, R.D.H.	3/2/2016
H7151	ELIZABETH ASHLEY PELLOW, R.D.H.	3/3/2016
H7152	MOLYNDA MC KIBBEN, R.D.H.	3/3/2016
H7153	KATIE J SOBER, R.D.H.	3/10/2016
H7154	INESSA ILLINICHNA TEREKHIN, R.D.H.	3/10/2016
H7155	STEPHANIE MARIE NELSON, R.D.H.	3/10/2016
H7156	ANGELIA C SPIEGEL, R.D.H.	3/23/2016

H7157	KENNEDY GABRIELLE HILGERS, R.D.H.	4/6/2016
H7158	JOHN V RUSSO, R.D.H.	4/6/2016
H7159	TRICIA L MONTEZ, R.D.H.	4/6/2016

DENTISTS

D10396	NICOLE CONNORS SMITH, D.M.D.	2/12/2016
D10397	STEVEN J WORLEY, D.D.S.	2/22/2016
D10398	NATHAN D LENOX, D.M.D.	2/25/2016
D10399	SEAN P HENRIE, D.M.D.	2/25/2016
D10400	JONATHAN C GARCIA, D.D.S.	2/25/2016
D10401	ANA K PUENTE, D.D.S.	2/26/2016
D10402	MICHAEL J LONGLET, D.D.S.	2/26/2016
D10403	ERICA GOSS, D.D.S.	2/26/2016
D10404	CHELSEA MARIE LONGLET, D.D.S.	3/2/2016
D10405	VICTOR RONALD MANCUSO, D.D.S.	3/10/2016
D10406	DAVID MARK DE CILLIS, D.D.S.	3/10/2016
D10407	STEPHEN I CAMPBELL, D.D.S.	3/10/2016
D10408	COLIN STUART GRASER, D.M.D.	3/14/2016
D10409	TESS A SIMMONS, D.D.S.	3/23/2016
D10410	DIEU-HIEN V HUYNH, D.M.D.	4/6/2016
D10411	THOMAS LEE MOSLEY, D.M.D.	4/6/2016
D10412	ADAM T FOX, D.M.D.	4/6/2016
D10413	NIOUSHA SAGHAFI, D.D.S.	4/6/2016

DENTAL FACULTY

DF0035	HIDEHIKO WATANABE	3/2/2016

Strategic Planning Discussion

Mr. Prisby reviewed the agenda for tomorrow's session and thanked the Board and staff for their participation.

Lori Lindley made a presentation on the role of the Oregon Board of Dentistry in general, and the ethical and legal responsibilities of the Board members.

Sue Diciple reviewed the agenda for the Strategic Planning Session and began the workshop portion of the Session.

Announcement

No announcements.

DRAFT

ADJOURNMENT

The meeting was adjourned at 4:01 pm. President Harvey stated that the next Board meeting would take place June 17, 2016.

_____
Alton Harvey, Sr.
President

DRAFT

OREGON BOARD OF DENTISTRY
Strategic Planning Session
MINUTES
April 23, 2016

MEMBERS PRESENT: Julie Ann Smith, D.D.S., M.D., M.C.R., President
Todd Beck, D.M.D., Vice-President
Alton Harvey, Sr.
Amy B. Fine, D.M.D.
Jonna E. Hongo, D.M.D.
Yadira Martinez, R.D.H.
James Morris
Alicia Riedman, R.D.H.
Brandon Schwindt, D.M.D.
Gary Underhill, D.M.D.

STAFF PRESENT: Stephen Prisby, Executive Director
Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator (portion of meeting)
Daryll Ross, Investigator (portion of meeting)
Harvey Wayson, Investigator (portion of meeting)
Teresa Haynes, Exam and Licensing Manager (portion of meeting)
Ingrid Nye, Office Specialist (portion of meeting)

ALSO PRESENT: Lori Lindley, Sr. Assistant Attorney General
Sue Diciple, strategic planning facilitator

VISITORS PRESENT: none

The session was held at:
Marriott Hotel- Downtown Portland
Pearl Conference Room
1401 SW Naito Pkwy
Portland, Or 97201
Pearl Conference Room

Session Opening Remarks and Welcome
Stephen Prisby thanked everyone for their attendance reviewed the overall plan for the day. He introduced OBD President, Dr. Julie Ann Smith. Dr. Smith also thanked everyone for their attendance and stated that the last time the OBD conducted a strategic planning session was in 2007. She said that this was a momentous occasion and an opportunity for the Board and staff to focus their efforts on carrying out the OBD's mission and revamping the strategic plan. Sue Diciple then spoke and reviewed the agenda and next steps for the meeting.

Agenda Review and Session Working Agreements
Sue Diciple explained the day's plan and housekeeping rules for everyone. She reviewed the feedback from the conversations and survey of all participants. A strengths, weaknesses opportunities and threats (SWOT) analysis was reviewed and a discussion among participants. The information was distilled and shared with participants.
Some of the comments made regarding the OBD's strengths, weaknesses opportunities and threats:
To continue to build trust with stakeholders through transparency, predictability, effective and updated means of communication, due process, and treating all with respect
To implement process improvement including conversion from paper to electronic media prior to the upcoming retirements of experienced staff members
To train new staff before attrition limits the opportunity for knowledge transfer; and to institute continuous learning for Board Members beginning at on-boarding and continuing throughout their OBD service
To retain OBD autonomy and organizational alignment
To ensure ongoing Board education and development
The paradigm shift toward corporate dentistry and managed care creates challenges for regulation of oral health care providers in Oregon
Negative perception among a small but vocal number of licensees
Insufficient flexibility and access to facilitative technologies with the potential to streamline processes and procedures, saving time and cost and offering enhanced decision support
Small regulatory boards in Oregon risk losing autonomy to larger state bureaucracies
Potential limits to or redefinition of the OBD's mission through legislative action
A diverse, open, ethical, committed Board whose members "put the patient first"
Staff expertise, work ethic and experience.
To achieve faster case disposition assuring a fair and thorough investigative process that results in well-vetted reports, recommendations and decisions
Lack of control over funding
Timeliness limited by staffing level
Upcoming staff attrition not yet addressed with a plan
Length of time required to bring new board and staff members up-to-speed

Café style questions and information sharing. Staff and board members addressed questions and discussed in small groups the following topics: Complexity and Caseload: Attrition and Succession: Adapting the OBD Mission for the Future.

Open Discussion Other factors to carry forward into strategic planning

Paradigm Shifts In The Practice & Business Model Of Dentistry

The growth of national corporate entities providing dentistry services in Oregon has complicated the regulatory landscape and is emerging as a challenge to the standards of patient care upheld in Oregon. Linking complaints to a specific office location or practitioner within a large corporate dentistry provider can be difficult, and response to investigative requests for information is slow and complicated.

Regardless of organizational structure, the practice of dentistry is increasingly following trends in the market. In the rush to capture emerging demand some practitioners are offering services for which they do not have the requisite training and expertise. The volume of complaints

submitted to the OBD continues to follow historical patterns: communication break-down, lack of documentation and now implant failures are adding to the complaints. This trend can be anticipated to grow as the practice of dentistry becomes increasingly competitive and market-driven.

Caseload & Case Complexity

The number of complaints received by the OBD has grown to about 240 per year, collateral with an increase in case complexity due to shifts in the practice of and market for oral health care services. Key contributors to increases in complaints and complexity include growing demand for surgical procedures such as implants, practitioners performing procedures outside of their skill set, and a trend toward case litigation.

Stakeholder Perception of the OBD

The OBD sees its mission as elevating the standard of oral health care in Oregon, not solely though regulation but through information, outreach and education. A review of surveys conducted in 2014 indicated an 85% approval rating for the OBD among licensees; however there is a segment of licensees and other stakeholders who express dissatisfaction with the OBD or question the OBD's motivations. The OBD has positioned equity as a key value and has explicitly incorporated that value into its mission. But more remains to be done to insure that oral healthcare practitioners in Oregon are informed and educated about required standards of care.

Succession Planning

A significant percentage of OBD staff is becoming eligible for retirement. This will result in an exodus of expertise and institutional knowledge. Impacts of unfilled positions or lengthy ramp-up time could include stress on remaining staff, added cost, and lost time. The OBD is endeavoring in this planning cycle to anticipate attrition in key positions and plan for timely and effective succession.

Emerging Technology to Support Process Improvement

Technology, such as scanner-reading software, has the potential to enhance and accelerate the investigation process. The transition from paper-based processes to electronic can improve decision calibration, timeliness and consistency of case outcomes.

Mission Adaptation & Alignment

The OBD mission exhorts the agency to ensure high standards and quality of oral health care. However economic forces and a widening income-to-cost-of-living gap in Oregon are forcing many to seek lowest-cost dentistry options. Defining "high quality oral health care" that is accessible at all income levels while providing clear guidelines for practitioners and for OBD's investigative staff is a mission-critical challenge.

A core concern for the OBD and its mission is the trend toward consolidation of regulatory entities into the auspices of large state bureaucracies. The OBD considers its autonomy to be a key factor in the high confidence placed in it by state policymakers and licensees, its capacity to act both nimbly and equitably, and its ability to attract practitioners with the requisite levels of experience and qualifications to serve as board members.

The staff were thanked for their attendance and dismissed for the day.

Lunch

Board members, Stephen Prisby, Lori Lindley and facilitator, Sue Diciple continued meeting**.**

Environmental Scan

- Issues, trends, opportunities, challenges
- Budget and legislative impact
- Impact assessment

EXECUTIVE SESSION: The Board entered into Executive Session pursuant to ORS 192.606 (1)(f), (h) and (k); ORS 676.165; ORS 676.175 (1), and ORS 679.320 to review records exempt from public disclosure, to review confidential investigatory materials and investigatory information, and to consult with counsel.

OPEN SESSION: The Board returned to Open Session.

Mission Alignment

- What are the mission critical elements of the OBD's work?
- Within OBD's resources how can we best align with our mission?
- Discussion of possible new mission statements

Strategic Objectives & Priorities 2017-2020

- Establish priorities
- Anticipated milestones
- Measure of success

Summary
A draft document incorporating the main points would be first distributed to staff to fine-tune further. The Board would review that document and finalize the document.

The Strategic planning session adjourned at 4:08pm

The next Board meeting would take place June 17, 2016.

_____
Dr. Julie Ann Smith D.D.S., M.D., M.C.R.
President

DRAFT

DRAFT

OREGON BOARD OF DENTISTRY
Special Board Teleconference Meeting Minutes
May 4, 2016

MEMBERS PRESENT:	Julie Ann Smith, D.D.S. M.D., M.C.R., President Todd Beck, D.M.D., Vice-President Amy B. Fine, D.M.D. Alton Harvey Sr. Yadira Martinez, R.D.H. James Morris Brandon Schwindt, D.M.D. Gary Underhill, D.M.D.
STAFF PRESENT:	Stephen Prisby, Executive Director Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator
ALSO PRESENT:	Lori Lindley, Sr. Assistant Attorney General
VISITORS PRESENT:	None

Call to Order: The meeting was called to order by the President at 1:05 p.m. at the Board office; 1500 SW 1st Ave., Suite 770, Portland, Oregon.

EXECUTIVE SESSION: The Board entered into Executive Session pursuant to ORS 192.660 (2)(f),(h) and (k); ORS 676.165; ORS 676.175 (1), and ORS 679.320 to review records exempt from public disclosure, to review confidential investigatory materials and investigatory information, and to consult with counsel.

OPEN SESSION: The Board returned to Open Session. **1:16 p.m.**

Mr. Morris moved and Dr. Beck seconded that in the matter of cases 2011-0184, 2012-0031, 2012-0147, 2012-0172, 2013-0035 and 2014-0081 move to issue an Order of Dismissal, dismissing one allegation in the Notice of Proposed License Suspension, dated 11/16/15, that being, "Between July 22, 2015 and August 1, 2015 you failed to respond within 10 days of the Board's July 22, 2015 written request for information." The motion passed with Dr. Smith, Dr. Fine, Dr. Beck, Mr. Morris, Ms. Martinez and Dr. Underhill voting aye. Dr. Schwindt recused himself.

ADJOURNMENT

The meeting was adjourned at 1:18 p.m.

Approved by the Board June 17, 2016.

_____
Julie Ann Smith, D.D.S., M.D., M.C.R.
President

DRAFT

ASSOCIATION REPORTS

Nothing to report under this tab

COMMITTEE REPORTS

Draft 1

Enforcement and Discipline Committee Meeting
Minutes
May 17, 2016

MEMBERS PRESENT:	Committee Members: James Morris, Chair Alicia Riedman, R.D.H., E.P.P. – via telephone Todd Beck, D.M.D. Jason Bajuscak, D.M.D. - ODA Representative Jill Mason, R.D.H. - ODHA Representative Mary Harrison, CDA, EFDA, EFODA, FADAA - ODAA Representative
STAFF PRESENT:	Stephen Prisby, Executive Director Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator Ingrid Nye, Acting Examination and Licensing Manager
ALSO PRESENT:	Lori Lindley, Sr. Assistant Attorney General – via telephone Julie Ann Smith, D.D.S., M.D., M.C.R.
VISITORS PRESENT:	Thomas Haymore D.M.D., R. Owen Combe D.M.D., Harold Hickok

Call to Order: The meeting was called to order by the Chair at 6:00 p.m. at the Board office; 1500 SW 1st Ave., Suite 770, Portland, Oregon.

MINUTES

Ms. Mason moved and Ms. Harrison seconded that the minutes of the May 7, 2015 Enforcement and Discipline Committee meeting be approved as presented. The motion passed with Ms. Riedman, Dr. Bajuscak, Ms. Mason, and Ms. Harrison voting aye. Dr. Beck was not present for the vote.

General discussion on standard protocols for general consent orders, discipline for licensees, and unprofessional conduct.

Dr. Beck arrived at 6:08 p.m.

DRAFT

OAR 818-012-0030 – Unprofessional Conduct

The Committee and visitors discussed the proposed changes to OAR 818-012-0030.

Dr. Beck moved and Ms. Mason seconded that the Committee recommend that the Board send OAR 818-012-0030 as amended to the Rules Oversight Committee for further review and discussion. The motion passed with Dr. Beck, Ms. Mason, Ms. Riedman, Ms. Harrison, and Dr. Bajuscak voting aye.

Unprofessional Conduct

~~The Board finds that in addition to the conduct set forth in ORS 679.140(2), a licensee engages in unprofessional conduct if the licensee does or permits any person to:~~ **The Board finds that in addition to the conduct set forth in ORS 679.140(2), unprofessional conduct includes, but is not limited to, the following in which a licensee does or permits any person to:**

(1) Attempt to obtain a fee by fraud**, lying** or misrepresentation.

(2) Obtain~~ing~~ a fee by fraud**, lying** or misrepresentation.

(a) A licensee obtains a fee by fraud if the licensee ~~obtains a fee by~~ knowingly mak~~ing~~**es,** or permit~~ting~~**s** any person to make**,** a material, false statement intending that a recipient**,** who is unaware of the truth**,** rely upon the statement.

(b) A licensee obtains a fee by misrepresentation if the licensee obtains a fee through making or permitting any person to make a material, false statement.

(c) Giving cash discounts and not disclosing them to third party payors is not fraud or misrepresentation.

(3) Offer rebates, split fees, or commissions for services rendered to a patient to any person other than a partner, employee, or employer.

(4) Accept rebates, split fees, or commissions for services rendered to a patient from any person other than a partner, employee, or employer.

(5) Initiate, or engage in, with a patient, any behavior with sexual connotations. The behavior can include but is not limited to, inappropriate physical touching; kissing of a sexual nature; gestures or expressions, any of which are sexualized or sexually demeaning to a patient; inappropriate procedures, including, but not limited to, disrobing and draping practices that reflect a lack of respect for the patient's privacy; or initiating inappropriate communication, verbal or written, including, but not limited to, references to a patient's body or clothing that are sexualized or sexually demeaning to a patient;

and inappropriate comments or queries about the professional's or patient's sexual orientation, sexual performance, sexual fantasies, sexual problems, or sexual preferences.

(6) Engage in an unlawful trade practice as defined in ORS 646.605 to 646.608.

(7) Fail to present a treatment plan with estimated costs to a patient upon request of the patient or to a patient's guardian upon request of the patient's guardian.

(8) Misrepresent any facts to a patient concerning treatment or fees.

(9)(a) Fail to provide a patient or patient's guardian within 14 days of written request:

(A) Legible copies of records; and

(B) Duplicates of study models**,** ~~and~~radiographs **of the same quality as the originals, and** photographs ~~or legible copies thereof~~ if the**y** ~~radiographs, photographs or study models~~ have been paid for.

(b) The dentist may require the patient or guardian to pay in advance a fee reasonably calculated to cover the costs of making the copies or duplicates. The dentist may charge a fee not to exceed $30 for copying 10 or fewer pages of written material and no more than $0.50 per page for pages 11 through 50 and no more than $0.25 for each additional page (including records copied from microfilm), plus any postage costs to mail copies requested and actual costs of preparing an explanation or summary of information, if requested. The actual cost of duplicating ~~x-rays~~ **radiographs** may also be charged to the patient. Patient records or summaries may not be withheld from the patient because of any prior unpaid bills, except as provided in (9)(a)(B) of this rule.

(10) Fail to identify to a patient, patient's guardian, or the Board the name of an employee, employer, contractor, or agent who renders services.

(11) Use prescription forms pre-printed with any Drug Enforcement Administration number, name of controlled substances, or facsimile of a signature.

(12) Use a rubber stamp or like device to reproduce a signature on a prescription form or sign a blank prescription form.

(13) Order drugs listed on Schedule II of the Drug Abuse Prevention and Control Act, 21 U.S.C. Sec. 812, for office use on a prescription form.

(14) Violate any Federal or State law regarding controlled substances.

(15) Becomes addicted to, or dependent upon, or abuses alcohol, illegal or controlled drugs, or mind altering substances**, or practice with an untreated substance use disorder diagnosis that renders the licensee unable to safely conduct the practice**

of dentistry or dental hygiene.

(16) Practice dentistry or dental hygiene in a dental office or clinic not owned by an Oregon licensed dentist(s), except for an entity described under ORS 679.020(3) and dental hygienists practicing pursuant to ORS 680.205(1)(2).

(17) Make an agreement with a patient or person, or any person or entity representing patients or persons, or provide any form of consideration that would prohibit, restrict, discourage or otherwise limit a person's ability to file a complaint with the Oregon Board of Dentistry; to truthfully and fully answer any questions posed by an agent or representative of the Board; or to participate as a witness in a Board proceeding.

(18) Fail to maintain at a minimum a current BLS for Healthcare Providers certificate or its equivalent. (Effective January 2015).

(19) Conduct unbecoming a licensee or detrimental to the best interests of the public, including conduct contrary to the recognized standards of ethics of the licensee's profession or conduct that endangers the health, safety or welfare of a patient or the public.

(20) Knowingly deceiving or attempting to deceive the Board, an employee of the Board, or an agent of the Board in any application or renewal, or in reference to any matter under investigation by the Board. This includes but is not limited to the omission, alteration or destruction of any record in order to obstruct or delay an investigation by the Board, or to omit, alter or falsify any information in patient or business records.

(21) Knowingly practicing with a physical or mental impairment that renders the Licensee unable to safely conduct the practice of dentistry or dental hygiene.

(22) Take any action which could reasonably be interpreted to constitute harassment or retaliation towards a person whom the licensee believes to be a complainant or witness.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.140(1)(c), 679.140(2), 679.170(6) & 680.100

Hist.: DE 6, f. 8-9-63, ef. 9-11-63; DE 14, f. 1-20-72, ef. 2-10-72; DE 5-1980, f. & ef. 12-26-80; DE 2-1982, f. & ef. 3-19-82; DE 5-1982, f. & ef. 5-26-82; DE 9-1984, f. & ef. 5-17-84; Renumbered from 818-010-0080; DE 3-1986, f. & ef. 3-31-86; DE 1-1988, f. 12-28-

88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0020; DE 1-1990, f. 3-19-90, cert. ef. 4-2-90; DE 2-1997, f. & cert. ef. 2-20-97; OBD 3-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06; OBD 1-2007, f. & cert. ef. 3-1-07; OBD 3-2007, f. & cert. ef. 11-30-07; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14; OBD 3-2015, f. 9-8-15, cert. ef. 10-1-15

OAR 818-012-0060 – Failure to Cooperate with Board

The Committee and visitors discussed the proposed changes to OAR 818-012-0060.

Ms. Mason moved and Dr. Beck seconded that the Committee recommend that the Board send OAR 818-012-0060 as amended to the Rules Oversight committee for further review and discussion. The motion passed with Dr. Beck, Ms. Harrison, Ms. Mason, Ms. Riedman, and Dr. Bajuscak voting aye.

Failure to Cooperate with Board

(1) No licensee shall:

(~~1~~a) Fail to report to the Board violations of the Dental Practice Act.

(~~2~~b) Use threats or harassment to delay or obstruct any person in providing evidence in any investigation, contested case, or other legal action instituted by the Board.

(~~3~~c) Discharge an employee based primarily on the employee's attempt to comply with or aid in the compliance with the Dental Practice Act.

(~~4~~d) Use threats or harassment to obstruct or delay the Board in carrying out its functions under the Dental Practice Act.

(~~5~~e) Deceive or attempt to deceive the Board with respect to any matter under investigation including altering or destroying any records.

(~~6~~f) Make an untrue statement on any document, letter, or application submitted to the Board.

(~~7~~g) Fail to temporarily surrender custody of original patient records to the Board when the Board makes a written request for the records. For purposes of this rule, the term records includes, but is not limited to, the jacket, treatment charts, models, radiographs, photographs, health histories, billing documents, correspondence and memoranda.

(h) Fail to attend a Board requested investigative interview or failure to fully cooperate in any way with an ongoing Board investigation.

(2) No ~~person~~ **applicant** shall:

(~~8~~**a**) Deceive or attempt to deceive the Board with respect to any matter under investigation including altering or destroying any records.

(~~9~~**b**) Make an untrue statement on any document, letter, or application submitted to the Board.

(c) Fail to fully cooperate with the Board during the course of an investigation, including but not limited to, waiver of confidentiality privileges, except attorney-client privilege.

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.060(4), 679.170(5), 679.250(8), 679.290, 679.310(1), 680.050(4) & 680.100

Hist.: DE 9-1984, f. & ef. 5-17-84; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0050; DE 2-1997, f. & cert. ef. 2-20-97; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08

Meeting adjourned at 7:47 p.m.

DRAFT

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

MEETING NOTICE

ENFORCEMENT AND DISCIPLINE COMMITTEE

OREGON BOARD OF DENTISTRY
1500 SW 1st AVENUE, SUITE 770
PORTLAND, OREGON 97201

MAY 17, 2016
6:00 P.M.

Committee Members:
James Morris, Chair
Alicia Riedman, R.D.H., E.P.P.
Todd Beck, D.M.D.
Julie Ann Smith, D.D.S., M.D., M.C.R.
Jason Bajuscak, D.M.D. - ODA Representative
Jill Mason, R.D.H. - ODHA Representative
Mary Harrison, CDA, EFDA, EFODA, FADAA - ODAA Representative

AGENDA

Call to Order James Morris, Chair

Review Minutes of May 7, 2015 Committee Meeting

May 7, 2015 Minutes **Attachment #1**

Review, discuss and make recommendations to the Board regarding standard protocols for general consent orders.

Standard Protocols for General Consent Orders **Attachment #2**

Review, discuss and make recommendations to the Board regarding OAR 818-012-0030.

Draft OAR 818-012-0030 Unprofessional Conduct **Attachment #3**

Review, discuss and make recommendations to the Board regarding OAR 818-012-0060.

Draft OAR 818-012-0060 Failure to Cooperate with the Board **Attachment #4**

Any other business

Adjournment

The meeting location is accessible to persons with disabilities. A request for an interpreter for the hearing impaired or for other accommodations for persons with disabilities should be made at least 48 hours before the meeting to Teresa Haynes, (971) 673-3200.

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

Memorandum

To: Attendees of OBD Meetings

From: Stephen Prisby, Executive Director

Re: OBD/Crown Plaza Conference Room access

The Crown Plaza closes the 1st floor lobby/access at 6:00 p.m.

The building must be accessed on the 2nd floor. There is a security desk/guard that you will need to sign in with and show I.D.

The parking garage is directly across the street from our building (The Crown Plaza). The access is via two walkways on the 2nd floor. If you walk up to the building there are stairs that take you to the second floor.

Enforcement and Discipline Committee Meeting
Minutes
May 7, 2015

MEMBERS PRESENT:	Committee Members: Julie Ann Smith, D.D.S., M.D., Chair Todd Beck, D.M.D. Amy B. Fine, D.M.D. via Telephone Alicia Riedman, R.D.H., E.P.P. Jason Bajuscak, D.M.D. - ODA Rep. Lynn Ironside, R.D.H. - ODHA Rep. Mary Harrison, CDA, EFDA, EFODA, FADAA - ODAA Rep.
STAFF PRESENT:	Stephen Prisby, Interim Executive Director Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator Harvey Wayson, Investigator Nadia Roberts, Office Specialist
ALSO PRESENT:	Lori Lindley, Sr. Assistant Attorney General
VISITORS PRESENT:	Alton Harvey, Sr., Board Member; Jonna Hongo, D.M.D., Board Member

Call to Order: The meeting was called to order by the Chair at 6:00 p.m. at the Board office; 1500 SW 1st Ave., Suite 770, Portland, Oregon.

MINUTES

Dr. Beck moved and Ms. Ironside seconded that the minutes of the June 30, 2004 Enforcement and Discipline Committee meeting be approved as presented. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Ms. Riedman, Dr. Bajuscak, Ms. Ironside and Ms. Harrison voting aye.

General discussion on standard protocols for general consent orders, discipline for licensees, and unprofessional conduct.

FALSE CERTIFICATION OF CONTINUING EDUCATION

Ms. Ironside moved and Ms. Harrison seconded that the Committee recommend to the Board to update the protocols regarding False Certification of Continuing Education, increasing the potential fine to $2,000.00 for dentists and $1,000.00 for dental hygienists. The motion passed with Dr. Smith, Dr. Beck, Dr. Fine, Ms. Riedman, Ms. Ironside, Ms. Harrison and Dr. Bajuscak voting aye.

Meeting adjourned at 7:21 p.m.

DRAFT

STANDARD PROTOCOLS FOR GENERAL CONSENT ORDERS

CIVIL PENALTIES

Licensee shall pay a $____ civil penalty in the form of a cashier's, bank, or official check, made payable to the Oregon Board of Dentistry and delivered to the Board offices within 30 days of the effective date of the Order.

> **NOTE:** The Board will allow licensed dentists a 30-day payment period for each civil penalty increment of $2,500
>
> **NOTE:** The Board will allow licensed dental hygienists a 30-day payment period of each civil penalty increment of $500

RESTITUTION PAYMENTS

Licensee shall pay $___ in restitution in the form of a cashier's, bank, or official check made payable to patient __ and delivered to the Board offices within 30 days of the effective date of the Order.

> **NOTE:** The Board will allow licensed dentists a 30-day payment period for each restitution increment of $2,500

REIMBURSEMENT PAYMENTS

Licensee shall provide the Board with documentation verifying reimbursement payment made to ___, the patient's insurance carrier, within 30 days of the effective date of the Order.

NOTE: The Board will allow licensed dentists a 30-day payment period for each reimbursement increment of $2,500

CONTINUING EDUCATION – BOARD ORDERED

Licensee shall successfully complete ___ hours of ___ (OPTIONS: Board pre-approved, hands-on, mentored), continuing education in the area of ___ within ___ (OPTIONS: years, months) of the effective date of this Order, unless the Board grants an extension, and advises the Licensee in writing. This ordered continuing education is in addition to the continuing education required for the licensure period ___ (OPTIONS: April 1, XXX to March 31, XXX OR October 1, XXX to September 30, XXX). As soon as possible after completion of a Board ordered course, Licensee shall submit documentation to the Board verifying completion of the course.

COMMUNITY SERVICE

Licensee shall provide ___ hours of Board approved community service within ___ (OPTIONS: years, months) of the effective date of this Order, unless the Board grants an extension, and advises the Licensee in writing. The community service shall be pro bono, and shall involve the Licensee providing direct dental care to patients. Licensee shall submit documentation verifying completion of the community service within the specified time allowed for the community service.

FALSE CERTIFICATION OF CONTINUING EDUCATION

Licensee shall be reprimanded, pay a $____ ($2,000 for dentists OR $1,000 for dental hygienists) civil penalty, complete ten hours of community service within 60 days and complete the balance of the ___ (40 OR 24) hours of continuing education for the licensure period (4/1/-- to 3/31/-- OR 10/1/-- to 9/30/--), within 60 days of the effective date of this Order. As soon as possible following completion of the continuing education the Licensee shall provide the Board with documentation certifying the completion.

WORKING WITHOUT A CURRENT LICENSE

Licensee shall pay a $___ civil penalty in the form of a cashier's, bank, or official check, made payable to the Oregon Board of Dentistry and delivered to the Board offices within 30 days of the effective date of the Order.

> **NOTE:** A licensed dentist, who worked any number of days without a license will be issued a Notice of Proposed Disciplinary Action and offered a Consent Order incorporating a reprimand and a $5,000 civil penalty.

> **NOTE:** A licensed dental hygienist who worked any number of days without a current license, will be issued a Notice of Proposed Disciplinary Action and offered a Consent Order incorporating a reprimand and civil penalty of $2,500.

ALLOWING A PERSON TO PERFORM DUTIES FOR WHICH THE PERSON IS NOT LICENSED OR CERTIFIED

Licensee shall pay a $___ civil penalty in the form of a cashier's, bank, or official check, made payable to the Oregon Board of Dentistry and delivered to the Board offices within 30 days of the effective date of the Order, unless the Board grants an extension, and advises the Licensee in writing.

> **NOTE:** The Licensee will be charged $2,000 for the first offense and $4,000 for the second, and each subsequent offense.

FAILURE TO CONDUCT WEEKLY BIOLOGICAL TESTING OF STERILIZATION DEVICES

Licensee shall pay a $ ____ civil penalty in the form of a cashier's, bank, or official check made payable to the Oregon Board of Dentistry and delivered to the Board offices within _____ days of the effective date of the Order, complete ____ hours of Board approved community service within _____ (months, year) of the effective date of the Order, and, for a period of one year of the effective date of the Order, submit, by the fifteenth of each month, the results of the previous month's weekly biological monitoring testing of sterilization devices.

NOTE: Failure to do biological monitoring testing one to five times within a calendar year will result in a Letter of Concern.

NOTE: Failure to do biological monitoring testing six to ten times within a calendar year will result in the issuance of a Notice of Proposed Disciplinary Action and an offer of a Consent Order incorporating a reprimand.

NOTE: Failure to do biological monitoring testing 11 to 20 times within a calendar year will result in the issuance of a Notice and an offer of a Consent Order incorporating a reprimand, a $3,000 civil penalty to be paid within 60 days, 20 hours of Board approved community service to be completed within six months, and monthly submission of spore testing results for a period of one year from the effective date of the Order.

NOTE: Failure to do biological monitoring testing more than 20 times within a calendar year will result in the issuance of a Notice and an offer of a Consent Order incorporating a reprimand, a $6,000 civil penalty to be paid within 90 days, 40 hours of Board approved community service to be completed within one year, and monthly submission of spore testing results for a period of one year from the effective date of the Order.

STANDARD PROTOCOLS FOR CONSENT ORDERS SPECIFICALLY RELATED TO ALCOHOL ABUSE

ALCOHOL

Licensee shall, for an indefinite length of time, be subject to the following conditions of this Consent Order:

Licensee shall not apply for relief from these conditions within five years of the effective date of the Order, and then must do so in writing.

Licensee shall not use alcohol, controlled drugs, or mood altering substances at any place or time unless prescribed by a licensed practitioner for a bona fide medical condition and upon prior notice to the Board and care providers, except that prior notice to the Board and care providers shall not be required in the case of a bona fide medical emergency.

Licensee shall undergo an evaluation by a Board approved addictionologist or treatment center within 30 days of the effective date of the Order and make the written evaluation and treatment recommendations available to the Board.

Licensee shall adhere to, participate in, and complete all aspects of any and all residential care programs, continuing care programs and recovery treatment plans recommended by Board approved care providers and arrange for a written copy of all plans, programs, and contracts to be provided to the Board within 30 days of the effective date of this Order.

Licensee shall advise the Board, in writing, of any change or alteration to any residential care programs, continuing care programs, and recovery treatment plans 14 days before the change goes into effect.

Licensee shall instruct all health care providers participating in the residential, continuing care, and recovery programs to respond promptly to any Oregon Board of Dentistry

inquiry concerning Licensee's compliance with the treatment plan and to immediately report to the Board, any positive test results or any substantial failure to fully participate in the programs by the Licensee. Licensee shall instruct the foregoing professionals to make written quarterly reports to the Board of Licensee's progress and compliance with the treatment programs.

Licensee shall waive any privilege with respect to any physical, psychiatric, or psychological evaluation or treatment in favor of the Board for the purposes of determining compliance with this Order, or the need to modify this Order, and shall execute any waiver or release upon request of the Board.

Licensee shall submit to a Board approved, random, supervised, urinalysis testing program, at Licensee's expense, with the frequency of the testing to be determined by the Board, but initially at a minimum of 24 random tests per year. Licensee shall arrange for the results of all tests, both positive and negative, to be provided promptly to the Board.

Licensee shall advise the Board, within 72 hours, of any alcohol, illegal or prescription drug, or mind altering substance related relapse, any positive urinalysis test result, or any substantial failure to participate in any recommended recovery program.

Licensee shall personally appear before the Board, or its designated representative(s), at a frequency to be determined by the Board, but initially at a frequency of three times per year.

Licensee shall, within three days, report the arrest for any misdemeanor or felony and, within three days, report the conviction for any misdemeanor or felony.

Licensee shall assure that, at all times, the Board has the most current addresses and telephone numbers for residences and offices.

STANDARD PROTOCOLS FOR CONSENT ORDERS SPECIFICALLY RELATED TO SUBSTANCE ABUSE

DRUGS

Licensee shall, for an indefinite length of time, be subject to the following conditions of this Consent Order:

Licensee shall not apply for relief from these conditions within five years of the effective date of the Order and then must do so in writing.

Licensee shall not use controlled drugs or mind altering substances at any place or time unless prescribed by a licensed practitioner for a bona fide medical condition and upon prior notice to the Board and care providers, except that prior notice to the Board and care providers shall not be required in the case of a bona fide medical emergency.

NOTE: It may be appropriate to add “alcohol” to this condition.

Licensee shall undergo an evaluation by a Board approved addictionologist or treatment center within 30 days of the effective date of the Order and make the written evaluation and treatment recommendations available to the Board.

License shall adhere to, participate in, and complete all aspects of any and all residential care programs, continuing care programs and recovery treatment plans recommended by Board approved care providers and arrange for a written copy of all plans, programs, and contracts to be provided to the Board within 30 days of the effective date of the Order.

Licensee shall advise the Board, in writing, of any change or alteration to any residential care programs, continuing care programs, and recovery treatment plans 14 days before the change goes into effect.

Licensee shall instruct all health care providers participating in the residential, continuing care, and recovery programs to respond promptly to any Oregon Board of Dentistry inquiry concerning Licensee's compliance with the treatment plan and to immediately report to the Board, any positive test results or any substantial failure to fully participate in the programs by the Licensee. Licensee shall instruct the foregoing professionals to make written quarterly reports to the Board of Licensee's progress and compliance with the treatment programs.

Licensee shall waive any privilege with respect to any physical, psychiatric, or psychological evaluation or treatment in favor of the Board for the purposes of determining compliance with this Order, or the need to modify this Order and shall execute any waiver or release upon request of the Board.

Licensee shall submit to a Board approved, random, supervised, urinalysis testing program, at Licensee's expense, with the frequency of the testing to be determined by the Board, but initially at a minimum of 24 random tests per year. Licensee shall arrange for the results of all tests, both positive and negative, to be provided to the Board.

Licensee shall advise the Board, within 72 hours, of any drug related relapse, any positive urinalysis test result, or any substantial failure to participate in any recommended recovery program.

Licensee shall personally appear before the Board, or its designated representative(s), at a frequency to be determined by the Board, but initially at a frequency of three times per year.

IF APPROPRIATE –

Licensee will not order or dispense any controlled substance, nor shall Licensee store any controlled substance in his/her office.

Licensee shall immediately begin using pre-numbered triplicate prescription pads for prescribing controlled substances. Said prescription

pads will be provided to the Licensee, at his/her expense, by the Board. Said prescriptions shall be used in their numeric order. Prior to the 15th day of each month, Licensee shall submit to the Board office, one copy of each triplicate prescription used during the previous month. The second copy to the triplicate set shall be maintained in the file of the patient for whom the prescription was written. In the event of a telephone prescription, Licensee shall submit two copies of the prescription to the Board monthly. In the event any prescription is not used, Licensee shall mark all three copies void and submit them to the Board monthly.

Licensee shall maintain a dental practice environment in which nitrous oxide is not present or available for any purpose, or establish a Board approved plan to assure that Licensee does not have singular access to nitrous oxide. The Board must approve the proposed plan before implementation.

Licensee shall immediately surrender his/her Drug Enforcement Administration Registration.

STANDARD PROTOCOLS FORCONSENT ORDERS SPECIFICALLY RELATED TO SEXUAL VIOLATIONS

SEX RELATED VIOLATIONS

Licensee shall, for an indefinite length of time, be subject to the following conditions of this Consent Order:

Licensee shall not apply for relief from these conditions within five years of the effective date of the Order, and then must do so in writing.

Licensee shall undergo an assessment by a Board approved evaluator, within 30 days of the effective date of the Order, and make the written evaluation and treatment recommendations available to the Board.

Licensee shall adhere to, participate in, and complete all aspects of any and all residential care programs, continuing care programs and recovery treatment plans recommended by Board approved care providers and arrange for a written copy of all plans, programs, and contracts to be provided to the Board within 30 days of the effective date of the Order.

Licensee shall advise the Board, in writing, of any change or alteration to any residential care programs, continuing care programs, and recovery treatment plans 14 days before the change goes into effect.

Licensee shall instruct all health care providers participating in the residential, continuing care, and recovery programs to respond promptly to any Oregon Board of Dentistry inquiry concerning Licensee's compliance with the treatment plan and to immediately report to the Board, any substantial failure to fully participate in the programs by the Licensee. Licensee shall instruct the foregoing professionals to make written quarterly reports to the Board of Licensee's progress and compliance with the treatment programs.

Licensee shall waive any privilege with respect to any physical, psychiatric, or psychological evaluation or treatment in favor of the Board for the purposes of determining compliance with this Order, or the need to modify this Order, and shall execute any waiver or release upon request of the Board.

Licensee shall submit to a polygraph examination or plethysmograph examination, at Licensee's expense, at the direction of the Board or a counseling provider.

Licensee shall advise the Board, within 72 hours, of any substantial failure to participate in any recommended recovery program.

Licensee shall personally appear before the Board, or its designated representative(s), at a frequency to be determined by the Board, but initially at a frequency of three times per year.

IF APPROPRIATE –

Require Licensee to advise his/her dental staff or his/her employer of the terms of the Consent Order at least on an annual basis. Licensee shall provide the Board with documentation attesting that each dental staff member or employer reviewed the Consent Order. In the case of a Licensee adding a new employee, the Licensee shall advise the individual of the terms of the Consent Order on the first day of employment and shall provide the Board with documentation attesting to that advice.

STANDARD PROTOCOLS FOR CONSENT ORDERS REQUIRING CLOSE SUPERVISION

CLOSE SUPERVISION

a. For a period of at least six months, Licensee shall only practice dentistry in Oregon under the close supervision of a Board approved, Oregon licensed dentist (Supervisor), in order to demonstrate that clinical skills meet the standard of care. Periods of time Licensee does not practice dentistry as a dentist in Oregon, shall not apply to reduction of the (six) month requirement

b. Licensee will submit the names of any other supervising dentists for Board approval. Licensee will immediately advise the Board of any change in supervising dentists.

c. Licensee shall only treat patients when another Board approved Supervisor is physically in the office and shall not be solely responsible for emergent care.

d. The Supervisor will review and co-sign Licensee's treatment plans, treatment notes, and prescription orders.

e. Licensee will maintain a log of procedures performed by Licensee. The log will include the patient's name, the date of treatment, and a brief description of the procedure. The Supervisor will review and co-sign the log. Prior to the 15th of each month, Licensee will submit the log of the previous month's treatments to the Board.

f. For a period of two weeks, or longer if deemed necessary by the Supervisor, the Supervisor will examine the appropriate stages of dental work performed by Licensee in order to determine clinical competence.

g. After two weeks, and for each month thereafter for a period of six months, the Supervisor will submit a written report to the Board describing Licensee's level of clinical competence. At the end of six months, the Supervisor, will submit a written report attesting to the level of Licensee's competency to practice dentistry in Oregon.

h. At the end of the restricted license period, the Board will re-evaluate the status of Licensee's dental license. At that time, the Board may extend the restricted license period, lift the license restrictions, or take other appropriate action.

STANDARD PROTOCOLS – DEFINITIONS

Group practice: On 10/10/08, the Board defined "group practice" as two or more Oregon licensed dentists, one of which may be a respondent, practicing in the same business entity and in the same physical location.

When ordering a licensee to practice only in a group practice, add the caveat, "**Periods of time Licensee is not practicing dentistry as a dentist in Oregon, shall not apply to reduction of the (five year) requirement.**

STANDARD PROTOCOLS – PARAGRAPHS

WHEREAS, based on the results of an investigation, the Board has filed a Notice of Proposed Disciplinary Action, dated XXX, and hereby incorporated by reference; and

Division 12

818-012-0030

Unprofessional Conduct

~~The Board finds that in addition to the conduct set forth in ORS 679.140(2), a licensee engages in unprofessional conduct if the licensee does or permits any person to:~~ **The Board finds that in addition to the conduct set forth in ORS 679.140(2), unprofessional conduct includes, but is not limited to, the following in which a licensee does or permits any person to:**

(1) Attempt to obtain a fee by fraud**, lying** or misrepresentation.

(2) Obtain~~ing~~ a fee by fraud**, lying** or misrepresentation.

(a) A licensee obtains a fee by fraud if the licensee ~~obtains a fee by~~ knowingly mak~~ing~~**es,** or permit~~ting~~**s** any person to make**,** a material, false statement intending that a recipient**,** who is unaware of the truth**,** rely upon the statement.

(b) A licensee obtains a fee by misrepresentation if the licensee obtains a fee through making or permitting any person to make a material, false statement.

(c) Giving cash discounts and not disclosing them to third party payors is not fraud or misrepresentation.

(3) Offer rebates, split fees, or commissions for services rendered to a patient to any person other than a partner, employee, or employer.

(4) Accept rebates, split fees, or commissions for services rendered to a patient from any person other than a partner, employee, or employer.

(5) Initiate, or engage in, with a patient, any behavior with sexual connotations. The behavior can include but is not limited to, inappropriate physical touching; kissing of a sexual nature; gestures or expressions, any of which are sexualized or sexually demeaning to a patient; inappropriate procedures, including, but not limited to, disrobing and draping practices that reflect a lack of respect for the patient's privacy; or initiating inappropriate communication, verbal or written, including, but not limited to, references to a patient's body or clothing that are sexualized or sexually demeaning to a patient; and inappropriate comments or queries about the professional's or patient's sexual orientation, sexual performance, sexual fantasies, sexual problems, or sexual preferences.

(6) Engage in an unlawful trade practice as defined in ORS 646.605 to 646.608.

35 (7) Fail to present a treatment plan with estimated costs to a patient upon request of the
36 patient or to a patient's guardian upon request of the patient's guardian.
37 (8) Misrepresent any facts to a patient concerning treatment or fees.
38 (9)(a) Fail to provide a patient or patient's guardian within 14 days of written request:
39 (A) Legible copies of records; and
40 (B) Duplicates of study models**,** ~~and~~ **diagnostic quality** radiographs, **and** photographs
41 ~~or legible copies thereof~~ if the**y** ~~radiographs, photographs or study models~~ have been
42 paid for.
43 (b) The dentist may require the patient or guardian to pay in advance a fee reasonably
44 calculated to cover the costs of making the copies or duplicates. The dentist may charge
45 a fee not to exceed $30 for copying 10 or fewer pages of written material and no more
46 than $0.50 per page for pages 11 through 50 and no more than $0.25 for each additional
47 page (including records copied from microfilm), plus any postage costs to mail copies
48 requested and actual costs of preparing an explanation or summary of information, if
49 requested. The actual cost of duplicating ~~x-rays~~ **radiographs** may also be charged to
50 the patient. Patient records or summaries may not be withheld from the patient because
51 of any prior unpaid bills, except as provided in (9)(a)(B) of this rule.
52 (10) Fail to identify to a patient, patient's guardian, or the Board the name of an
53 employee, employer, contractor, or agent who renders services.
54 (11) Use prescription forms pre-printed with any Drug Enforcement Administration
55 number, name of controlled substances, or facsimile of a signature.
56 (12) Use a rubber stamp or like device to reproduce a signature on a prescription form or
57 sign a blank prescription form.
58 (13) Order drugs listed on Schedule II of the Drug Abuse Prevention and Control Act, 21
59 U.S.C. Sec. 812, for office use on a prescription form.
60 (14) Violate any Federal or State law regarding controlled substances.
61 (15) Becomes addicted to, or dependent upon, or abuses alcohol, illegal or controlled
62 drugs, or mind altering substances**, or practice with a substance use disorder**
63 **diagnosis.**
64 (16) Practice dentistry or dental hygiene in a dental office or clinic not owned by an
65 Oregon licensed dentist(s), except for an entity described under ORS 679.020(3) and
66 dental hygienists practicing pursuant to ORS 680.205(1)(2).
67 (17) Make an agreement with a patient or person, or any person or entity representing
68 patients or persons, or provide any form of consideration that would prohibit, restrict,

discourage or otherwise limit a person's ability to file a complaint with the Oregon Board of Dentistry; to truthfully and fully answer any questions posed by an agent or representative of the Board; or to participate as a witness in a Board proceeding.

(18) Fail to maintain at a minimum a current BLS for Healthcare Providers certificate or its equivalent. (Effective January 2015).

(19) Conduct unbecoming a licensee or detrimental to the best interests of the public, including conduct contrary to the recognized standards of ethics of the licensee's profession or conduct that endangers the health, safety or welfare of a patient or public.

(20) Deceiving or attempting to deceive the Board, an employee of the Board, or an agent of the Board in any application or renewal, or in reference to any matter under investigation by the Board. This includes but is not limited to the omission, alteration or destruction of any record in order to obstruct or delay an investigation by the Board, or to omit, alter or falsify any information in patient or business records.

(21) Practicing with a physical or mental impairment that renders the Licensee unable or potentially unable to safely conduct the practice of dentistry or dental hygiene.

(22) Take any action, or permit any other person to take any action, to determine the identity of a complainant or witness beyond mere inquiry in an ongoing Board investigation.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.140(1)(c), 679.140(2), 679.170(6) & 680.100

Hist.: DE 6, f. 8-9-63, ef. 9-11-63; DE 14, f. 1-20-72, ef. 2-10-72; DE 5-1980, f. & ef. 12-26-80; DE 2-1982, f. & ef. 3-19-82; DE 5-1982, f. & ef. 5-26-82; DE 9-1984, f. & ef. 5-17-84; Renumbered from 818-010-0080; DE 3-1986, f. & ef. 3-31-86; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0020; DE 1-1990, f. 3-19-90, cert. ef. 4-2-90; DE 2-1997, f. & cert. ef. 2-20-97; OBD 3-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06; OBD 1-2007, f. & cert. ef. 3-1-07; OBD 3-2007, f. & cert. ef. 11-30-07; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14; OBD 3-2015, f. 9-8-15, cert. ef. 10-1-15

818-012-0060

Failure to Cooperate with Board

(1) No licensee shall:

(~~1~~a) Fail to report to the Board violations of the Dental Practice Act.

(~~2~~b) Use threats or harassment to delay or obstruct any person in providing evidence in any investigation, contested case, or other legal action instituted by the Board.

(~~3~~c) Discharge an employee based primarily on the employee's attempt to comply with or aid in the compliance with the Dental Practice Act.

(~~4~~d) Use threats or harassment to obstruct or delay the Board in carrying out its functions under the Dental Practice Act.

(~~5~~e) Deceive or attempt to deceive the Board with respect to any matter under investigation including altering or destroying any records.

(~~6~~f) Make an untrue statement on any document, letter, or application submitted to the Board.

(~~7~~g) Fail to temporarily surrender custody of original patient records to the Board when the Board makes a written request for the records. For purposes of this rule, the term records includes, but is not limited to, the jacket, treatment charts, models, radiographs, photographs, health histories, billing documents, correspondence and memoranda.

(h) Fail to attend a Board requested investigative interview or failure to fully cooperate in any way with an ongoing Board investigation.

(2) No ~~person~~ **Applicant** shall:

(~~8~~a) Deceive or attempt to deceive the Board with respect to any matter under investigation including altering or destroying any records.

(~~9~~b) Make an untrue statement on any document, letter, or application submitted to the Board.

(c) Fail to fully cooperate with the Board during the course of an investigation, including but not limited to, waiver of confidentiality privileges, except attorney-client privilege.

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.060(4), 679.170(5), 679.250(8), 679.290, 679.310(1), 680.050(4) & 680.100

Hist.: DE 9-1984, f. & ef. 5-17-84; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f.

1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0050; DE 2-1997, f. & cert. ef. 2-20-97; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08

LICENSING, STANDARDS AND COMPETENCY COMMITTEE

Minutes
May 19, 2016

MEMBERS PRESENT: Amy B. Fine, D.M.D., Chair
Gary Underhill, D.M.D.
Yadira Martinez, R.D.H.
Todd Beck, D.M.D.
Daren L. Goin, D.M.D. – ODA Representative
Susan Kramer, R.D.H. – ODHA Representative
Mary Harrison, CDA, EFDA, EFODA – ODAA Representative

STAFF PRESENT: Stephen Prisby, Executive Director
Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator
Teresa Haynes, Acting Office Manager
Daniel Blickenstaff, D.D.S., Investigator

ALSO PRESENT: Lori Lindley, Sr. Assistant Attorney General via telephone

BOARD MEMBERS PRESENT:
Alton Harvey Sr.
Brandon Schwindt, D.M.D.
Julie Ann Smith, D.D.S., MD, MCR
Alicia Riedman, R.D.H. via telephone
James Morris, Via telephone

VISITORS PRESENT: Harold Hickok
Thomas Lant Haymore, D.M.D.
Laleh Hedayat, D.D.S.

Call to Order: The meeting was called to order by Dr. Fine, at 6:30 p.m.

MINUTES
Ms. Martinez moved and Dr. Beck seconded that the minutes of the October 14, 2015 Licensing, Standards and Competency Committee meeting be approved as presented. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Ms. Kramer and Ms. Harrison voting aye.

Dr. Goin joined the meeting at 6:36 p.m.

Correspondence
The Committee reviewed and discussed Dr. Louis Malcmacher's correspondence regarding

education and using dermal fillers as part of a dental treatment plan, in addition the Committee reviewed information provided by OBD staff on other State Dental Boards rules, regulations and policies regarding the administration of dermal fillers. Dr. Goin moved and Ms. Harrison seconded that the Committee recommend the Board refer OAR 818-012-0005 Scope of Practice, to the Rules Oversight Committee to amended OAR 818-012-0005 to allow dentists to administer dermal fillers with appropriate education, and to remove lip augmentation. The motion passed with Fine, Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

OAR 818-012-0005 – Scope of Practice
818-012-0005

Scope of Practice

(1) No dentist may perform any of the procedures listed below:

(a) Rhinoplasty;

(b) Blepharoplasty;

(c) Rhydidectomy;

(d) Submental liposuction;

(e) Laser resurfacing;

(f) Browlift, either open or endoscopic technique;

(g) Platysmal muscle plication;

(h) Otoplasty;

(i) Dermabrasion;

~~*(j) Lip augmentation;*~~

(j) ~~*(k)*~~ *Hair transplantation, not as an isolated procedure for male pattern baldness; and*

(k) ~~*(l)*~~ *Harvesting bone extra orally for dental procedures, including oral and maxillofacial procedures.*

(2) Unless the dentist:

(a) Has successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), and

(b) Has successfully completed a clinical fellowship, of at least one continuous year in duration, in esthetic (cosmetic) surgery recognized by the American Association of Oral and Maxillofacial Surgeons or by the American Dental Association Commission on Dental Accreditation, or

(c) Holds privileges either:

(A) Issued by a credentialing committee of a hospital accredited by the Joint Commission

on Accreditation of Healthcare Organizations (JCAHO) to perform these procedures in a hospital setting; or

(B) Issued by a credentialing committee for an ambulatory surgical center licensed by the State of Oregon and accredited by either the JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC).

(3) A dentist may utilize Botulinum Toxin Type A ***and dermal fillers*** *to treat a condition that is within the scope of the practice of dentistry after completing a minimum of 16 hours in a hands on clinical course(s)****, which includes both Botulimum Toxin Type A and dermal fillers, and*** ~~***in which***~~ *the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP).*

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.010(2), 679.140(1)(c), 679.140(2), 679.170(6) & 680.100

Hist.: OBD 6-2001, f. & cert. ef. 1-8-01; OBD 1-2013, f. 5-15-13, cert. ef. 7-1-13; OBD 3-2013, f. 10-24-13, cert. ef. 1-1-14; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

OAR 818-012-0010 – Unacceptable Patient Care

Dr. Underhill moved and Dr. Beck seconded that the Committee recommend the Board send OAR 818-012-0010 as amended to the Rules Oversight Committee. The motion passed with Fine, Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-012-0010

Unacceptable Patient Care

The Board finds, using the criteria set forth in ORS 679. 140(4), that a licensee engages in or permits the performance of unacceptable patient care if the licensee does or permits any person to:

(1) Provide treatment which exposes a patient to risk of harm when equivalent or better treatment with less risk to the patient is available.

(2) Fail to seek consultation whenever the welfare of a patient would be safeguarded or advanced by having recourse to those who have special skills, knowledge and experience; provided, however, that it is not a violation of this section to omit to seek consultation if other competent licensees in the same locality and in similar circumstances would not have sought such consultation.

(3) Fail to provide or arrange for emergency treatment for a patient currently receiving

treatment.

(4) Fail to exercise supervision required by the Dental Practice Act over any person or permit any person to perform duties for which the person is not licensed or certified.

(5) Render services which the licensee is not licensed to provide.

(6) Fail to comply with ORS 453.605 to 453.755 or rules adopted pursuant thereto relating to the use of x-ray machines.

(7) Fail to maintain patient records in accordance with OAR 818-012-0070.

(8) Fail to provide goods or services in a reasonable period of time which are due to a patient pursuant to a contract with the patient or a third party.

(9) Attempt to perform procedures which the licensee is not capable of performing due to physical or mental disability.

(10) Perform any procedure for which the patient or patient's guardian has not previously given informed consent provided, however, that in an emergency situation, if the patient is a minor whose guardian is unavailable or the patient is unable to respond, a licensee may render treatment in a reasonable manner according to community standards.

(11) Use the behavior management technique of Hand Over Mouth (HOM) without first obtaining informed consent for the use of the technique.

(12) Use the behavior management technique of Hand Over Mouth Airway Restriction (HOMAR) on any patient.

(13) Fail to document a dental justification prior to ordering a Cone Beam CT series with field greater than 10x10 cm for patients under 20 years of age.

(14) Fail to advise a patient of any treatment complications or treatment outcomes.

Stat. Auth.: ORS 679 & ORS 680
Stats. Implemented: ORS 679.140(1)(e), ORS 679.140(4) & ORS 680.100
Hist.: DE 6, f. 8-9-63, ef. 9-11-63; DE 14, f. 1-20-72, ef. 2-10-72; DE 5-1980, f. & ef. 12-26-80; DE 2-1982, f. & ef. 3-19-82; DE 5-1982, f. & ef. 5-26-82; DE 9-1984, f. & ef. 5-17-84; Renumbered from 818-010-0080; DE 3-1986, f. & ef. 3-31-86; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89, DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0020; DE 2-1997, f. & cert. ef. 2-20-97; DE 3-1997, f. & cert. ef. 8-27-97; OBD 7-2001, f. & cert. ef. 1-8-01

OAR 818-012-0040 – Infection Control

Dr. Goin moved and Ms. Harrison seconded that the Committee recommend the Board send OAR 818-012-0040 as presented to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-012-0040

Infection Control Guidelines

In determining what constitutes unacceptable patient care with respect to infection control, the Board may consider current infection control guidelines such as those of the Centers for Disease Control and Prevention and the American Dental Association.

(1) *Additionally, licensees must comply with the following requirements:*

*(**a**) (~~1~~)Disposable gloves shall be worn whenever placing fingers into the mouth of a patient or when handling blood or saliva contaminated instruments or equipment. Appropriate hand hygiene shall be performed prior to gloving.*

*(**b**) (~~2~~)Masks and protective eyewear or chin-length shields shall be worn by licensees and other dental care workers when spattering of blood or other body fluids is likely.*

*(**c**)(~~3~~) Between each patient use, instruments or other equipment that come in contact with body fluids shall be sterilized.*

*(**d**) (~~4~~)Environmental surfaces that are contaminated by blood or saliva shall be disinfected with a chemical germicide which is mycobactericidal at use.*

*(**e**)(~~5~~) Impervious backed paper, aluminum foil, or plastic wrap may be used to cover surfaces that may be contaminated by blood or saliva and are difficult or impossible to disinfect. The cover shall be replaced between patients.*

*(**f**) (~~6~~)All contaminated wastes and sharps shall be disposed of according to any governmental requirements.*

(2) Dentists must comply with the requirement that *heat sterilizing devices shall be tested for proper function by means of a biological monitoring system that indicates micro-organisms kill each calendar week in which scheduled patients are treated. Testing results shall be retained by the* ***dentist*** *~~licensee~~ for the current calendar year and the two preceding calendar years.*

*Stat. Auth.: ORS 679.120, 679.250(7), **679.535,** 680.075 & 680.150*
Stats. Implemented: ORS 679.140, 679.140(4) & 680.100
Hist.: DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; DE 2-1992, f. & cert. ef. 6-24-92; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 3-2013, f. 10-24-13, cert. ef. 1-1-14; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

DRAFT

OAR 818-012-0070 – Patient Records

Dr. Beck moved and Dr. Underhill seconded that the Committee recommend the Board send OAR 818-012-0040 to the Rules Oversight Committee for further consideration. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-012-0070

Patient Records

(1) Each licensee shall have prepared and maintained an accurate record for each person receiving dental services, regardless of whether any fee is charged. The record shall contain the name of the licensee rendering the service and include:

(a) Name and address and, if a minor, name of guardian;

(b) Date description of examination and diagnosis;

(c) An entry that informed consent has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or "SOAP" (Subjective Objective Assessment Plan) or their equivalent.

(d) Date and description of treatment or services rendered;

*(e) Date ~~and~~, description **and documentation of informing the patient** of treatment complications **or treatment outcomes**;*

(f) Date and description of all radiographs, study models, and periodontal charting;

(g) Health history; and

(h) Date, name of, quantity of, and strength of all drugs dispensed, administered, or prescribed.

*(2) Each ~~dentist~~ **licensee** shall have prepared and maintained an accurate record of all charges and payments for services including source of payments.*

*(3) Each ~~dentist~~ **licensee** shall maintain patient records and radiographs for at least seven years from the date of last entry unless:*

*(a) The patient requests the records, radiographs, and models be transferred to another ~~dentist~~ **licensee** who shall maintain the records and radiographs;*

*(b) The ~~dentist~~ **licensee** gives the records, radiographs, or models to the patient; or*

*(c) The ~~dentist~~ **licensee** transfers the ~~dentist's~~ **licensee's** practice to another ~~dentist~~ **licensee** who shall maintain the records and radiographs.*

(4) When changing practice locations, closing a practice location or retiring, each licensee must retain patient records for the required amount of time or transfer the

custody of patient records to another licensee licensed and practicing dentistry in Oregon. Transfer of patient records pursuant to this section of this rule must be reported to the Board in writing within 14 days of transfer, but not later than the effective date of the change in practice location, closure of the practice location or retirement. Failure to transfer the custody of patient records as required in this rule is unprofessional conduct.

(5) Upon the death or permanent disability of a licensee, the administrator, executor, personal representative, guardian, conservator or receiver of the former licensee must notify the Board in writing of the management arrangement for the custody and transfer of patient records. This individual must ensure the security of and access to patient records by the patient or other authorized party, and must report arrangements for permanent custody of patient records to the Board in writing within 90 days of the death of the licensee.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.140(1)(e) & ORS 679.140(4)

Hist.: DE 9-1984, f. & ef. 5-17-84; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89, DE 1-1989, f. 1-27-90, cert. ef. 2-1-90; Renumbered from 818-011-0060; DE 1-1990, f. 3-19-90, cert. ef. 4-2-90; OBD 7-2001, f. & cert. ef. 1-8-01

OAR 818-012-XXXX – Diagnostic Records

Dr. Underhill moved and Dr. Goin seconded that the Committee recommend the Board send OAR 818-012-XXXX as amended to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

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818-012-XXXX

Diagnostic records.

1) Licensees shall provide duplicates of physical diagnostic records that have been paid for to patient or patient's guardian within 14 days of written request.

(A) Physical records include silver emulsion radiographs, physical study models, paper charting and chart notes.

(B) Licensees may require the patient or patient's guardian to pay in advance the fee reasonably calculated to cover costs of making the copies or duplicates.

(i) Licensee may charge a fee not to exceed $30 for copying 10 or fewer pages of

written material and no more than $0.50 per page for 11-50 and no more than $0.25 for each additional page, including cost of microfilm plus any postage costs to mail copies requested and actual costs of preparing an explanation or summary of information, if requested. The actual costs of duplicating radiographs may also be charged to the patient.

2) Licensees shall provide duplicates of digital patient records within 3 clinical days of written request by the patient or patient's guardian.

A) Digital records include any patient diagnostic image, study model, test result or chart record in digital form.

B) Licensees may require the patient or patient's guardian to pay for the typical retail cost of the digital storage device, such as a CD, thumb drive, or DVD as well as associated postage.

C) Licensees shall not charge any patient or patient's guardian to transmit requested digital records over email if total records do not exceed 25 Mb.

D) A clinical day is defined as a day during which the dental clinic treated scheduled patients.

E) Licensees may charge up to $5 for duplication of digital records up to 25Mb and up to $30 for more than 25Mb.

F) Any transmission of patient records shall be in compliance with the Health Insurance Portability and Accountability Act (HIPAA Act) and the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

G) Duplicated digital records shall be of the same quality as the original digital file.

3) If a records summary is requested by patient or patient's guardian, the actual cost of creating this summary and its transmittal may be billed to the patient or patient's guardian.

OAR 818-021-0011- Application for License to Practice Dentistry Without Further Examination

Dr. Goin moved and Ms. Harrison seconded that the Committee recommend the Board send OAR 818-021-0011 as amended to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

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Division 21

818-021-0011

Application for License to Practice Dentistry Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Having passed the dental clinical examination conducted by a regional testing agency or by a state dental licensing authority; and

(d) Holding an active license to practice dentistry, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

(e) Having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately prior to application. ***For licensed dentists employed by a dental education program, documentation from the dean or appropriate administration of the institution regarding length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching all disciplines of clinical dentistry, and any adverse actions or restrictions****; and*

(f) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

(3) A dental license granted under this rule will be the same as the license held in another state; i.e., if the dentist holds a general dentistry license, the Oregon Board will issue a general (unlimited) dentistry license. If the dentist holds a license limited to the practice of a specialty, the Oregon Board will issue a license limited to the practice of that specialty.

If the dentist holds more than one license, the Oregon Board will issue a dental license which is least restrictive.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.060, 679.065, 679.070, 679.080 & 679.090
Hist.: OBD 4-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 4-2001, f. & cert. ef. 1-8-01; OBD 12-2001(Temp), f. & cert. ef. 1-9-01 thru 7-7-01; OBD 14-2001(Temp), f. 8-2-01, cert. ef. 8-15-01 thru 2-10-02; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 1-2002(Temp), f. & cert. ef. 7-17-02 thru 1-12-03; Administrative correction 4-16-03; OBD 1-2003, f. & cert. ef. 4-18-03; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

OAR 818-021-0025 – License to Practice Dental Hygiene Without Further Examination

Ms. Martinez moved and Dr. Goin seconded that the Committee recommend the Board send OAR 818-021-0025 as amended to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-021-0025

Application for License to Practice Dental Hygiene Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dental hygienist who holds a license to practice dental hygiene in another state or states if the dental hygienist meets the requirements set forth in ORS 680.040 and 680.050 and submits to the Board satisfactory evidence of:
(a) Having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and
*(c) ~~Evidence of h~~**Having** passed the clinical dental hygiene examination conducted by a regional testing agency or by a state dental or dental hygiene licensing authority; and*
(d) Holding an active license to practice dental hygiene, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dental hygiene, without restrictions, and

whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

*(e) Having conducted licensed clinical practice in Oregon, in other states or in the Armed Forces of the United States, the United States Public Health Service, the United States Department of Veterans Affairs, or teaching all disciplines of clinical dental hygiene at a dental hygiene education program accredited by the Commission on Dental Accreditation of the American Dental Association for a minimum of 3,500 hours in the five years immediately preceding application. For **licensed** dental hygienists employed by a dental hygiene program, documentation from the dean or appropriate administration of the institution regarding length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching all disciplines of clinical dental hygiene, and any adverse actions or restrictions; and*

(f) Having completed 24 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

Stat. Auth.: ORS 680

Stats. Implemented: ORS 680.040, 680.050, 680.060, 680.070 & 680.072

Hist.: OBD 4-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 4-2001, f. & cert. ef. 1-8-01; OBD 12-2001(Temp), f. & cert. ef. 1-9-01 thru 7-7-01; OBD 14-2001(Temp), f. 8-2-01, cert. ef. 8-15-01 thru 2-10-02; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 1-2002(Temp), f. & cert. ef. 7-17-02 thru 1-12-03; Administrative correction 4-16-03; OBD 1-2003, f. & cert. ef. 4-18-03; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 4-2011, f. & cert. ef. 11-15-11

OAR 818-042-0020 – Dentist and Dental Hygienist Responsibility

Ms. Martinez moved and Dr. Goin seconded that the Committee recommend the Board send OAR 818-042-0020 as presented to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

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Division 42

818-042-0020

Dentist and Dental Hygienist Responsibility

(1) A dentist is responsible for assuring that a dental assistant has been properly trained, has demonstrated proficiency, and is supervised in all the duties the assistant performs in the dental office. Unless otherwise specified, dental assistants shall work under indirect supervision in the dental office.

*(2) A dental hygienist who works under general supervision may supervise ~~a~~ dental assistant**s** in the dental office if the dental assistant**s** ~~is~~ **are** rendering assistance to the dental hygienist in providing dental hygiene services and the dentist is not in the office to provide indirect supervision. A dental hygienist with an Expanded Practice Permit may hire and supervise ~~a~~ dental assistant**s** who will render assistance to the dental hygienist in providing dental hygiene services.*

(3) The supervising dentist or dental hygienist is responsible for assuring that all required licenses, permits or certificates are current and posted in a conspicuous place.

(4) Dental assistants who are in compliance with written training and screening protocols adopted by the Board may perform oral health screenings under general supervision.

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 2-2012, f. 6-14-12, cert. ef. 7-1-12

OAR 818-042-0120 – Certification by Credentials

Ms. Harrison moved and Ms. Kramer seconded that the Committee recommend the Board send OAR 818-042-0120 as presented to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

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818-042-0120

Certification by Credential

*(1) Dental Assistants who wish to be certified by the Board in Radiologic Proficiency or as Expanded Function Dental Assistants, ~~or as~~ Expanded Function Orthodontic Dental Assistants**, or as Expanded Function Preventive Dental Assistants** shall:*

(a) Be certified by another state in the functions for which application is made. The training and certification requirements of the state in which the dental assistant is certified must be substantially similar to Oregon's requirements; or

(b) Have worked for at least 1,000 hours in the past two years in a dental office where such employment involved to a significant extent the functions for which certification is

sought; and

(c) Shall be evaluated by a licensed dentist, using a Board approved checklist, to assure that the assistant is competent in the expanded functions.

(2) Applicants applying for certification by credential in Radiologic Proficiency must obtain certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, of having successfully completed training equivalent to that required by OAR 333-106-0055 or approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.020, 679.025 & 679.250

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

OAR 818-042-XXXX – Expanded Functions Preventive Dental Assistants

Dr. Goin moved and Ms. Harrison seconded that the Committee recommend the Board add OAR 818-042-XXXX as presented to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

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818-042-XXXX

Expanded Function Preventive Dental Assistants (EFPDA)

The following duties are considered Expanded Function Preventive Duties and may be performed only after the dental assistant complies with the requirements of 818-042-XXXX:

(1) Polish the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains; and

(2) Apply pit and fissure sealants provided the patient is examined before the sealants are placed. The sealants must be placed within 45 days of the procedure being authorized by a dentist or dental hygienist.

DRAFT

OAR 818-042-XXXX – Certification Expanded Functions Preventive Dental Assistants

Dr. Underhill moved and Dr. Beck seconded that the Committee recommend the Board add OAR 818-042-XXXX as amended to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-042-XXXX

Certification — Expanded Function Preventive Dental Assistants (EFPDA)

The Board may certify a dental assistant as an expanded function preventive dental assistant:

(1) By credential in accordance with OAR 818-042-0120, or

(2) If the assistant submits a completed application, pays the fee and provides evidence of;

(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Oregon Basic or Certified Preventive Functions Dental Assistant (CPFDA) examination, and the Expanded Function Dental Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by an Oregon licensed dentist that the applicant has successfully polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains on six patients; and

(c) Completion of a Board approved course in pit and fissure sealants.

DRAFT

OAR 818-042-0130 – Certification by Credentials

Dr. Beck moved and Ms. Harrison seconded that the Committee recommend the Board send OAR 818-042-0130 as presented to the Rules Oversight Committee. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-042-0130

Application for Certification by Credential

An applicant for certification by credential shall submit to the Board:

(1) An application form approved by the Board, with the appropriate fee;

(2) Proof of certification by another state and any other recognized certifications (such as CDA or COA certification) and a description of the examination and training required by the state in which the assistant is certified submitted from the state directly to the Board; or

(3) Certification that the assistant has been employed for at least 1,000 hours in the past two years as a dental assistant performing the functions for which certification is being sought.

*(4) If applying for certification by credential as an EFDA, ~~or~~ EFODA **or EFPDA**~~,~~ certification by a licensed dentist that the applicant is competent to perform the functions for which certification is sought; and*

(5) If applying for certification by credential in Radiologic Proficiency, certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, or the Oregon Board of Dentistry, that the applicant has met that agency's training requirements for x-ray machine operators, or other comparable requirements approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.020, 679.025 & 679.250

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

DRAFT

Course Format – Placing Cord Subgingivally

Dr. Beck moved Ms. Martinez seconded that the Committee recommend that the Board approve the Board Approved Course in Placing Cord Subgingivally as presented. The motion passed with Dr. Underhill, Ms. Martinez, Dr. Beck, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

There was general discussion about dental therapist programs and pilot programs in Oregon.

The meeting adjourned at 8:00 p.m.

DRAFT

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

MEETING NOTICE

LICENSING, STANDARDS AND COMPETENCY COMMITTEE

OREGON BOARD OF DENTISTRY
1500 SW 1st AVENUE, SUITE 770
PORTLAND, OREGON 97201

MAY 19, 2016
6:30 P.M.

Committee Members:
Amy B. Fine, D.M.D., Chair
Gary Underhill, D.M.D.
Yadira Martinez, R.D.H., E.P.P.
Todd Beck, D.M.D.
Daren L. Goin, D.M.D. - ODA Representative
Susan Kramer, R.D.H. - ODHA Representative
Mary Harrison, CDA, EFDA, EFODA, FADAA - ODAA Representative

AGENDA

Call to Order — Amy B. Fine, D.M.D., Chair

Review Minutes of October 14, 2015 Committee Meeting

October 14, 2015 Minutes **Attachment #1**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-012-0005 Scope of Practice.

OAR 818-012-0005 Scope of Practice **Attachment #2**

Review and discuss correspondence from Dr. Louis Malcmacher regarding dermal fillers**. Attachment #3**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-012-0010 Unacceptable Patient Care.

Draft OAR 818-012-0010 Unacceptable Patient Care **Attachment #4**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-012-0040 Infection Control Guidelines.

Draft OAR 818-012-0040 Infection Control Guidelines **Attachment #5**

The meeting location is accessible to persons with disabilities. A request for an interpreter for the hearing impaired or for other accommodations for persons with disabilities should be made at least 48 hours before the meeting to Teresa Haynes, (971) 673-3200.

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-012-0070 Patient Records.

Draft OAR 818-012-0070 Patient Records **Attachment #6**

Review, discuss and make possible recommendations to the Board regarding adding rule OAR 818-012-XXXX Diagnostic Records.

Draft OAR 818-012-XXXX Diagnostic Records **Attachment #7**

Dr. Schwindt provided additional information on patient safety and radiographs **Attachment #8**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-021-0011 Application for License to Practice Dentistry Without Further Examination.

Draft OAR 818-021-0011 Application for License to Practice Dentistry Without Further Examination **Attachment #9**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-021-0025 Application for License to Practice Dental Hygiene Without Further Examination.

Draft OAR 818-021-0025 Application for License to Practice Dental Hygiene Without Further Examination **Attachment #10**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-042-0020 Dentist and Dental Hygienist Responsibility.

Draft OAR 818-042-0020 Dentist and Dental Hygienist Responsibility **Attachment #11**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-042-0120 Certification by Credential.

Draft 818-042-0120 Certification by Credentials **Attachment #12**

Review, discuss and make possible recommendations to the Board regarding adding rule OAR 818-042-XXXX Expanded Functions Preventive Dental Assistants (EFPDA).

Draft 818-042-XXXX Expanded Functions Preventive Assistants (EFPDA) **Attachment #13**

Review, discuss and make possible recommendations to the Board regarding adding rule OAR 818-042-XXXX Certification – Expanded Functions - Preventive Dental Assistants (EFPDA).

Draft 818-042-XXXX Certification – Expanded Functions Preventive Dental Assistants **Attachment #14**

Review, discuss and make possible recommendations to the Board regarding proposed rule changes to OAR 818-042-0130 Application for Certification by Credentials.

Draft 818-042-0130 Application for Certification by Credential **Attachment #15**

Review and discuss course outline for approving courses for expanded functions dental assistants placing cord subgingivally.

Draft Couse Outline Placing Cord Subgingivally **Attachment #16**

Any other business

Adjourn

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

Memorandum

To: Attendees of OBD Meetings

From: Stephen Prisby, Executive Director

Re: OBD/Crown Plaza Conference Room access

The Crown Plaza closes the 1st floor lobby/access at 6:00 p.m.

The building must be accessed on the 2nd floor. There is a security desk/guard that you will need to sign in with and show I.D.

The parking garage is directly across the street from our building (The Crown Plaza). The access is via two walkways on the 2nd floor. If you walk up to the building there are stairs that take you to the second floor.

Draft 1

LICENSING, STANDARDS AND COMPETENCY COMMITTEE TELECONFERENCE

Minutes
October 14, 2015

MEMBERS PRESENT: Amy B. Fine, D.M.D., Chair
via Teleconference Gary Underhill, D.M.D.
Yadira Martinez, R.D.H.
Daren L. Goin, D.M.D. – ODA Representative
Susan Kramer, R.D.H. – ODHA Representative
Mary Harrison, CDA, EFDA, EFODA – ODAA Representative

STAFF PRESENT: Stephen Prisby, Executive Director
Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator
Teresa Haynes, Examination and Licensing Manager
Jessica Conway, Office Manager

BOARD MEMBERS PRESENT:
via Teleconference Alton Harvey Sr., President
Brandon Schwindt, D.M.D.
Alicia Riedman, R.D.H.

Call to Order: The meeting was called to order by Dr. Fine, at 6:00 p.m. via Teleconference.

MINUTES

Dr. Underhill moved and Dr.Goin seconded that the minutes of the December 18, 2014 Licensing, Standards and Competency Committee meeting be approved as presented. The motion passed with Dr. Fine, Dr. Underhill, Ms. Martinez, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

CORRESPONDENCE

The Committee reviewed and discussed the Dental Assisting National Board's (DANB) certifications for dental assistants and correspondence.

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Request for the addition certificate for pediatric and/or prevention focused expanded function assistant.

The Committee reviewed and discussed the request for an additional expanded function certification category that would focus on pediatric or prevention functions. Dr. Goin moved and Ms. Harrison seconded that the Committee recommend that the Board refer to the Rules Oversight Committee issue of developing a new EFDA category with a new check off list appropriate for that certification level. The motion passed with Dr. Fine, Dr. Underhill, Ms. Martinez, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

OAR 818-042-0070 – Expanded Function Dental Assistants (EFDA)

The Committee reviewed and discussed if a patient, whose has had their teeth polished by an Expanded Functions Dental Assistant "EFDA", would need to be seen by a dentist or dental hygienist prior to discharge.

Dr. Fine moved and Ms. Harrison seconded that the Committee recommend that the Board send OAR 818-042-0070(1) to the Rules Oversight Committee to add verbiage regarding when a patient would need to be seen prior to discharge. The motion passed with Dr. Fine, Dr. Underhill, Ms. Martinez, Dr. Goin, Ms. Kramer and Ms. Harrison voting aye.

818-042-0070

Expanded Function Dental Assistants (EFDA)

The following duties are considered Expanded Function Duties and may be performed only after the dental assistant complies with the requirements of 818-042-0080:

(1) Polish the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains **providing the patient is checked by a dentist or dental hygienist after the procedure is performed, prior to discharge**;

(2) Remove temporary crowns for final cementation and clean teeth for final cementation;

(3) Preliminarily fit crowns to check contacts or to adjust occlusion outside the mouth;

(4) Place temporary restorative material (i.e., zinc oxide eugenol based material) in teeth providing that the patient is checked by a dentist before and after the procedure is performed;

(5) Place and remove matrix retainers for alloy and composite restorations;

(6) Polish amalgam or composite surfaces with a slow speed hand piece;

(7) Remove excess supragingival cement from crowns, bridges, bands or brackets with hand instruments providing that the patient is checked by a dentist after the procedure is performed;

(8) Fabricate temporary crowns, and temporarily cement the temporary crown. The cemented crown must be examined and approved by the dentist prior to the patient being released;

(9) Under general supervision, when the dentist is not available and the patient is in discomfort, an EFDA may recement a temporary crown or recement a permanent crown with temporary cement for a patient of record providing that the patient is rescheduled for follow-up care by a licensed dentist as soon as is reasonably appropriate; and

(10) Perform all aspects of teeth whitening procedures.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-

2005, f. 10-26-05, cert. ef. 11-1-05; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 3-2015, f. 9-8-15, cert. ef. 10-1-15

OAR 818-042-0090 – Additional Functions of EFDAs

The Committee reviewed and discussed if there should be any specific requirements in a course the Board approves that allows EFDAs packing cord subgingivally. No action was taken by the Committee. All materials provided by DANB will be made available for the Board to review.

The meeting was adjourned at 6:52 p.m.

DRAFT

Division 12

818-012-0005

Scope of Practice

(1) No dentist may perform any of the procedures listed below:
(a) Rhinoplasty;
(b) Blepharoplasty;
(c) Rhydidectomy;
(d) Submental liposuction;
(e) Laser resurfacing;
(f) Browlift, either open or endoscopic technique;
(g) Platysmal muscle plication;
(h) Otoplasty;
(i) Dermabrasion;
(j) Lip augmentation;
(k) Hair transplantation, not as an isolated procedure for male pattern baldness; and
(l) Harvesting bone extra orally for dental procedures, including oral and maxillofacial procedures.
(2) Unless the dentist:
(a) Has successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), and
(b) Has successfully completed a clinical fellowship, of at least one continuous year in duration, in esthetic (cosmetic) surgery recognized by the American Association of Oral and Maxillofacial Surgeons or by the American Dental Association Commission on Dental Accreditation, or
(c) Holds privileges either:
(A) Issued by a credentialing committee of a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to perform these procedures in a hospital setting; or
(B) Issued by a credentialing committee for an ambulatory surgical center licensed by the State of Oregon and accredited by either the JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC).
(3) A dentist may utilize Botulinum Toxin Type A to treat a condition that is within the scope of the practice of dentistry after completing a minimum of 16 hours in a hands on clinical course(s)

DRAFT

35 in which the provider is approved by the Academy of General Dentistry Program Approval for
36 Continuing Education (AGD PACE) or by the American Dental Association Continuing
37 Education Recognition Program (ADA CERP).
38 Stat. Auth.: ORS 679 & 680
39 Stats. Implemented: ORS 679.010(2), 679.140(1)(c), 679.140(2), 679.170(6) & 680.100
40 Hist.: OBD 6-2001, f. & cert. ef. 1-8-01; OBD 1-2013, f. 5-15-13, cert. ef. 7-1-13; OBD 3-2013, f.
41 10-24-13, cert. ef. 1-1-14; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14
42

DRAFT

Teresa Haynes

From: Stephen Prisby
Sent: Wednesday, May 4, 2016 10:31 AM
To: Teresa Haynes
Subject: Dermal Filler Information for the Oregon Dental Board

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From: Louis Malcmacher [mailto:dryowza@gmail.com]
Sent: Monday, May 02, 2016 4:32 AM
To: Stephen Prisby
Cc: 'Louis Malcmacher'
Subject: RE: Dermal Filler Information for the Oregon Dental Board

Hi, Stephen, hope you had a great weekend!

We have put together one large pdf with all the documents. The file is too big to email so you can download it here - https://www.dropbox.com/s/y245gs26r4famrj/Dermal%20filler%20Information%20Oregon%20Board.pdf?dl=0 .

Let me know if that works.

There is a page titled Dental education facial injectable courses which has a list of most of the venues where Botox and dermal filler dental continuing education has occurred.

Most of the documents are self-explanatory, including a number of articles using dermal fillers within the scope of dental practice as well as an ADA Professional Product Review this past August on Botox and dermal fillers in dentistry.

The Photo Patient Documentation Series that the AAFE teaches includes smiling photos as these are crucial in determining the use of dermal fillers for establishing/creating proper lip lines and smiles lines as part of a dental treatment plan.

Hope that helps, please let me know if you need anything else from me.

Thanks and have a great day!

Dr. Louis Malcmacher
2120 South Green Road
Beachwood, Ohio 44121
800 952-0521 extension 706 for Kate Peake, Executive Assistant
Fax 216 393-0100
www.FacialEsthetics.org

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From: Stephen Prisby [mailto:Stephen.Prisby@state.or.us]
Sent: Thursday, April 28, 2016 4:15 PM
To: Louis Malcmacher <dryowza@gmail.com>
Subject: RE: Dermal Filler Information for the Oregon Dental Board

Thank you for putting them into 1 pdf for the public/board members, then we can ensure the info. is provided as you intended.

I will pass on your invitation to the Board, to take an AAFE Course.

Sincerely,
Stephen

From: Louis Malcmacher [mailto:dryowza@gmail.com]
Sent: Thursday, April 28, 2016 12:42 PM
To: Stephen Prisby
Subject: RE: Dermal Filler Information for the Oregon Dental Board

With that weblink, you can download all those documents in pdf form and print them out.

I can have all of them put into 1 pdf if you like.

Let me know which works, I will take out the dermal filler syllabus if that is the case with it all being open meetings.

We would also welcome a state dental board member to take an aafe course as our guest if none have taken it already.

Thanks and have a great day!

Dr. Louis Malcmacher
2120 South Green Road
Beachwood, Ohio 44121
800 952-0521 extension 706 for Kate Peake, Executive Assistant
Fax 216 393-0100
www.FacialEsthetics.org

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Dental education on Botox and dermal fillers for general dentists for therapeutic and esthetic purposes in the oral and maxillofacial areas 2008 – 2015

This partial list includes continuing education dental lectures and/or hands-on training programs that have been presented at the following dental universities (in residencies and continuing education courses for general dentists) and at the following dental associations and societies:

UCLA School of Dentistry
USC School of Dentistry
UCSF School of Dentistry
UMDNJ School of Dentistry
Loma Linda School of Dentistry
University of Washington School of Dentistry
University of Toronto School of Dentistry
University of Buffalo School of Dentistry
Iowa University Dental Society Meeting
Tufts University School of Dentistry
Boston University School of Dentistry
University of Michigan School of Dentistry
University of British Columbia School of Dentistry
Louisiana State University School of Dentistry
Nova Southeastern University School of Dentistry
University of Alabama School of Dentistry
American Dental Association Annual Meeting
American Academy of Facial Esthetics
Academy of General Dentistry
American Academy of Cosmetic Dentistry
California Dental Association Annual Meeting
Greater New York Dental Annual Meeting
Chicago Dental Society Annual Meeting
Northeastern Regional Dental Association
Kentucky Dental Association Annual Meeting
North California Academy of General Dentistry
Indiana Dental Association
Wisconsin Dental Association Annual Meeting
American Association of Dental Boards
Quebec Dental Association Annual Meeting
Arizona Dental Association Annual Meeting
Texas Dental Association Meeting
Florida Dental Association Annual Meeting
Valley Forge Dental Association Meeting
Greater Long Island Dental Meeting
Hinman Dental Meeting
New Orleans Dental Conference
Dentaltown Annual Meeting
New Jersey Academy of General Dentistry
Sacramento District Dental Society
Maryland State Dental Association Meeting
Michigan Dental Association Meeting
Northern Virginia Dental Association Meeting
Buffalo Niagara Dental Annual Meeting
Oregon Dental Association Annual Meeting
Texas Academy of General Dentistry Annual Meeting
Ontario Academy of General Dentistry Annual Meeting
Alabama Academy of General Dentistry Annual Meeting
Pennsylvania Academy of General Dentistry
Illinois Academy of General Dentistry Annual Meeting
Beverly Hills Dental Study Club
Ohio Dental Association Annual Meeting
Maine Dental Association Annual Meeting
Detroit District Dental Society
Utah Academy of General Dentistry
Florida National Dental Congress
Hawaii Dental Association Annual Meeting
Yankee Dental Congress

The American Academy of Facial Esthetics trains dentists in the use of Botox and dermal fillers in the oral and maxillofacial areas for dental esthetic and dental therapeutic uses. In the last 7 years, the American Academy of Facial Esthetics has educated over 10,000 healthcare professionals including over 8000 dental professionals including general dental and dental specialty offices from all 50 states and 42 countries through over 150 live patient training courses a year which has been become the model and standard for accepted dental education in these procedures.

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South Euclid, OH 44121

800.952.0521 | WWW.FACIALESTHETICS.ORG

COURSE OBJECTIVES

Dermal Fillers Training for Dental Professionals

- Learn about the role dermal fillers are used in dental esthetic and therapeutic options for patients
- Review the natural course of the aging face as well as strategies to address the different dimension of are related facial changes
- Learn about the types of dermal filler options available, their capabilities, characteristics and pros and cons
- Learn about hyaluronic acid and its role in dermal fillers
- Learn indications and contraindications for dermal fillers
- Evaluation, patient consultation, diagnosis and patient selection
- Discuss, observe and practice specific injection technique to achieve long-lasting natural results
- View and practice live injection techniques
- Understand potential pitfalls, complications, and adverse effects as well as how to prevent and remedy them
- Cover specifics for successful lip enhancement treatments as part of every dental treatment plan
- Using dermal fillers to create proper smile lines, lip lines and treating the oral and peri-oral areas as part of every dental treatment plan
- Integrating dermal filler treatments into your existing practice for best therapeutic and esthetic patient outcomes

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- Discuss proper fee strategies and practice management techniques

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DENTAL CHARTING EXAMPLES

Dental esthetic and dental therapeutic uses of botulinum toxin and dermal fillers include but are not limited to the following:

- TMD/bruxism/headache/migraine/facial pain treatment or differential diagnosis
- Establishing proper lip lines for dental esthetic, implant, restorative and crown and bridge cases
- Establishing proper smile lines for dental esthetic, implant, restorative and crown and bridge cases
- Treatment of maxillary or mandibular gingival excess
- Lip enhancement for dental esthetics and/or phonetics
- Treatment of angular chelitis/cracked lips/corners of lips
- Oral and peri-oral soft tissue enhancement for dental esthetics, implant, restorative, crown and bridge cases, phonetics, gummy smile and therapeutic cases
- Orthodontic relapse and depressed orthodontic appearance
- Reducing muscle hyperactivity for retention of removable prosthodontics
- Establishing lip volume for proper phonetics in addition or as opposed to teeth lengthening with fixed or removable prosthodontics

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Full Face at Rest

Full Face Surprised

Full Face Pucker

Full Face Angry

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Left Lateral at Rest

Right Lateral Smile or Squinting

Right Lateral at Rest

Left Lateral Smile or Squinting

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CLINICIAN'S CORNER

ADA Professional Product Review®
A Publication of the Council on Scientific Affairs

A Discussion about Dermal fillers, Botox and Dentistry

ADA Professional Product Review editor Dr. David Sarrett invites three experts to share their insights.

Today, the quest for a youthful appearance is stronger than ever. The American Society of Plastic Surgeons reported[1] that cosmetic minimally invasive procedures increased 3 percent, to more than 13.4 million procedures in 2013. The top two minimally invasive procedures in 2013 were botulinum toxin type A (Botox) (6.3 million injections) and soft tissue fillers (2.2 million procedures), representing increases of 3 and 13 percent, respectively from 2012. Some dental offices provide these services; however, state laws regarding who can administer Botox and dermal fillers vary widely. (See "State Regulations" sidebar below.)

For this article, the PPR editor Dr. David Sarrett (DS) poses questions to three clinicians about the use of these products: Dr. Gary D. Hack (GH) is Associate Professor at the University of Maryland School of Dentistry, Dr. Louis Malcmacher (LM) is president of the American Academy of Facial Esthetics and Dr. Joe Niamtu (JM) is a board-certified oral and maxillofacial surgeon.

DS: The U.S. Food and Drug Administration (FDA) approves injectable dermal fillers (also known as "wrinkle fillers" or "soft tissue fillers") as medical devices. Generally, these products are injected into the skin to help fill facial wrinkles and restore a smoother appearance. How do they work?

GH: As we age, our faces naturally lose subcutaneous fat; therefore the muscles of facial expression are functioning closer to the skin's surface, and so wrinkles become significantly more apparent. By directly injecting a naturally derived material — the most widely known is hyaluronic acid — or synthetic material into the wrinkle or crease, such as the deep lines from the corners of the nose to the corners of the mouth (nasolabial folds), the skin is plumped up to the point where the wrinkle, depression, or fold is significantly reduced. This improvement can last from 3 months to 2 years or longer depending on the type of filler used, how well the patient takes care of his or her skin, and how the patient's face continues to age. Dermal fillers can be used to plump thin lips and can be very helpful in treating patients with early signs of aging. Botulinum toxin injections reduce muscle movements that can result in skin wrinkles, which are known as dynamic wrinkles. Botox injections have nothing to do with the plumping or smoothing effect that dermal fillers have. Many people get both Botox and dermal fillers because the combination can produce a significantly younger-looking face.

JN: Botox, Dysport and Xeomin are all FDA-approved neurotoxins used for cosmetic and therapeutic uses. All of these products are derived from botulinum toxin A, produced by laboratory grown *Clostridia botulinum* bacteria. Neuromodulators block the release of acetylcholine at the myoneural junction. They are injected in facial muscles to decrease their function, paralyzing the muscles for about 90 days. Weakening the brow depressors improves frown lines, weakening the frontalis muscle improves horizontal forehead wrinkles, and injecting the lateral orbicularis oculi muscles improves crow's feet wrinkles.

DS: What made you decide to incorporate Botox into your practice? How has this changed your practice?

LM: Botox is well known for its esthetic uses and with all of the esthetic dentistry we do Botox completes the esthetic result by treating the soft tissue in the maxillofacial areas. Botox has been in the literature as being used for TMJ and orofacial pain for over 20 years but received little attention by clinicians. Like most clinicians, I continued to be frustrated when treating patients with TMJ/orofacial pain. Along with other faculty from the American Academy of Facial Esthetics (AAFE), we have used and taught Botox for dental and facial esthetics. [Anecdotally], patients reported relief from their TMJ, headaches and orofacial pain following receipt of Botox injections. Because 85% of TMJ and orofacial pain comes from muscles and Botox reduces the contraction intensity

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of muscles, the AAFE developed protocols with trigger point therapy and found Botox to be an effective intervention. It completely changed the way we plan treatment for both esthetic and therapeutic therapy because it gives us a minimally invasive therapy option that may be used prior to resorting to irreversible dentistry. This is better for us as clinicians and certainly better for our patients.

JN: I was an early adopter and have been using Botox for over 15 years. I was and continue to [communicate] with the doctors who developed botulinum toxin for cosmetic usage and became familiar with it early on. My practice is limited to cosmetic facial surgery and injectables (facial fillers and neuromodulators), which have become very popular as non-surgical, minimally invasive treatments and are a [necessity for] cosmetic practice. Botox treatment for facial wrinkles is the most popular cosmetic intervention in the world. I am a Diamond Level Botox provider, which places me in the top 3 percent of all providers in the United States. (Note: Allergan, the pharmaceutical specialty manufacturer offers a "Partner Privileges" incentive program to providers. The various levels mentioned throughout this article refer to that program.)

GH: My interest in this topic is from an educational and research point of view. Given that many dentists now use Botox and dermal fillers in their private offices, I want to ensure that the dental profession develops and maintains the highest standards in training dentists to perform these procedures. Moreover, I am investigating the role that neuromodulators like Botox play in reducing head and neck pain. I am particularly interested in what positive impact these medications may have on reducing pain in the newly described anatomic structures, the Sphenomandibularis Muscle and the Myodural Bridge. Lastly, I am developing methods to enhance and extend the cosmetic effects of botulinum toxin injections.

DS: Some reports indicate that dentists are ideal providers of Botox. Why is that?

GH: A 2013 survey[2] found that a majority of dentists support offering botulinum toxins such as Botox to their dental patients. Most of the survey respondents reported that dentists are one of the most suitable professionals to provide these injections, as dentists routinely deal with the head, neck and jaw as much or more than other medical specialties. In addition, there is a good fit between "refresh" Botox injections, which are typically two or three times a year, and routine dental cleanings, whitening or recall appointments. Botox therapy is similar to teeth whitening, as both procedures are temporary and need to be refreshed periodically. Not only are dentists experienced injectors, they are also extremely knowledgeable about the muscles of mastication and facial expression, which are routinely treated with botulinum toxins. A 2013 task force[3] concluded that this is an area that dentists can definitely work in and deliver care safely, given their background and training. It is, however, imperative to insure that dentists providing this therapy have an intimate understanding of the pharmacodynamics of these injectables.

LM: AAFE has trained nearly 10,000 dental professionals in the use of Botox and dermal fillers for both esthetic and therapeutic pain uses since 2008. Dentists now have a proven track record of outstanding patient outcomes using Botox and dermal fillers. The excellent facial esthetic outcomes and resolution of facial pain with Botox and dermal fillers likely from the same kind of precision that dentists are already familiar with. What is even more interesting is that dentists have discovered uses of Botox and dermal fillers that solve frustrating treatment including gummy smiles, deficient interdental papilla (black triangles), lip and smile line discrepancies, as well as addressing bruxism, TMJ and orofacial pain cases. Botox and dermal fillers have completely changed the way we now plan treatment for these patients.

JN: Like any treatment that is popular or remunerative, lots of politics are involved concerning who should or shouldn't provide those treatments. Many states allow general dentists to administer neuromodulators and many do not. In my state of Virginia, general dentists are only allowed to use Botox, Dysport or Xeomin for TMJ or perioral related usage, but not for cosmetic purposes, which is only permitted for oral and maxillofacial surgeons. Competing specialties may say that general dentists should not be providing cosmetic treatments in the upper face that is so removed from dentistry. Proponents make the point that many of the providers who administer neuromodulators have less training in facial anatomy and administer fewer facial injections than do dentists. States have to draw the line somewhere, so they can either limit the usage to certain specialties that are classically trained in cosmetic procedures or broaden the scope. In cases where the states allow any licensed provider (family practice, Ob/Gyn, urology, nurses, etc.) to provide cosmetic Botox injections, dentistry should be included.

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DS: What type of training or certification is necessary?

LM: Education must include the relevant anatomy, pharmacology, physiology, diagnosis, treatment planning, proper injection techniques, possible adverse results, how to avoid and correct complications. Top quality training includes one-on-one mentored live patient treatment. It is very important to learn the use of Botox and dermal fillers from an anatomically based approach because these are pharmaceuticals and like any pharmaceutical, proper dosing based on the relevant anatomy is critical in achieving optimal patient outcomes.

JN: Like any other procedure, you need to be safe and proficient and have the same or similar training as competing specialties. If these procedures are taught in dental school, then it is core training. Otherwise, potential providers need to gain proficiency by post graduate training. We need to properly train anyone in dentistry who is going to do this and set the bar as high as or higher than competing specialties.

GH: A thorough understanding of the anatomy and neurophysiology of the face, and the relevant biochemistry is essential. This training should include instruction in the anatomy of the head and neck, neurophysiology, patient selection, pharmacological effects and contraindications, management of complications, informed consent, and hands-on training in the administration of these agents.

DS: Besides the obvious esthetic purposes, are there clinical and/or therapeutic uses for Botox in dentistry?

GH: The elimination of deficient interdental papillae can be achieved with the proper use of dermal fillers. Some orthodontists[4] are using Botox to lessen muscle hyperactivity, thereby helping to prevent teeth from shifting from their established position after the braces are removed. Periodontists also can benefit from using botulinum toxin. Gingival attachment loss due to excessive muscle pulls on the frenulum, can be reduced with appropriate Botox therapy. Similarly, prosthodontists can use Botox injections to control excessive muscle activity that can cause denture destabilization.

JN: [Although the vast majority of the Botox injections I do address cosmetic concerns], I also treat patients for hypertrophic masseter muscles, patients with TMD and increased bite force by injecting masticatory muscles and migraine headache patients. Botulinum toxin A has also been used to treat apthous ulcers.

LM: The AAFE is involved in a lot of interesting work in this area. One of the most exciting new areas is a study on the use of Botox for sleep-related bruxism and reducing the patient's apnea/hypopnea index in obstructive sleep apnea cases.

DS: How can a dentist determine if Botox is right for his/her practice?

GH: Minimally invasive procedures, such as Botox treatments, can achieve very satisfactory results for patients, and many dentists want to add this effective modality to their armamentarium of cosmetic treatments.

LM: Botox and dermal fillers [can be] right for every dental practice that provides restorative, esthetic, implant, endodontic, periodontic, orthodontic and oral surgery services. If you provide any of these treatments, which every dentist does, then there are Botox and dermal filler uses that are not only available but many times are the preferred treatment of choice because of their ability to provide minimally invasive results faster, easier, and better than conventional methods. Botox and dermal fillers are now able to offer dental patients minimally invasive options like never before.

JN: Providing Botox treatments may sound appealing to some dentists who begin treatment only to see that there is also a significant downside. Cosmetic patients can be quite finicky and may return to the office demanding a refund because their wrinkles did not go away. Others may complain of asymmetries, bruising, headaches and other problems. Although serious complications are rare, it is possible to over-treat areas and end up with droopy brows and eyelids and even eyelids that can be totally closed. I have seen a lot of complications from other providers in all specialties and have experienced them myself. A bad outcome with an elective procedure like Botox could cause a patient to lose confidence in the dentist or even leave the practice. Being a Botox provider sounds great, but it's not a panacea and some dentists find the problems with unreasonable patients and treatment complications to be more of a distraction than an attraction. Whether to offer neuromodulator or injectable filler treatment in a dental practice is solely a personal decision.

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DS: Are there particular patients who should not receive Botox?

GH: Patients who are pregnant, actively nursing, or who have preexisting neuromuscular conditions such as myasthenia gravis, Lou Gehrig's disease (amyotrophic lateral sclerosis), or Lambert-Eaton syndrome should not receive Botox. Likewise, patients with breathing disorders like asthma or emphysema should not receive Botox treatments.

JN: There are warnings with certain medications as well as distant spread of the toxin. Providers should be well versed in the indications and contraindications of any medication they administer.

LM: Patients with allergies to injectables, patients who are fearful of needles and patients with autoimmune disorders should not receive Botox or dermal fillers. I always tell dentists that if they have any questions about a patient, call the patient's physician and ask if the patient is an appropriate candidate for Botox and dermal fillers.

DS: What are the risks and potential side effects?

JN: Headaches, eyelid ptosis, blurry vision from extraocular muscle involvement, lip incompetence, smile irregularities from inadvertent lip elevator injection, swallowing difficulties from neck injection, and animation asymmetry are some of the more common side effects. Although they are not permanent, they can produce very unhappy patients and there is no reversing neurotoxins. You have to wait until they wear off and that can be a long three months.

LM: The primary risks and side effects are related to the actual injection procedure of Botox and dermal fillers such as bruising, edema, bleeding, and infection. The main side effects will come from improper Botox dosing which can include a droopy eyebrow or droopy eyelid. Because Botox only lasts three months, these situations are temporary and usually only last two weeks or so. Too much dermal filler can give the patient an unnatural appearance and also can cause vascular compression or occlusion. Dermal filler complications can be reversed with hyaluronidase, an enzyme that breaks down the dermal filler. All of these side effects are easily avoided with a good understanding of the anatomy and great training of the injection technique.

GH: Patients generally experience minimal discomfort with Botox injections. Sequela that can occur at any site due to percutaneous injection of a neurotoxin can include pain, edema, erythema, ecchymosis and headache. Injection discomfort can be decreased by use of topical anesthetics such as EMLA cream (a topical anesthetic cream of lidocaine and prilocaine) before injection, and the use of a small gauge needle. Ice applied immediately after injection can reduce pain as well as edema and erythema associated with any neurotoxin injection. Ecchymosis can be minimized by avoiding aspirin, aspirin-containing products, and NSAIDs (nonsteroidal anti-inflammatory drugs) for 7-10 days before injection with neurotoxins.

DS: Anything else you'd like to add?

LM: Yes, and this is really important. With 1 out of every 3 patients exhibiting bruxism, we now have available bruxism monitoring that can tell us the patient's bruxism episodes index (BEI), which is the number of times a patient bruxes their teeth per hour of sleep. Using this objective data, clinicians can quantify bruxism to properly dosage Botox to eliminate bruxism. This is a major advancement in bruxism therapy. I don't start a case without measuring a patient's bruxism so that I can ensure a good long-term prognosis for restorative and implant cases.

GH: A precise knowledge and understanding of the functional anatomy of the facial muscles is absolutely necessary to correctly use botulinum toxins in clinical dental practice. In addition to cosmetic treatments, botulinum toxins now plays a very significant role in the management of a wide variety of medical conditions such as headaches, and hyper-salivation. Why shouldn't dental professionals broaden their horizons and use all the tools available to them? Botulinum therapy is a conservative, minimally invasive treatment that can expand cosmetic as well as therapeutic options for the benefit of dental patients. Patients are motivated to accept these procedures and are willing to have them performed by their dentist.

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ADA Professional Product Review

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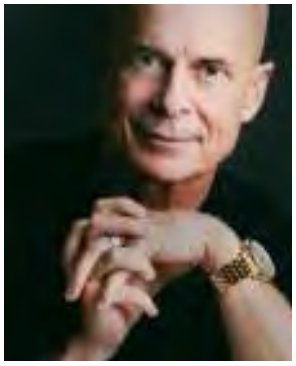

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Disclosures. Dr. Malcmacher is president of the American Academy of Facial Esthetics.

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State Regulations

Can you administer dermal fillers or Botox in your office? It all depends on your state dental practice act and decisions of your dental board. Check with your state dental association for the most current information. Even if these treatments are allowed in your state, your malpractice policy may not cover these procedures, so it would be prudent to check your policy provisions concerning coverage.

FDA Oversight and Recommendations

All FDA-approved injectable dermal fillers are Class III (high-risk) medical devices and manufacturers are required to submit a premarket application that includes clinical data supporting safety and effectiveness, for the FDA's review prior to marketing the dermal filler in the United States. The FDA provides the following recommendations1 for health-care providers, including:

- Do not inject soft tissue fillers if you do not have the appropriate training or experience.
- Make sure that you are familiar with the anatomy at and around the site of injection, keeping in mind that blood vessel anatomy can vary among patients.
- Before injection, thoroughly inform the patient of all risks of the procedure and the specific product you intend to use.
- Note that the approved indications for use of soft tissue fillers vary depending on the product. The FDA may not have reviewed use of soft tissue fillers in some locations in the body.
- During injection, take extra care when injecting soft tissue fillers, such as, injecting the product slowly and applying the least amount of pressure necessary.
- Know the signs and symptoms associated with injection into blood vessels, and have an updated plan detailing how the patient will be treated should this occur. This may include on-site treatment and/or immediately referring the patient to another health care provider for treatment.
- Immediately stop the injection if a patient exhibits any signs or symptoms associated with injection into a blood vessel, such as changes in vision, signs of a stroke, white appearance (or blanching) of the skin, or unusual pain during or shortly after the procedure.
- Tell patients that they should seek immediate medical attention after the procedure if they experience signs and symptoms associated with injection into a blood vessel.
- Educate facility staff and employees on how to quickly assist patients calling with signs and symptoms of filler complications on how to receive appropriate medical care.
- Report to the FDA and the manufacturer if you become aware of any adverse event associated with the use of soft tissue fillers, including unintentional injection of soft tissue filler into a blood vessel.[1]

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The Hottest Topic in Dentistry

Botox and Dermal Fillers Offer Creative Treatment Options

It's interesting that when I give my most popular continuing education course, "The Hottest Topics in Dentistry," I talk about the full range of general dentistry—from what is new in restorative dentistry, crown and bridge, periodontics, endodontics, prosthodontics, implants, and the next generation no-prep veneers, to advanced practice management techniques. I also discuss Botox® and dermal fillers in dentistry, which is one of the hottest topics today. However, I always have to save that topic for later in the presentation, because if I talk about Botox first, many times that is all the dental audience wants to discuss. One of the reasons for this is because Botox and dermal fillers are new and exciting to dentistry. Additionally, once a dentist understands what Botox and dermal fillers actually do, their dental creativity immediately kicks in, and they have a whole new set of treatment options for their daily practice of dentistry.

There is no question that Botox and dermal fillers are well-known for the esthetic results they deliver in smoothing skin and replacing lost volume in the face, especially in the oral and peri-oral areas. Botulinum toxin (Botox and Dysport®) is essentially a muscle relaxer that will smooth wrinkled skin by dynamic movement of the underlying muscles. Dermal fillers, such as Juvéderm® and Restylane®, are volumizers—or plumpers—that fill out lips and static folds in the face caused by loss of collagen and fat. Once you have been trained in these procedures and thoroughly understand the anatomy, physiology, pharmacology, and related adverse reactions, you will find many, many therapeutic uses for both functional and dental esthetic purposes. Now that most states allow dentists to use botulinum toxin and dermal fillers for both dento-facial esthetic and therapeutic purposes, we are finding more and more treatment uses for Botox and dermal fillers in dentistry.

Figure 1. Preoperative smile; patient reports her front tooth is loose.

Figure 2. Tooth No. 9 has a horizontal fracture.

Figure 3. Successful implant integration replacing the left central incisor.

Figure 4. Insufficient interdental papilla creating black triangles.

Figure 5. Diode laser (Picasso® Lite) used to create space within the interdental papilla.

Figure 6. Dermal filler (Juvéderm® Ultra Plus XC) used to add volume and create proper contours of the interdental papilla.

Successful treatment outcomes

Here are but a few examples of dental esthetic and dental therapeutic uses for botulinum toxin and dermal fillers:

- TMD cases
- Bruxism and clenching cases
- Facial pain cases, including treating trigger points
- Treatment of angular chelitis
- Gummy smile cases
- Orthodontic relapse and depressed orthodontic appearance
- Reducing muscle hyperactivity for retention of removable prosthodontics
- Oral and maxillofacial esthetics to smooth skin
- Establishing esthetic dental lip lines and smile lines in esthetic dentistry cases as an alternative to gingivectomy, crown lengthening, and veneers
- Re-establishing lip volume for proper phonetics (in addition or as opposed to teeth lengthening with fixed or removable prosthodontics)
- Adding lip and perioral volume around the mouth for retention of removable prosthodontics
- Oral and maxillofacial esthetics, including lip augmentations and replacing volume in the intra-orally and extra-orally

TMJ and facial pain have haunted dental practitioners for years and are among the most frustrating of cases. Studies show that as many as 85 percent of TMJ and facial pain cases are mostly muscle-related. Dentists have previously concentrated their treatment on the occlusion and teeth first, and the muscles later. It is time to completely rethink this treatment progression. Now, using botulinum toxin therapeutically for facial pain and TMJ, it is possible to eliminate the pain coming from the muscle pathology first. Once we are able to see how much of a factor this pain is, we may go ahead and treat the occlusion or the actual joint much more easily and accurately than ever before.

Dealing with the 'black triangle'

Here is a perfect example of a new treatment option with a protocol developed by the faculty of the American Academy of Facial Esthetics (*www.facialesthetics.org)*. The dreaded "black triangle" usually tops the list of dentists' frustration after the preparation of crowns, bridges, and especially after implant and periodontal surgery. After treatment, the patient finally has a nice new tooth surrounded by one or two big black holes on either side of it, which the patient spits through or catches food in. While the patient should be thrilled that they don't have to wear a flipper or temporary anymore, they are disappointed at the esthetic results because of the lost tissue. What are our options? We can bond to adjacent teeth, we can redo the crown, remove the implant and try again with a new implant, or try a variety of other frustrating treatment options that are very aggressive and which may or may not work. The placement of dermal fillers in these areas to literally plump up papilla is a minimally invasive way to create proper and more pleasing gingival contours.

Let's take a look at the case above. Figure 1 shows the pre-op photo of a patient who has two all-ceramic crowns on teeth No. 8 and 9 and some veneers. The crown on tooth No. 9 is loose and the radiograph in figure 2 shows why—the tooth has fractured at the gumline. Figure 3 shows the new implant in place. The dreaded "black triangles" in figure 4 is one of the most challenging esthetic problems we deal with, for which there are very limited successful treatment options. Compare that to her original pre-op picture again in figure 1 and you can see why it bothers her. In addition to that, now food collects in these areas, and when she speaks, she finds herself, "spitting while I talk," something she has never done before. The patient loves and hates her new implant all at the same time. In figure 5, we treated her with a diode laser (Picasso® Lite, AMD Lasers) to loosen the gingival attachment and create space within the remaining papilla. Then we placed .15 mL of dermal filler (Juvéderm Ultra Plus XC, Allergan Corporation) into the papilla to rebuild it. Figure 6 shows the rebuilt gingival papilla, which fills up the black triangles and takes care of the patients' esthetic and functional concerns. The treatment appointment was approximately five minutes, and this outcome can be expected to last for eight months or longer—at which point the treatment will need to be repeated. This is a very minimally invasive approach to a very difficult dental situation, and it completely satisfies the needs of the patient and gives the dental operator a very successful treatment outcome.

Essential training

It is our legal and ethical duty to give patients all of the options available for their dental treatment. In this day and age, to do that, we need to get trained in the use of Botox and dermal fillers, as these are well-established viable dental treatment options. The treatments described in this article clearly fall under the definition of dentistry in nearly all of the state dental practice acts. Once dentists understand the use of botulinum toxin and dermal fillers in dentistry for dental therapeutic and dental esthetic cases and become proficient in their use through proper training, they will be able to offer these treatments in conjunction with, or in addition to, their current treatment options to patients. The American Academy of Facial Esthetics continues to develop successful proven techniques and trains dentists to integrate these procedures into dental esthetic and dental therapeutic treatment plans. Get trained today! ◆

Louis Malcmacher, DDS, MAGD, is a practicing general dentist and an internationally known lecturer and author known for his comprehensive and entertaining style. An evaluator emeritus for *Clinicians Report*, Dr. Malcmacher has served as a spokesman for the AGD and is the president of the American Academy of Facial Esthetics *(www.FacialEsthetics.org)*. You can contact him at *drlouis@FacialEsthetics.org*.

Changing the face of dentistry

Author_Louis Malcmacher, DDS, MAGD

_Dentistry is not just about teeth any more, as will be demonstrated in this case presentation article. In the past few years, with thousands of dentists being trained in the use of non-surgical, minimally invasive facial injectables, such as Botox and dermal fillers, dental esthetic and functional treatment has changed for the better.

This article seeks to demonstrate how the use of facial injectables in the oral and maxillofacial areas directly relates to the teeth in terms of function, smile lines, lip lines, phonetics and esthetic dentistry, thereby clearly showing the totality of this oral and maxillofacial treatment is indeed dental treatment.

_Case study

This patient's story starts a few years ago when she had two all-ceramic crowns on the upper right and upper left central incisors as well as veneers placed on the upper and lower teeth (Fig. 1). One day, she noticed that her upper left central incisor crown seemed loose. A radiograph was taken and you can clearly see in Figure 2 that a horizontal fracture is present. This tooth is obviously non-restorable and so it was extracted and an implant was placed, as shown in Figure 3.

The implant was restored with a Procera crown and the patient is enjoying the newfound stability of this tooth. What she does not enjoy is the creation of deficient interdental papilla known as black triangles (Fig. 4). This is one of the most frustrating esthetic challenges that can happen in any kind of implant or crown and bridge procedure.

A new innovative procedure that I have pioneered in conjunction with the American Academy of Facial Esthetics (*www.facialesthetics.org*) is using dermal fillers (Juvederm Ultra XC) to plump the interdental papilla to eliminate these black triangles, which was successful, as seen in Figure 5.

A few months later, the patient was interested in retreatment of her crowns and veneers because she wanted whiter teeth and a fuller smile. Some of the issues that she complained about with her current smile are seen in Figure 6: the new crown on the upper left central incisor is a slightly darker shade than the other teeth and when she goes into a full smile, she does not show as many teeth as she would like.

She also requested that all of the teeth be whiter. She has also exhibited over the past few years a number of chips on the veneers, especially on the lower teeth (Fig. 7), and an occasional veneer has pop-off that had to be recemented from time to time. This has resulted in making the lower teeth look "very short and stubby," as she explained. This patient also has a very deep overbite, as demonstrated in Figure 8.

With proper training in both oral and maxillofa-

Fig. 1_Patient presents with a loose crown on tooth #9. (Photos/Provided by Dr. Louis Malcmacher)

Fig. 2_Horizontal fracture on tooth #9.

Fig. 3_Implant placed using conventional techniques.

Fig. 1

Fig. 2

Fig. 3

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Fig. 4

Fig. 5

Fig. 6

Fig. 4_Deficient interdental papilla (black triangles) as a result of implant surgery.

Fig. 5_Dermal fillers used to restore volume and eliminate black triangles.

Fig. 6_Smile is limited because of facial aging.

cial esthetics, let me give you my perspective as to what I look for now in this kind of case and why the facial conditions here are part of her dental esthetic treatment. Let's take another lookat this patient in a full-face picture and in a pre-operative full smile, as shown in Figure 6.

Here in a full smile, she does not clearly show the buccal corridors, which would give her a fuller looking smile. As dentists, in the past, we would never think about why she is unable to deliver a fuller looking smile, thinking incorrectly that there was nothing we could do about it. We would just assume that we should place veneers on the bicuspids and that will be enough when, in most cases, it will not provide the desired result because other factors are at play here.

In addition, please notice in this photograph that in her present full smile, the upper lip is not in an esthetic relationship with the teeth. Ideally, for esthetic lip lines and smile lines, when the patient goes into a full smile, the bottom of the upper lip should straddle the gingival margins of the central incisors and cuspids, which should ideally be at the same heights.

_Facial aging happens to everyone

This patient clearly demonstrated a very typical scenario with facial aging, which is usually present after the patient reaches age 50. Dermal collagen and facial fat are lost in the oral and maxillofacial regions and the midfacial tissues begin to sag and drop. This results in patients showing less of their upper teeth and more of their lower teeth. This patient reports, and clearly demonstrates by pictures of her in her youth, that she had higher cheekbones and more volume in her face. At that point in her life, she had a much fuller smile.

You can clearly see in the full-face photograph (Fig. 6) that she has lost some of the volume in her face and try as she might, she can't pull her upper lip higher in a full smile because of the loss of volume in the zygomatic areas of her midface. As a result of this facial aging and loss of support, she also has deeper nasolabial folds, which again puts more pressure on depressing the upper lip in a full smile.

All of these factors together result in a dental esthetic challenge and are easily treated with Botox and dermal fillers, by properly trained clinicians, in addition to the use of veneers. The main point here is this: With her loss of facial volume as it was at the time, you could put a whole mouth full of veneers and she still wouldn't show the bicuspids and buccal corridors because her full smile is not a function of her teeth but rather of the oral and maxillofacial structures.

Figure 9 shows the patient post facial injectable treatment with Botox and dermal fillers, and you can see the desired result of showing more teeth and proper lip and smile lines before the re-treatment of the veneers. Take a close look at her cheeks and you will find significantly more volume as well as much less prominence of her nasolabial folds.

When she goes into a full smile, she shows a lot more teeth than before because her upper lip now has greater support from the added volume in the midface. This was accomplished by using a calcium hydroxylapatite dermal filler (Radiesse) with 1.3 ml used in the left zygomatic area and 1.1 ml in the right zygomatic area. A hyaluronic acid dermal filler (Juvederm Ultra XC) was used in the naso-labial folds with 1 ml used in the left nasolabial fold and 0.9 ml in the right nasolabial fold.

You can now see when she goes into a full smile in Figure 9 that she has the proper lip lines and smile lines, and the bottom of her upper lip straddles the gingival margin of the upper central incisors and cuspids. This clearly shows the direct relationship between dermal filler procedures in the nasolabial and zygomatic areas as dental esthetic and therapeutic treatment.

_New face, new smile

Once this patient could see her teeth better and showed more teeth when she smiled, she wanted new veneers to make the teeth whiter. Now we could address the challenges discussed above and proceed with veneers. One other issue that the patient was concerned about due to her broad smile was the upper left central incisor having a higher gingival

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Fig. 7

Fig. 8

Fig. 9

Fig. 10

Fig. 11

Fig. 12

Fig. 7_Close-up view shows significant chipping of existing veneers made from a low-strength ceramic.

Fig. 8_Patient demonstrates a deep overbite.

Fig. 9_Patient shows a much wider smile after cheek and lower face volume restoration with dermal fillers.

Fig. 10_ The central incisors have uneven gingival margins.

Fig. 11_Veneer preparations and precise laser-assisted, closed osseous crown lengthening to even the gingival margins (Waterlase iPlus, Biolase).

Fig. 12_Laboratory prep guide used for minimal and full veneer preparations.

margin than the upper right central incisor because that is the area where an implant was placed (Fig. 10). Once we had addressed the underlying cause of her deficient smile, we were ready to proceed with new porcelain veneers.

The treatment plan consisted of 10 new veneers on the upper teeth and 10 new veneers on the lower teeth. The upper central incisors, however, did produce somewhat of a challenge. Cutting off a Procera crown on a tooth with an implant is no dentist's idea of fun in the office. In fact, significant damage can be done to the implant abutment and it is not a wise choice if other options are available.

In this case, we chose to bond a porcelain veneer onto the existing upper central incisor crowns instead of trying to remove them. The system we chose was Cristal Veneers by Aurum Ceramics. Cristal Veneers is the next generation of no/minimal preparation veneer systems with veneers that can be made as thin as 0.3 mm and exhibit very high strength and excellent esthetics. Cristal Veneers can also be made as thick as any other veneer.

This case had multiple thicknesses of every type of veneer possible. In Figure 11 you may see the teeth after preparation. All of the previous veneers were removed on the upper and lower teeth. A hard- and soft-tissue laser (Waterlase iPlus, Biolase) was used on the upper right central incisor to perform not only a gingivectomy, but also a closed sulcus crown lengthening procedure to match the gingival height of the upper left central incisor. The closed sulcus crown lengthening procedure at this point is a very well established procedure and can be done very precisely and conservatively with an erbium laser, such as the Waterlase iPlus.

As a matter of fact, at this same veneer preparation appointment we performed this closed sulcus crown lengthening and because of its predictable nature, we were able to take the final impression on the very same day.

Figure 12 shows the prep guide created by Aurum Ceramics and demonstrates the very minimal preparation on the two upper central incisor crowns so that the Cristal Veneers on these teeth will be approximately 0.3 mm in thickness while the veneers on the lateral incisors will be anywhere between 2.5 mm to 3 mm in thickness.

All of the other veneers were of various thicknesses as well, as you can imagine by looking at the lower no/minimal veneer preparations of the lower teeth in Figure 13.

_Challenges with veneers

Let's talk about this issue for a moment because this is a challenge when seating a veneer case such as this one. Every dentist knows that when he or she is seating veneers with different thicknesses, the biggest challenge is trying to match up the final shade. Many times seating these veneers is very time

Fig. 13

Fig. 14

Fig. 15

consuming in the office as the dentist is trying to use different resin cement shades and even different values of the resin cement shade to achieve a color match of all of the veneers.

Personally, I have always believed that this should not be the dentist's problem but it should be the laboratory's responsibility if it has the esthetic expertise necessary and the technicians know the porcelains that they are using. Cristal Veneers porcelain was developed by Aurum Ceramics and they have the esthetic expertise to understand the optical qualities of the porcelain they are using, as well as the different opacities that will go into a challenging veneer case such as this one.

This case then came back to my office with all of the different thicknesses of porcelain veneers (sometimes there are even different thicknesses on the same porcelain veneer), and because of this laboratory's expertise in producing these veneers, I was able to seat all of these veneers with one shade of cement.

It is a huge advantage to have such a talented laboratory, and here is where your choice of laboratories can make all of the difference in the world in terms of the ease of cementation, saving time and producing an esthetic result that you and the patient are proud of.

Figure 14 shows the veneers cemented into place. The veneer shade is 020 and the corresponding cement was used. Note a few of the challenges presented above have been addressed completely. Look at the gingival margin of the upper right central incisor and notice that now it exactly matches the gingival margin of the upper left central incisor. Remember that the veneers on the central incisors are approximately 0.3 mm and the rest of the veneers are anywhere from 1 mm to 3.5 mm in thickness, and all of these veneers are the exact same shade.

There was absolutely no need to try to use different shades of cement to achieve a final matching shade, but only one shade of cement was used. Notice also that the lower veneers now restore the proper height to the teeth and they are no longer short and stubby as the patient complained about before.

Bonding veneers to existing porcelain crowns includes the use of a number of agents and a sequenced approach. Please go to my website *www.commonsensedentistry.com* for a full step-by-step technique as how to bond a porcelain veneer to an existing porcelain crown.

_Total facial esthetics results in happy patients

Figure 15 shows a very happy patient who has been treated with total facial esthetics and we have addressed all of her concerns. The final dental esthetic and therapeutic result is a combination of each of the oral and maxillofacial treatments in and around the mouth.

This article sought to demonstrate how the use of Botox and dermal fillers in the face are as much responsible for the success of dental esthetic cases as are porcelain veneers, crowns and implants._

Fig. 13_Lower, minimal veneer preparations.

Fig. 14_Final Cristal veneers (Aurum Ceramics); note the even gingival margins on central incisors.

Fig. 15_Total facial esthetics completed with Botox, dermal fillers and veneers to lift the lower face so patient can show her beautiful smile.

_about the author

cosmetic dentistry

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Lip Service

Understand Lip Anatomy to Maximize Esthetics

When it comes to esthetic or anterior dentistry—veneers, crowns, implants, or dentures—many dentists make the mistake of only focusing on the teeth. A great smile, however, involves much more than just the teeth—it includes the lips, cheeks, and chin, which frame the mouth. It's also important to make sure the patient has the appropriate relationship and proportions between his or her lips and teeth, measured by lip and smile lines.

To maximize function and esthetics, dentists should routinely treat all of the soft tissue surrounding the mouth. What is "esthetic" about placing 10 porcelain veneers on someone's upper teeth if he or she has deficient lip volume and/or radial crease lines extending from the lips? If you do a beautiful porcelain veneer case, or even a full-mouth reconstruction, without addressing any of the surrounding extraoral soft tissue, your work may not be complete.

Understanding the anatomy

When considering dental esthetics, dentists typically think only about the anatomy of the teeth and how they relate to one another. In order to establish proper lip and smile lines, however, you also must consider the anatomy of the lips, which determines the shape and color of the perioral region, and thus influences the esthetic outcome.

The lips have a detailed anatomical shape. The orbicularis oris is the underlying muscle that determines shape of the perioral area and the lips. This interesting muscle consists of numerous muscle fiber strata that come from different directions and surround the mouth orifice. Many dental professionals mistakenly think of this muscle as a circular sphincter, but it is actually composed of four independent, interlacing muscle quadrants that partially consist of fibers from other muscles of facial expression, primarily the buccinator muscle.

The middle buccinator fibers decussate at the angle of the mouth on both sides, with the upper buccinators fibers originating in the maxilla and passing to the lower lip, and the lower buccinator fibers originating in the mandible and passing to the upper lip. The uppermost and lowermost buccinator fibers pass across the lips from side to side without decussation. These oblique muscle fibers pass from the under surface of the skin to the mucous membrane through the thickness of the lip.

The intensity of the muscle action determines the shape and anatomy of the lips. It is the crossover of these buccinator fibers at the angle of the mouth that gives the lips the ability to pucker and close.

Photos courtesy of the American Academy of Facial Esthetics

Figure 1. These before and after photos demonstrate esthetic soft tissue occlusion, with a subtle "S" shape.

Photos courtesy of the American Academy of Facial Esthetics

Figure 2. These before and after profiles show 3-D lip eversion, which supports esthetic lip and smile lines.

The philtrum is a vertical groove that extends from the bottom of the nose to the middle of the upper lip, bordered by muscle fibers attached to the nasal septum. This is a key aspect of a well-defined Cupid's bow, which is essential to a truly esthetic upper lip shape.

The vermilion border is the demarcation between the lip and the adjacent skin, created by the change in the epidermis from highly keratinized skin to the less keratinized lip. Sometimes this border is sharp, but it often becomes less defined as people age.

Anatomy's impact on appearance

How do these muscles impact a patient's facial esthetics? The skin covering the lips is only three to five cellular layers thick, while the cutaneous skin outside the vermilion border is typically 14 to 18 cellular layers thick. The skin covering the lips also has very few melanocytes, and the lips have high vascularity, so the blood vessels appear through the skin of the lips. This determines their color, which can range from pink to red.

The skin on the lips and the vermilion border does not contain hair follicles, sebaceous glands, or sweat glands. Therefore, it does not have the usual protection layer of sweat and body oils to keep the skin smooth, inhibit pathogens, and regulate warmth, which is why lips dry out faster and become chapped more easily than other areas of skin. Certainly, every dentist understands this. Whenever a patient is undergoing a long dental procedure, you can see his or her lips drying out right before your eyes.

If you look closely at the lips, you can see hills and valleys of soft tissue. The upper lip area between the philtral columns, which is called the tubercle, will have slightly more volume in an esthetic lip. As the philtrum approaches the upper lip, there should be an eversion from the cutaneous portion to the vermilion border, which creates the labial support for the upper lip's 3-D appearance. This anatomy is important to understand when doing lip enhancements so that dermal filler material can be placed in these dermal planes to enhance or re-establish this esthetic lip anatomy.

Let me also introduce you to a term that I call "soft tissue occlusion," which refers to the area where the upper lip meets the lower lip. Most people think that lips come together in a straight line, but this is not the case in most patients. In esthetic lips, there is a subtle S-shaped curve from one commissure to the other. The place where the lips meet also defines the wet-dry line in each lip; the dry part is the visible lip portion, which is where the clinician should concentrate when volumizing the lips with dermal fillers to create the proper lip and smile lines.

The before and after photos in figures 1 and 2 demonstrate these esthetic lip anatomy principles. In order to enhance or re-establish facial esthetics, it's important to understand how this anatomy impacts appearance.

The lips do much more than just surround the entrance to the oral cavity. They keep food and drink in the mouth during mastication. They affect the uttered sounds that facilitate spoken language and provide changes of facial expression that facilitate unspoken language. They are an essential part of the beautiful facial frame that showcases a great-looking smile. It is vitally important for any dentist who practices esthetic dentistry with BOTOX® and dermal fillers to be trained in establishing proper lip and smile lines for every anterior dentistry case. ◆

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The Next Step in Esthetic Dentistry

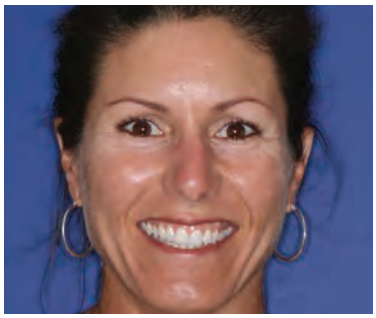
Using Dermal Fillers on Soft Tissue Around the Mouth

Esthetic dentistry has been a vital part of dental practices for the last three decades. Any dentist who places tooth-colored composite resin restorations is practicing under the cosmetic dentistry umbrella, and most dentists perform whitening procedures, esthetic crowns and bridges, and veneers—all of which have become part and parcel of daily general dental practice around the world. Dentistry has made huge advancements in the esthetic realm, and now that esthetic dentistry has evolved to become a staple in most dental practices, it is time to take a step back and see where we are and if we're fully accomplishing the esthetic goals of our patients.

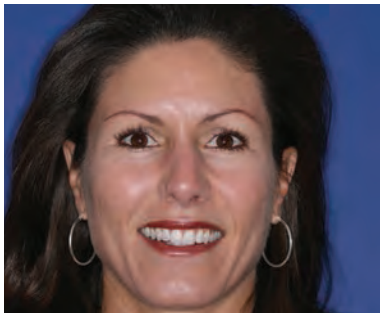
The question is, where else is there to go? When it comes to esthetics, patients desire white, straight teeth, and we can give them what they want through a number of methodologies and treatments. But we have hit our limits—teeth can only be so straight, and we can't get them any whiter without patients looking like they are from Mars. How else can we help patients accomplish that perfect smile and total facial esthetics? What is the next on the horizon when it comes to esthetic dentistry?

A 43-year-old patient presents moderate nasolabial folds and thinning lips.

Dermal filler therapy fills out the nasolabial folds and adds volume for a subtle lip enhancement.



A full-face photo of the same patient shows an asymmetrical, gummy smile.



BOTOX and dermal fillers are used as a nonsurgical treatment to correct the gummy smile and achieve esthetic lip and smile lines.

Completing the picture

Imagine that you have just completed a beautiful anterior veneer, crown, or implant case. Your patient looks at her new teeth and she is happy—until she notices how deficient her lips look. She wants to know if you also can do anything with the "parentheses around her mouth," as those deep nasolabial folds hide many of the teeth that you just worked so hard to create. This example reminds us of just how important the soft tissue around the mouth is to esthetic dentistry.

There is no question that dentists have already utilized BOTOX® and dermal fillers in the oral and maxillofacial areas. The perioral soft tissue that we ignored previously now is an integral part of every esthetic dentistry case. For a long time, we didn't consider this area in the final esthetic result, but we understand now how oral and perioral tissues complete the entire picture.

While BOTOX gets a large amount of patient interest, dermal filler therapy also has found many uses, both extraorally and intraorally, in dental esthetic and dental therapeutic treatment plans. Dermal fillers are widely accepted by patients in North America, much more so than traditional esthetic dentistry. You don't need to believe me—just ask the women in your life and in your office if they have had or heard of dermal fillers, and you will quickly find that these are immensely popular nonsurgical, minimally invasive esthetic treatments.

Understanding dermal fillers

But what exactly does a dermal filler do? Simply put, a dermal filler is a material that is injected underneath the skin to add volume, smoothing out perioral folds and areas of reduced volume. Many factors may contribute to this soft tissue and collagen volume loss, including aging,

disease, loss of vertical dimension due to bruxism or loss of teeth, smoking, sun damage, and genetics.

Dermal fillers typically are injected in the nasolabial folds, the oral commissures, marionette lines, the lips, and the deficient interdental papilla, which are commonly called "black triangles." Dermal fillers are commonly used for lip enhancement, with the goal of establishing ideal smile lines, lip lines, and phonetics.

The offices of plastic surgeons and dermatologists traditionally have been the most common providers of these services. Notice that I said that their *offices* provide these services, as nurses or medical estheticians in these offices place most dermal fillers. However, dentists are better trained to provide this treatment than many of the health care providers who do so currently. The areas that frame the mouth are certainly within the realm of dentistry as defined by most state dental practice acts.

One of the biggest advantages a dentist has in performing dermal filler therapy is the ability to deliver profound dental anesthesia for these procedures. Most of the other health professionals who deliver this therapy are poorly educated in dental anesthesia techniques, and even after learning them, often are unable to accomplish profound anesthesia (something the dental professional does multiple times a day). Therefore, many physicians and nurses forego dental anesthesia and use some form of topical anesthesia cream or an ointment on the skin for a period of 20 to 45 minutes prior to performing dermal filler therapy. Unfortunately, most of the patients I have encountered who had received topical anesthetic creams were very uncomfortable during their dermal filler procedures and said they would never receive these treatments again.

However, in the past couple of years, the manufacturers of dermal filler products have introduced lidocaine into their formulations. While this does not help with the initial injections—which often can be uncomfortable—these products eliminate the need to use regional anesthesia in patients who can tolerate the initial injections.

In my discussions with health care colleagues, cosmetic dermatologists and facial plastic surgeons often wonder why it has taken so long for dentists to get into the dermal filler field, seeing that it is a natural fit and a complement to everything we are trying to accomplish in esthetic dentistry. Many also acknowledge that general dentists have the natural skill set to accomplish dermal filler therapy.

Using dermal fillers

How long do dermal fillers last? Well, there are temporary dermal fillers and there are permanent dermal fillers, and depending on the type used, the effects of therapy can last anywhere from six months to several years. Today, most of the dermal fillers are temporary in nature, dissolving in six to 18 months. The advantages of using temporary fillers are obvious—any complications that may occur will disappear before long. Additionally, one of the biggest challenges with permanent fillers is that the filler will not change, though all the facial structures around it keep aging. This can result in distorted facial contours within a short period of time, depending on the aging process of the patient.

The most popular types of dermal fillers are hyaluronic acid products. Hyaluronic acid is a naturally occurring substance in the body that is lost as we age. Hyaluronic acid products add and replace the volume lost from the dental and facial structures as a result of the aging process. These fillers are thick gels that may last anywhere from six months to one year. Juvéderm® Ultra XC and Restylane®-L are the most popular hyaluronic acid dermal fillers, and both of these formulations contain lidocaine.

Because of the temporary nature of the dermal filler materials, liability issues and treatment complications are very limited. The areas where dermal fillers are used will return to normal completely within six to 18 months, so there are virtually no long-lasting negative results that can occur with this treatment. However, as with any other treatment, you have to take into account the anatomy and physiology of your patient, what you are trying to accomplish, and which dermal filler materials will work best in each circumstance.

Training is the key to developing the skill to perform this treatment for patients. To become competent in dermal filler therapy, you need to understand the mechanisms of these materials; review the facial expression muscles; understand indications, risks, and benefits of these treatments; and participate in live-patient, hands-on training in placing these materials, as well as preventing and managing complications. With some practice, you could be well on your way to performing these procedures. Most state dental boards now allow dentists to deliver these facial injectable therapies for dental esthetic and dental therapeutic purposes, and their use is taught at major dental meetings across the U.S., including the Academy of General Dentistry (AGD) Annual Meeting & Exhibits.

Implementing dermal filler therapy is a natural progression of where we are going in esthetic dentistry. General dentists can easily accomplish these procedures with proper training. Further, patients are motivated to accept these procedures and excited to have them done under local dental anesthesia. These treatments are more than a complement to esthetic dentistry—BOTOX and dermal fillers are now an integral part of every esthetic dental treatment plan. ◆

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Total Dental Aesthetics

Louis Malcmacher, DDS

INTRODUCTION

For years, those who teach aesthetic dentistry have given lip service (no pun intended) to the oral and maxillofacial areas surrounding the teeth and the importance of the extraoral soft tissue to aesthetic dentistry. I would like to challenge this thought process and say that we as dental clinicians and educators have been wrong for the last 30 years. The facial soft tissue is part and parcel of aesthetic dentistry and is as important or, dare I say, more important than the teeth in delivering a great-looking smile. Perhaps the patient has beautiful teeth with the new crowns you placed and has maxillary gingival excess (gummy smile); is that all there is to aesthetic dentistry? Maybe you have just placed and restored 6 anterior implants, and then the patient leaves your care with deficient lip volume and radial lip-lines. Is that aesthetic dentistry? What is the purpose of placing 20 veneers if patients cannot show their teeth because they can't raise their upper lip? In the past few years, with thousands of dentists being trained in the use of nonsurgical, minimally invasive facial injectables, such as Botox and dermal fillers, dental aesthetic and dental therapeutic (temporomandibular disorders, bruxism, myofascial pain), treatment has changed dentistry forever.

This article will present a case that clearly demonstrates how the right choices of dental technology, materials, and facial injectables in the oral and maxillofacial areas directly contribute to aesthetic dentistry in terms of function, smile-lines, lip-lines, and phonetics. You will see that the totality of intraoral and extraoral maxillofacial treatment is all truly aesthetic dentistry and with the right training, can be performed by every general dentist.

CASE REPORT

A few years ago, this patient had 2 all-ceramic crowns placed on her upper central incisors. In addition, she also had veneers placed on the upper and lower teeth (Figure 1). One day, she noticed that her upper left central incisor crown (tooth No. 9) seemed loose, and she came into the office with the chief complaint that her tooth was "wiggly." I touched the tooth and it was indeed wiggly! A radiograph was taken and it was immediately clear that she had a horizontal fracture (Figure 2). This tooth was obviously nonrestorable, so it was extracted and a bone level implant was placed (Figure 3). The implant was restored with a Procera (Nobel Biocare) crown, and the patient enjoyed newfound stability of this tooth. What she did not enjoy was the creation of deficient interdental papilla known as "black triangles" (Figure 4). This is one of the most frustrating aesthetic challenges that can happen with any kind of implant or crown and bridge procedure. An innovative procedure, pioneered by this author and the American Academy of Facial Esthetics (facialesthetics.org), is using dermal fillers (Juvederm Ultra XC) to replace volume to the interdental papilla to eliminate black triangles (Figure 5).

Figure 1. Patient presents with a loose crown on upper left central incisor.

Figure 2. Horizontal fracture apparent on radiograph.

Figure 3. Implant placed using conventional techniques.

Figure 4. Deficient interdental papilla (black triangles) as a result of implant surgery.

Figure 5. Dermal fillers used to restore interdental volume and eliminate black triangles.

...treatment is all truly aesthetic dentistry and with the right training, can be performed by every general dentist.

One Thing Leads to Another

After this initial treatment, the patient became interested in retreatment of her crowns and veneers. The issues that she complained about can be seen in Figure 6. The new crown on the upper left central incisor was a slightly darker shade than the other teeth and, when she smiled fully, she did not show as many teeth as she would have liked. She also wanted whiter teeth. The lower veneers were also chipping slowly throughout the last few years (Figure 7) and she had experienced annoying veneer debonds that would have to be recemented from time to time. She stated, "My lower teeth look short and stubby." This patient also presented with a very deep overbite (Figure 8).

I, along with anyone who has had proper training in both oral and facial aesthetics, can give you a new perspective as to what to look for now in this kind of case, and how the facial conditions observed here are part of her dental aesthetic diagnosis and treatment. Here is what I mean in this case, as clearly demonstrated in Figure 6. Look at this patient when she goes into her widest smile. The buccal corridors in the bicuspid region are hidden, preventing her from

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Total Dental Aesthetics
continued from page 134

showing a full and aesthetic smile. Because dental professionals are typically only focused on the dentition, most dentists assume that the only way to correct this is to restore the bicuspids with crowns or veneers to correct the buccal corridor deficiency. On this patient, and those like her, there are no dental solutions that would solve this aesthetic challenge because of the loss of midface volume. Adding volume to her midface would also correct the aesthetic relationship of her upper lip and teeth. In a full smile, the bottom of her upper lip should straddle the gingival margins of the upper central incisors. This was to be part of our treatment plan as we both restored her teeth and corrected the volume deficiency.

Turning Back the Hands of Time

It is going to happen to all of us. People typically lose dermal collagen and facial fat from approximately age 40 years and on, with accelerating changes starting at about age 50 years. This causes the oral and maxillofacial areas to sag and drop. This patient is a good example of this, and she demonstrates this facial aging pattern clinically by showing less of her upper teeth and more of her lower teeth. Because of this natural aging progress, she does not have the high cheekbones that she used to have, and she also has deeper nasolabial folds; and all of this contributes to the fact that her upper lip does not have the support it used to have and hides some of her teeth, especially in the posterior regions of her mouth. This challenge in aesthetic dentistry cannot be solved with restorative dentistry alone. Botox and dermal fillers are necessary, in addition to veneers, to solve the combination of dental and facial aesthetic challenges seen in this case.

People typically lose dermal collagen and facial fat from approximately age 40 years and on....This causes the oral and maxillofacial areas to sag and drop.

Figure 9 shows the result using Botox and dermal fillers to correct muscular activity as well as the midfacial volume loss. Her zygomatic areas are now well supported and the volume restored. Now, she demonstrates the proper aesthetic smile and liplines when she is in function as described above. Her nasolabial folds demonstrate much less prominence, and now her upper lip has the support needed to show a wider smile. It is important in treatment planning a patient like this to have a well thought out plan of coordinating the soft-tissue treatment with the restorative dentistry.

In this case, a total 2.4 mL of a calcium hydroxylapatite dermal filler (Radiesse) was placed in the left and right zygomatic area, which supports the nasolabial folds and the upper lip. The nasolabial folds were treated with a total of 1.9 mL of a hyaluronic acid dermal filler (Juvederm Ultra XC) to restore them to more fullness and further support the upper lip. This case shows that treatment of this midface area is as much a part of aesthetic and therapeutic dentistry as is treating the dentition.

Changing the Face Changes the Smile

Veneer retreatment can now be accomplished to complete the aesthetic dentistry. This patient can now show more teeth and is ready for the new veneers. Now we can properly address the challenges discussed previously. One other issue that the patient became concerned about is this: the upper left central incisor had a higher gingival margin than the upper right central incisor because that was the area where an implant was placed (Figure 10). This challenge would now be integrated into our treatment plan. The treatment plan consisted of 10 new veneers on the upper teeth and 10 new veneers on the lower teeth. The upper central incisors, though, did produce a challenge. Cutting off a Procera crown on a tooth with an implant is no dentist's idea of fun in the office. As a matter of fact, significant damage can be done to the implant abutment, and it is not a wise choice if other options are available. In this case, we chose the option of bonding a porcelain veneer onto the existing upper central incisor crowns instead of trying to remove them. The system we chose to use was Cristal Veneers (Aurum Ceramics). Cristal Veneers are the next generation of a no-to-minimal preparation veneer system with veneers that can be made as thin as 0.3 mm and exhibit very high strength and excellent aesthetics. Cristal Veneers can also be made as thick as any other veneer.

All of the previous veneers were removed on the upper and lower teeth, and minimally invasive preparations were done on all of the teeth based on their treatment history. This case would have multiple thicknesses on every one of the veneers. Figure 11 shows the prep guide (Aurum Ceramics) and demonstrates the very minimal preparation on the 2 upper central incisor crowns so that the Cristal Veneers on these teeth will be approximately 0.3 mm in thickness while the veneers on the lateral incisors will be anywhere between 2.5 mm to 3 mm in thickness. All of the other veneers were of various thicknesses, as well as you can imagine by also looking at the lower no/minimal veneer preparations of the lower teeth in Figure 12.

At the veneer preparation appointment, the upper central incisor gingival levels were addressed. A hard- and soft-tissue laser (WaterLase iPlus [BIOLASE]) was used on the upper right central incisor to perform not only a gingivectomy, but also a closed sulcus crown lengthening procedure to match the gingival height of the upper left central incisor. The closed sulcus crown lengthening procedure is easy to accomplish with the proper technology and training. It can be done very precisely and conservatively with the WaterLase iPlus. Because of the predictable nature of this procedure, we were able to take the final impression on the very same day. You can see the teeth after preparation as well as after crown lengthening surgery in Figure 13. Because of the surgical aspect, precise temporization is especially crucial to make sure the gingiva can heal properly at the established gingival level. A new temporary material Dentocrown (Itena USA) was used because of its stability,

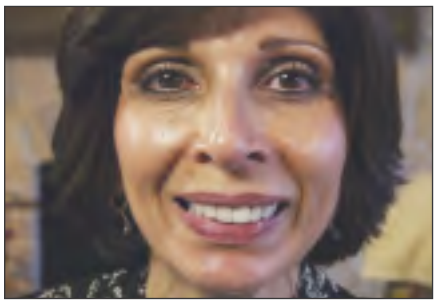

Figure 6. Smile is limited because of facial aging.

Figure 7. Close-up view shows significant chipping of existing veneers made from a low strength ceramic.

Figure 8. Patient demonstrates a deep overbite.

Figure 9. Patient shows a much wider smile after cheek and lower face volume restoration with dermal fillers.

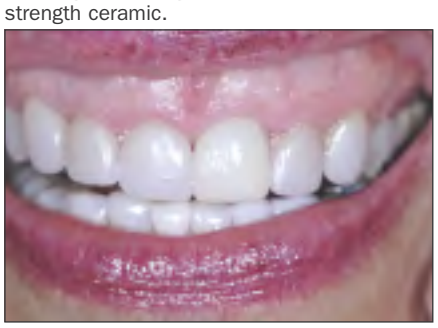

Figure 10. The central incisors have uneven gingival margins.

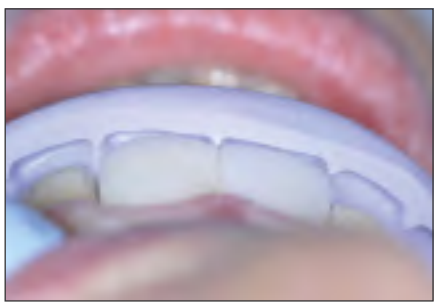

Figure 11. Prep guide used for minimal and full veneer preparations.

excellent gingival adaptation, and its self-polishing abilities which promote gingival health, was used as the temporary material of choice (Figure 14). The temporary performed very well during the time needed for healing and veneer fabrication.

NOW THE BIG CHALLENGE

Now that the veneers were fabricated and returned from the laboratory, the real challenges began. Local anesthesia was delivered and the temporaries were removed. The laser bony crown lengthening procedure was successful and the excellent gingival health (Figure 15) was a result of the laser precision and the unique temporary material used in this case.

Seating this case had a number of challenges. The first challenge was being able to effectively etch and bond to a variety of dental surfaces including enamel, dentin, cementum, and porcelain. Figure 16 shows the use of phosphoric acid etch on all enamel, dentin, and cementum surfaces; and a 4% buffered hydrofluoric acid etch Porcelain Etch (Ultradent Products) on all porcelain surfaces.

Figure 12. Lower minimal veneer preparations.

Figure 13. Veneer preparations and precise laser osseous closed sulcus crown lengthening to even the gingival margins (WaterLase iPlus [BIOLASE]).

Figure 14. Temporization of case with a unique temporary material (Dentocrown [Itena USA]).

Figure 15. Excellent gingival health can be seen after temporary removal.

Figure 16. Knowledge of how to etch various dental substrates is imperative.

Figure 17. Proper acid etching achieved as demonstrated by "frosty" appearance.

Figure 18. Final Cristal veneers (Aurum Ceramics). *Note the even gingival margins on central incisors.*

Figure 19. Total dental and facial aesthetics completed with porcelain veneers, Botox, and dermal fillers.

...aesthetic dentistry is not limited to only inside the oral cavity as previously thought.

The effectiveness of the etchant materials used can be seen in Figure 17. Silane was placed and thinned on the porcelain surfaces and Iperbond Ultra (Itena USA), a universal next generation bonding agent with excellent bonding strengths to all dental surfaces and substrates including many types of porcelains and zirconium, was placed on all the etched surfaces.

Anyone who has ever placed veneers with different thicknesses knows the biggest challenge is trying to match up the final shade. Seating these veneers is very time consuming in the office as the dentist is trying to use different resin cement shades and even different values of the resin cement shade to achieve a color match of all of the veneers. Personally, I have always believed that this should not be the dentist's problem. It should be the laboratory team's responsibility if they have the aesthetic expertise necessary and really understand the ceramics that they are using. Cristal Veneers porcelain was developed by Aurum Ceramics, giving them the aesthetic expertise to understand the optical qualities of the porcelain as well as the different opacities that will go into a challenging veneer case such as this one. This case came back to my office with all of the different thicknesses of porcelain veneers (and sometimes there are even different thicknesses on the same porcelain veneer), and because of this laboratory's expertise in producing these veneers, I was able to seat all of these veneers with one shade of cement. It is a huge advantage to have such a talented laboratory team, and here is where your choice of laboratories can make all of the difference in the world in terms of the ease of cementation, saving time, and producing an aesthetic result that you and the patient are proud of.

The chosen veneer shade was 020 for this case and the corresponding cement was used. I used a light-curing porcelain veneer cement (Nexus 3 [Kerr]) because of its ease of use, color stability, and great texture for seating any kind of veneer, whether thick or thin. Figure 18 shows the veneers cemented into place. The challenges presented above have been addressed completely. Look at the gingival margin of the upper right central incisor as it now exactly matches the gingival margin of the upper left central incisor. Remember that the veneers on the central incisors are approximately 0.3 mm and the rest of the veneers are anywhere from 1.0 to 3.5 mm in thickness and all of these veneers are the exact same shade. There was absolutely no need to try to use different shades of cement to achieve a final matching shade, but only one shade of cement was used. Notice also that the lower veneers now restore the proper height to the teeth, and they are no longer short and stubby, as the patient complained about before.

Bonding veneers to existing porcelain crowns includes the use of a number of agents and a sequenced approach. (Please go to my Web site commonsensedentistry.com for a full step-by-step technique as how to bond a porcelain veneer to an existing porcelain crown.)

Figure 19 shows a very happy patient who has been treated with total facial aesthetics, and we have addressed all of her concerns. The final dental aesthetic and therapeutic result is a combination of all of the oral and maxillofacial treatment both in and around the mouth. What is interesting about this case and similar treatment plans that include Botox, dermal fillers, and dental materials, is that the facial injectable treatment is much easier to perform with proper training.

CLOSING COMMENTS

This article clearly demonstrates that aesthetic dentistry is not limited to only inside the oral cavity as previously thought. Treatment of the oral and maxillofacial areas with intraoral treatment is true and total dental aesthetics.✦

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Disclosure: Dr. Malcmacher is president of the American Academy Facial Esthetics.

Treating Angular Cheilitis

A New Approach for Treating Lip Inflammation

Though dermal fillers are most often associated with volumizing the perioral areas and lips for esthetic purposes, they are used for a number of therapeutic purposes, too, including treatment of angular cheilitis. Angular cheilitis (also known as perleche or angular stomatitis) is an inflammation around the commissures of the lips that leads to deep, painful cracks around the corners of the mouth. It is one of the most frustrating challenges that dentists and other health care professionals treat, as the symptoms of this chronic condition are very difficult to control. Despite successful treatment, patients sometimes can relapse, experiencing red, wet, crusting lesions that are difficult to treat.

Figure 1: Deep skin folds that are causing angular cheilitis in the patient.

Figure 2: Sores at lip commissures upon opening the mouth.

Figure 3: One-week post-op showing commissures supported with dermal filler using the AAFE scaffolding technique.

The causes

The etiology of angular cheilitis is multifactorial, and like the proverbial chicken and egg, it's often difficult to assess where the problem actually started. Poor diet and/or malnutrition often are cited as primary causes, specifically zinc or vitamin B_2 deficiencies. Additionally, certain medications that dry out the skin, including retinoids, can cause angular cheilitis.

As dentists, we have known for a long time that loss of vertical dimension and/or poorly fitting dentures are primary causes of angular cheilitis as well. Even if occlusion is not an issue, age-related facial changes due to skeletal atrophy, loss of skin elasticity, and diminished subcutaneous fat pads create significant volume loss in the lower portion of the face. All of these factors contribute greatly to the persistence of angular cheilitis because, as the oral commissures deepen into skin folds, saliva pools and creates a chronic, wet environment. Once lesions begin to form here, they can persist due to bacterial and fungal infection, which often bring on stubborn, dry, splitting skin.

The solutions

A good search on the Internet will result in a myriad of sites with various remedies recommended by people who suffer from angular cheilitis, as well as companies that sell products claiming to cure it forever. Among these are vitamin regimens; antifungal, antiviral, and antibacterial creams; vitamin E; tea tree oil; and apple cider vinegar. Some out there claim that fish oil is the perfect cure, while others claim that fish oil is the cause. Sometimes these cures are a bit confusing, like the one that recommends using grapefruit seed oil and vodka. Is the vodka used topically, or do you drink it to dull the pain? As dentists, we are in a position to offer a much more effective solution.

In a patient who has not developed the folds of skin at the commissures of the lips, topical treatments have the potential to be helpful toward a long-term solution. However, we know that if we do not completely eliminate a problem, patients will be waiting at our door first thing on Monday morning for further treatment.

We are trained to remove the source of the problem first, whether it is plaque, decay, a dead nerve, or a fractured tooth. Then, we reconstruct and support what has been destroyed so that the patient can regain function. And, while nothing lasts forever, our treatments, for the most part, have tried and true longevity.

So, in the case of patients with deep folds of skin at the commissures of the mouth that were unsuccessfully treated by bite correction, why not try to correct the problem by supporting the weakened skin that is creating these skin folds in the first place?

Dermal fillers, such as Restylane® and Juvéderm®, are a very popular, noninvasive way to replace volume loss in the lower face. The use of these materials, combined with botulinum toxin type A (BTX-A)—BOTOX®, Dysport®, and Xeomin®—for selective relaxation of facial

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muscles and subsequent wrinkle smoothing, are the fastest growing esthetic procedures worldwide. In 2011, the U.S. Food and Drug Administration (FDA) approved BTX-A as a primary treatment for chronic migraine headaches, and it is being used extensively to control the painful symptoms of temporomandibular joint and myofascial disorders created by hypertonic muscles of mastication. While BTX-A is widely accepted for therapeutic procedures, careful consideration must be given to the therapeutic potential of dermal fillers as well.

A case report

An 83-year-old female patient reported a chief complaint of painful, crusting skin around the corners of her mouth (figure 1). When she opened her mouth, bleeding occurred as the wounds opened as well (figure 2). This patient reported having seen several dermatologists who prescribed various solutions, including Neosporin®, antifungal creams, antibiotic creams, steroid creams and pills, and even injections into the affected area. She also had been taking a variety of vitamins and making a diligent attempt to keep the areas dry using Aquaphor®, particularly when she slept. However, she reported that by morning, saliva had pooled in the affected area, negating any positive effects. The patient also tried several home remedies, all of which resulted in some temporary relief but no long-term, satisfactory result.

Clinical examination confirmed the patient had a severe case of angular cheilitis. Her occlusion was within normal limits and, after consulting with the patient's physician, treatment was initiated using dermal fillers as a scaffold to help support the weak areas of skin.

By using a simple crosshatching and threading technique, 0.8 mL of Juvéderm was injected into the mid-dermis area of the commissure of her lips. One week later, the patient was healing very well and experiencing significant relief from her symptoms (figure 3). This relief will last for approximately six months until re-treatment with dermal fillers.

As dentists, our ultimate purpose is to make a difference in our patients' quality of life. Dermal fillers are well-known for esthetic treatments; however, that doesn't mean they cannot be used to provide relief for non-esthetic issues, such as angular cheilitis. While conventional treatment planning is a start, there are many other areas of expertise from which we can draw to provide thorough and successful patient care. ◆

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818-012-0010

Unacceptable Patient Care

The Board finds, using the criteria set forth in ORS 679. 140(4), that a licensee engages in or permits the performance of unacceptable patient care if the licensee does or permits any person to:

(1) Provide treatment which exposes a patient to risk of harm when equivalent or better treatment with less risk to the patient is available.

(2) Fail to seek consultation whenever the welfare of a patient would be safeguarded or advanced by having recourse to those who have special skills, knowledge and experience; provided, however, that it is not a violation of this section to omit to seek consultation if other competent licensees in the same locality and in similar circumstances would not have sought such consultation.

(3) Fail to provide or arrange for emergency treatment for a patient currently receiving treatment.

(4) Fail to exercise supervision required by the Dental Practice Act over any person or permit any person to perform duties for which the person is not licensed or certified.

(5) Render services which the licensee is not licensed to provide.

(6) Fail to comply with ORS 453.605 to 453.755 or rules adopted pursuant thereto relating to the use of x-ray machines.

(7) Fail to maintain patient records in accordance with OAR 818-012-0070.

(8) Fail to provide goods or services in a reasonable period of time which are due to a patient pursuant to a contract with the patient or a third party.

(9) Attempt to perform procedures which the licensee is not capable of performing due to physical or mental disability.

(10) Perform any procedure for which the patient or patient's guardian has not previously given informed consent provided, however, that in an emergency situation, if the patient is a minor whose guardian is unavailable or the patient is unable to respond, a licensee may render treatment in a reasonable manner according to community standards.

(11) Use the behavior management technique of Hand Over Mouth (HOM) without first obtaining informed consent for the use of the technique.

(12) Use the behavior management technique of Hand Over Mouth Airway Restriction (HOMAR) on any patient.

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77 **(13) Fail to determine and document a dental justification prior to ordering a Cone Beam**
78 **CT series with field greater than 6x6 cm for patients under 20 years of age where**
79 **pathology, anatomical variation or potential treatment complications would not be readily**
80 **discernible with a Full Mouth Series, Panoramic or Cephometric radiographs.**
81 **(14) Fail to advise a patient of any treatment complications or treatment outcomes.**
82 Stat. Auth.: ORS 679 & ORS 680
83 Stats. Implemented: ORS 679.140(1)(e), ORS 679.140(4) & ORS 680.100
84 Hist.: DE 6, f. 8-9-63, ef. 9-11-63; DE 14, f. 1-20-72, ef. 2-10-72; DE 5-1980, f. & ef. 12-26-80;
85 DE 2-1982, f. & ef. 3-19-82; DE 5-1982, f. & ef. 5-26-82; DE 9-1984, f. & ef. 5-17-84;
86 Renumbered from 818-010-0080; DE 3-1986, f. & ef. 3-31-86; DE 1-1988, f. 12-28-88, cert. ef.
87 2-1-89, DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; Renumbered from 818-011-0020; DE 2-1997, f.
88 & cert. ef. 2-20-97; DE 3-1997, f. & cert. ef. 8-27-97; OBD 7-2001, f. & cert. ef. 1-8-01

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818-012-0040

Infection Control Guidelines

In determining what constitutes unacceptable patient care with respect to infection control, the Board may consider current infection control guidelines such as those of the Centers for Disease Control and Prevention and the American Dental Association.

(1) Additionally, licensees must comply with the following requirements:

(**a**) (~~1~~)Disposable gloves shall be worn whenever placing fingers into the mouth of a patient or when handling blood or saliva contaminated instruments or equipment. Appropriate hand hygiene shall be performed prior to gloving.

(**b**) (~~2~~)Masks and protective eyewear or chin-length shields shall be worn by licensees and other dental care workers when spattering of blood or other body fluids is likely.

(**c**)(~~3~~) Between each patient use, instruments or other equipment that come in contact with body fluids shall be sterilized.

(**d**) (~~4~~)Environmental surfaces that are contaminated by blood or saliva shall be disinfected with a chemical germicide which is mycobactericidal at use.

(**e**)(~~5~~) Impervious backed paper, aluminum foil, or plastic wrap may be used to cover surfaces that may be contaminated by blood or saliva and are difficult or impossible to disinfect. The cover shall be replaced between patients.

(**f**) (~~6~~)All contaminated wastes and sharps shall be disposed of according to any governmental requirements.

(2) Dentists must comply with the requirement that heat sterilizing devices shall be tested for proper function by means of a biological monitoring system that indicates micro-organisms kill each calendar week in which scheduled patients are treated. Testing results shall be retained by the **dentist** ~~licensee~~ for the current calendar year and the two preceding calendar years.

Stat. Auth.: ORS 679.120, 679.250(7), **679.535,** 680.075 & 680.150

Stats. Implemented: ORS 679.140, 679.140(4) & 680.100

Hist.: DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; DE 2-1992, f. & cert. ef. 6-24-92; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 3-2013, f. 10-24-13, cert. ef. 1-1-14; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

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818-012-0070

Patient Records

(1) Each licensee shall have prepared and maintained an accurate record for each person receiving dental services, regardless of whether any fee is charged. The record shall contain the name of the licensee rendering the service and include:

(a) Name and address and, if a minor, name of guardian;

(b) Date description of examination and diagnosis;

(c) An entry that informed consent has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or "SOAP" (Subjective Objective Assessment Plan) or their equivalent.

(d) Date and description of treatment or services rendered;

(e) Date ~~and~~**,** description **and documentation of informing the patient** of treatment complications **or treatment outcomes**;

(f) Date and description of all radiographs, study models, and periodontal charting;

(g) Health history; and

(h) Date, name of, quantity of, and strength of all drugs dispensed, administered, or prescribed.

(2) Each ~~dentist~~ **licensee** shall have prepared and maintained an accurate record of all charges and payments for services including source of payments.

(3) Each ~~dentist~~ **licensee** shall maintain patient records and radiographs for at least seven years from the date of last entry unless:

(a) The patient requests the records, radiographs, and models be transferred to another ~~dentist~~ **licensee** who shall maintain the records and radiographs;

(b) The ~~dentist~~ **licensee** gives the records, radiographs, or models to the patient; or

(c) The ~~dentist~~ **licensee** transfers the ~~dentist's~~ **licensee's** practice to another ~~dentist~~ **licensee** who shall maintain the records and radiographs.

(4) When changing practice locations, closing a practice location or retiring, each licensee must retain patient records for the required amount of time or transfer the custody of patient records to another licensee licensed and practicing dentistry in Oregon. Transfer of patient records pursuant to this section of this rule must be reported to the Board in writing within 14 days of transfer, but not later than the effective date of

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156 **the change in practice location, closure of the practice location or retirement. Failure to**
157 **transfer the custody of patient records as required in this rule is unprofessional conduct.**
158 **(5) Upon the death or permanent disability of a licensee, the administrator, executor,**
159 **personal representative, guardian, conservator or receiver of the former licensee must**
160 **notify the Board in writing of the management arrangement for the custody and transfer**
161 **of patient records. This individual must ensure the security of and access to patient**
162 **records by the patient or other authorized party, and must report arrangements for**
163 **permanent custody of patient records to the Board in writing within 90 days of the death**
164 **of the licensee.**
165 Stat. Auth.: ORS 679
166 Stats. Implemented: ORS 679.140(1)(e) & ORS 679.140(4)
167 Hist.: DE 9-1984, f. & ef. 5-17-84; DE 1-1988, f. 12-28-88, cert. ef. 2-1-89, DE 1-1989, f. 1-27-
168 90, cert. ef. 2-1-90; Renumbered from 818-011-0060; DE 1-1990, f. 3-19-90, cert. ef. 4-2-90;
169 OBD 7-2001, f. & cert. ef. 1-8-01
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171 818-012-XXXX

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173 Diagnostic Records

174

175 1) Licensees shall provide duplicates of physical diagnostic records that have been paid
176 for to patient or patient's guardian within 14 days of written request.
177 (A) Physical records include silver emulsion radiographs, physical study models, paper
178 charting and chart notes.
179 (B) Licensees may require the patient or patient's guardian to pay in advance the fee
180 reasonably calculated to cover costs of making the copies or duplicates.
181 (i) Licensee may charge a fee not to exceed $30 for copying 10 or fewer pages of written
182 material and no more than $0.50 per page for 11-50 and no more than $0.25 for each
183 additional page, including cost of microfilm plus any postage costs to mail copies
184 requested and actual costs of preparing an explanation or summary of information, if
185 requested. The actual costs of duplicating radiographs may also be charged to the
186 patient.
187 2) Licensees shall provide duplicates of digital patient records within 3 clinical days of
188 written request by the patient or patient's guardian.
189 A) Digital records include any patient diagnostic image, study model, test result or chart
190 record in digital form.
191 B) Licensees may require the patient or patient's guardian to pay for the typical retail
192 cost of the digital storage device, such as a CD, thumb drive, or DVD as well as
193 associated postage.
194 C) Licensees shall not charge any patient or patient's guardian to transmit requested
195 digital records over email if total records do not exceed 25 Mb.
196 D) A clinical day is defined as a day during which the dental clinic treated scheduled
197 patients.
198 E) Licensees may charge up to $5 for duplication of digital records up to 25Mb and up to
199 $30 for more than 25Mb.
200 F) Any transmission of patient records shall be in compliance with the Health Insurance
201 Portability and Accountability Act (HIPAA Act) and the Health Information Technology
202 for Economic and Clinical Health Act (HITECH Act).
203 G) Duplicated digital records shall be of equal diagnostic quality to the original digital
204 file.

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205 **3) If a records summary is requested by patient or patient's guardian, the actual cost of**
206 **creating this summary and its transmittal may be billed to the patient or patient's**
207 **guardian.**
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The New York Times

U.S.

Radiation Worries for Children in Dentists' Chairs

By WALT BOGDANICH and JO CRAVEN McGINTY NOV. 22, 2010

Because children and adolescents are particularly vulnerable to radiation, doctors three years ago mounted a national campaign to protect them by reducing diagnostic radiation to only those levels seen as absolutely necessary.

It is a message that has resonated in many clinics and hospitals. Yet there is one busy place where it has not: the dental office.

Not only do most dentists continue to use outmoded X-ray film requiring higher amounts of radiation, but orthodontists and other specialists are embracing a new scanning device that emits significantly more radiation than conventional methods, an examination by The New York Times has found.

Designed for dental offices, the device, called a cone-beam CT scanner, provides brilliant 3-D images of teeth, roots, jaw and even skull. This technology, its promoters say, is a safe way for orthodontists and oral surgeons to work with more precision and to identify problems that otherwise might go unnoticed.

But there is little independent research to validate these claims. Instead, the cone beam's popularity has been fueled in part by misinformation about its safety and efficacy, some of it coming from dentists paid or sponsored by manufacturers to give speeches, seminars and continuing education classes, as well as by industry-

sponsored magazines and conferences, according to records and dozens of interviews with dentists and researchers.

Last month, The Journal of the American Dental Association allowed one of the leading cone-beam manufacturers, Imaging Sciences International, to underwrite an issue devoted entirely to cone-beam technology. That magazine, which the association sent to 150,000 dentists, included a favorable article by an author who has equated a cone-beam CT with an airport scan. In fact, a cone beam can produce hundreds of times more radiation, experts say.

Cone-beam CT scans can help dentists deal with complex cases involving implants, impacted teeth and other serious problems. But many experts in dental radiation have raised alarms about what they see as their indiscriminate use. They worry that with few guidelines or regulations, well-meaning orthodontists and other specialists are turning to a new technology they do not fully understand, putting patients at risk, particularly younger ones.

Some orthodontists now use cone-beam CT scans to screen all patients, even though a number of dental groups in this country and in Europe have questioned whether the benefit of routine use justifies the added risk.

“All these different cone-beam CT scanners came out to a world that was unprepared,” said Keith Horner, a professor of oral radiology at the University of Manchester in Britain, who is coordinating a study of cone-beam scanners for the European Commission. “They are just pushed out there by manufacturers with the message that a 3-D image is always going to be better than a 2-D image, and that isn’t the case.”

One popular new brand of braces has helped cone-beam sales because it requires 3-D images, which doctors can obtain using either a cone-beam scanner with radiation, or a digital camera without it. Many orthodontists opt for radiation, because it is quicker.

Even those troubled by the widening use of cone-beam technology acknowledge that by itself, the risk from a single scan is relatively small. But patients often get more than one scan, and the lifetime risk increases with each exposure. Without a clear benefit, they say, there is only risk.

“So let me ask a question to the mother of a prospective orthodontic patient,” said Dr. Stuart C. White, former chairman of oral radiology at the UCLA School of Dentistry. “Would you like me to use a tool that is entirely safe — a camera — to record the position of your child’s teeth, or another method that may rarely cause cancer so that we can save time?”

The cone-beam business is lucrative for manufacturers and dentists. According to one industry estimate, more than 3,000 scanners and about 30 different models have been sold, at prices up to $250,000.

Dentists, some of whom charge several hundred dollars per scan, can profit by owning their own machines. “More profit per unit chair time,” promises Imaging Sciences, the cone-beam manufacturer.

Marketers increase interest in the technology by holding drawings for free cone-beam CT scanners and other gifts. A Washington State orthodontist, who gave an online lecture sponsored by Imaging Sciences, offers dentists coupons for free scans for their patients as a way to build referrals.

And then there is the “wow” factor, said Dr. Terry Sellke, an orthodontist in Illinois.

“Kids love to see that 3-D image,” Dr. Sellke said in a Webcast sponsored by Imaging Sciences. “They can go into our computer and look at their skull.” Another orthodontist talked about coloring 3-D skulls in green and purple. “Fun for the kids,” he said.

Dr. Allan G. Farman, president of the American Academy of Oral and Maxillofacial Radiology, cautions doctors not to become overly enamored of the new technology, citing the example of how shoe stores once took X-rays of customers’ feet to see if shoes fit.

“At least the shoe merchants were ignorant of the effects of radiation,” Dr. Farman said.

Regulators are just now recognizing how ill equipped they are to oversee this new technology. “There is not a lot of radiation exposure data out there,” said Jerry Hensley, a state radiation protection official in California.

While protocols and guidelines exist for other types of imaging, Mr. Hensley said, “cone beams are off in their own land right now.”

‘A Lack of Understanding’

Even before cone-beam scanners, the dental profession had problems keeping radiation levels low.

For years, dentists have been advised to stop using slow, D-speed film for X-rays because it requires more radiation than faster film. Yet, most still use the slower film, which requires up to 60 percent more radiation, according to dental experts and government records.

Brian Smith, a spokesman for Carestream Dental, the market leader in dental film, said 70 percent of its film sales in the United States are D-speed. The percentage is lower globally, suggesting that dentists elsewhere do a better job of reducing radiation.

There is no excuse for not switching, the Food and Drug Administration said, because faster films offer the same quality for only pennies more.

Dr. John B. Ludlow, a University of North Carolina professor who has published widely quoted studies on dental radiation, said he suspects that some dentists avoid faster film because they mistakenly believe it is harder to process.

A check of state dental boards found none that were aggressively pressing dentists to use the faster film. Digital X-rays use even less radiation than film, but a minority of dentists use them.

One expert in dental radiation, Dr. Joel E. Gray, said he has found as much as a 500 percent difference in radiation levels because of sloppiness in developing film, including using chemicals that were degraded or at the wrong temperature. To get clearer images, dentists compensate by increasing exposure time — and radiation, said Dr. Gray, whose company, Diquad, has contracts with three states, including California, to try to keep dental radiation in check.

New Jersey, which collects data on radiation exposure, found that 20 percent of its dental offices had high or “extremely high” radiation levels.

“There is a lack of understanding of the radiation in dental offices,” Dr. Gray said.

That has become even more important with the emergence of cone-beam CT scanners. When first introduced in the United States about a decade ago, they were viewed mostly as a cheaper, lower-radiation alternative to big, medical CT scanners that were often needed to diagnose serious ailments of the mouth and face.

But through aggressive marketing and technological improvements over the last several years, their use has rapidly expanded into other areas, including orthodontics. For many teenagers, getting scanned is now part of the ritual of getting braces.

“The parents of these children,” said Dr. Nicholas Dello Russo, a Boston periodontist who teaches at Harvard Dental School, “have no idea about the amount of radiation used in these CT scans, and even more frightening, neither do the dentists.”

Quick and Easy

In October, 26,000 people gathered in Orlando, Fla., for the annual conference of the American Dental Association.

The presence of cone-beam CT scanners could be seen and heard at every turn. There was the 3-D imaging center, cone-beam exhibits, demonstrations and continuing education lectures.

An open forum on cone-beam imaging was co-moderated by Dr. Michael Glick, editor of the Journal of the American Dental Association. Of the four panelists, one was a founder of Imaging Sciences, another was a consultant to the company’s distributor and a third was a paid speaker for another cone-beam company.

Cone-beam scanners are quick, easy to use, versatile and do not require much space. In most models, the patient sits in a chair for less than a minute while a small scanner circles the head. Enthusiasm for the technology is echoed by dentists around the country.

Dr. Steven A. Guttenberg of Washington said he uses the scanner “for every single implant that I do.” Dr. Rik Vanooteghem of Sunnyvale, Calif., added: “I really feel blindfolded if I don’t use it.”

Dr. Bradford Edgren of Greeley, Colo., said his scanner had found hidden teeth — among other things. “I found a rock in one child’s ear,” Dr. Edgren said. “Now she can hear and her grades have gone up.”

A California lawyer, Arthur W. Curley, suggested that dentists might even face legal liability for not using 3-D imaging. “Negligence may be the failure to incorporate new technologies that meet well-defined legal standards,” Mr. Curley said in a Web presentation.

Mr. Curley, along with Drs. Vanooteghem, Guttenberg and Edgren, share more than their enthusiasm. They have all received speaking fees from Imaging Sciences.

At the A.D.A.’s conference last month, six manufacturers spent nearly $290,000 to promote 3-D technology. And the A.D.A. said it had accepted somewhere under $100,000 from Imaging Sciences and its sister company — a specific figure was not given — from Imaging Sciences for the cone-beam supplement that came out around the time of the conference.

The company’s i-CAT scanner is one of the most popular on the market.

“I use my i-CAT for everything,” one orthodontist, Dr. Edward Y. Lin, proclaimed in a full-page advertisement in one magazine.

“I cringe every time I see that ad,” said Dr. Farman, the radiology academy president and a professor at the University of Louisville School of Dentistry. He calls the i-CAT an excellent device, but said there is not yet proof that it is better and safer than conventional imaging in all applications.

This month, the academy and the American Association of Endodontists issued a joint statement saying that cone-beam CT “must not” be used “for screening purposes in the absence of clinical signs and symptoms.”

Another cone-beam manufacturer, Sirona Dental Systems, has promoted its devices as better for detecting cavities than conventional methods, according to

Professor Horner, the European Commission study group leader. But Professor Horner and dental experts in the United States say that claim is unproven. A spokesman for Sirona, John Sweeney, said his company's reference to cavities appeared in an article several years old and was at the time the best information available.

Dr. Lee W. Graber, president of the American Association of Orthodontists, praises the technology and said dentists have worked to reduce radiation over the years. In his suburban Chicago practice, Dr. Graber has a machine capable of delivering both cone-beam scans and conventional images, but only uses the higher radiation method when necessary. "Our goal as clinicians is to try to minimize the risk," he said.

Vatech America, a cone-beam manufacturer, does not support using its scanner as a screening device, said Travis Harrison, the company's director of business development. "We don't want to just dose everyone with a CT," he said.

Imaging Sciences, a unit of the Danaher Corporation, a diversified manufacturing and technology company, declined repeated requests for interviews, saying it granted such requests only to trade publications, according to Dan Gagnier, a company spokesman.

In a statement, the company said cone-beam scans give dentists "the ability to view patient anatomy more accurately" than conventional 2-D X-rays, making it easier to avoid nerves, avoid placing implants in bones that will not support them and improve orthodontic care — all at radiation levels below "a number of competing technologies."

Weighing the Risks

On Nov. 10, more than 100 members of the Greater Philadelphia Society of Orthodontists met in the august, dark-paneled rooms of the Union League of Philadelphia.

They had come to hear Dr. James Mah, described by the society as one of the world's foremost experts on 3-D technology, and to earn six continuing education credits. Dr. Mah, an associate clinical professor at University of Southern

California and the University of Nevada, Las Vegas, “has made over 100 presentations nationally and internationally,” according to his biography from a recent conference.

When a Times reporter showed up for the lecture, a representative of the society welcomed the coverage. But after the representative said he needed to consult a “vendor representative,” society officials reversed course. Because actual cases were to be discussed, the officials said, the reporter’s presence would violate federal patient privacy laws. Dr. Mah declined to be interviewed, and the reporter was escorted off the premises by security personnel.

Dr. Mah’s views on cone-beam technology are hardly a secret. In an online lecture this year sponsored by Imaging Sciences, he proclaimed, “In orthodontics, we image every patient.”

In that lecture —“Why Dentists Can’t Wait for Cone-Beam CT” — he played down health concerns, saying a cone-beam scan produces no more radiation than a whole-body scan at the airport.

Equating a cone-beam scan with an airport scan is “very wrong — by a lot,” said Dr. David Brenner, who directs the Center for Radiological Research at Columbia University Medical Center. In fact, cone-beam scanners can be several hundred times as powerful, he said.

Yet in the special issue of the A.D.A. Journal underwritten by Imaging Sciences, Dr. Mah was the lead author on an article challenging the orthodontic association’s position that a cone-beam scan “is not routinely required for orthodontic radiography.”

Dr. Glick, the editor of the A.D.A. Journal, said that as long as authors can back up what they say with science, then he has no problem. “If they cannot back that up, then that’s a different story,” Dr. Glick said. He added that Dr. Mah’s article was peer reviewed.

Critics say aggressive marketing has produced a distorted picture of the safety and efficacy of cone-beam scanners.

Writing in the International Journal of Oral and Maxillofacial Surgery last

year, researchers concluded that the device's popularity "has resulted in numerous presentations at conferences, dozens of manufacturers' brochures and published papers resulting in an uncontrolled and non-evidence-based exchange of radiation dose values."

Some proponents of cone-beam scans say the radiation risk is no greater than what someone would experience flying cross-country or spending several days in the sun. They also minimize the risk by comparing radiation levels to imaging procedures not typically used in orthodontic care, such as medical CT scans done in hospitals and clinics.

"I don't like that comparison with how many days of daylight; I don't like that at all," said Dr. Christos Angelopoulos, the director of the division of oral and maxillofacial radiography at Columbia University College of Dental Medicine. "People still use it very frequently. That really in a way gives the feeling to the patient that it is not risky at all, whereas that's wrong."

Dr. Angelopoulos said radiation levels can vary greatly, depending on the scanner, its settings and scan time. "The numbers are all over the place," he said.

A report in the British Journal of Radiology last year concluded that cone-beam CT scans produced "significantly higher" levels of radiation than conventional dental imaging. The standard orthodontic scan for the i-CAT produces five times as much radiation as a 2-D panoramic scan, said Dr. Ludlow, the North Carolina radiation researcher. Depending upon the model and setting, other scanners produce 4 to 67 times as much as conventional X-rays, he added.

Whatever the radiation levels from a particular cone-beam scan, the risk is small, said Dr. Brenner, the Columbia University radiation researcher. But it is only worth taking, he said, if there is demonstrable benefit, particularly for young patients who are "typically 5 to 10 times more sensitive than adults."

Dr. Brenner said that a child faces up to a 1-in-10,000 chance of developing cancer from a single cone-beam scan. Yet orthodontic patients frequently get more than one scan during treatment and face a lifetime of additional X-rays, all of which scientists believe are cumulative. "You double the dose, you double the risk," Dr. Brenner said.

And, Dr. Ludlow said, there is not yet scientific data to prove that the 3-D technology, sometimes known as volumetric imaging, produces better results.

“Until we have that data, and it’s going to take time, we just need to use common sense, good judgment,” he said. “And part of that good judgment is recognizing that the youngest are more sensitive to radiation than adults, and do we really — for an uncomplicated orthodontic case, where we are just going to move some teeth a little bit — do we really need volumetric imaging?”

Time and Money

The after-school rush was about to begin, and Dr. Edward Y. Lin used a final moment of calm on a recent day to show a visitor the 3-D images of a former patient’s teeth and bone structure. “So we put her braces on right here — it was April 27, 2007,” he said. “And there’s the finished smile.”

It was a complicated case involving implants, Dr. Lin said, but with 3-D technology and a computer-assisted method of attaching braces, he was able to do the job better and many months faster.

Dr. Lin and his partners run a popular orthodontic practice in and around Green Bay, Wis. A visit there illustrates some of the factors involved in deciding whether to use cone beam and how it fits into the economics of a practice.

For several years, Dr. Lin has been using technology called SureSmile where a robot, guided by 3-D images, bends wires that move the teeth into desired positions. The technology is able to mold metal wires to a patient’s teeth with great precision.

The 3-D image can be taken with either a tiny camera, which uses light, not radiation, or a cone-beam scanner.

The nonradiation method is “really no different than taking a series of still pictures like you would with a digital camera,” said Dan De Silva, vice president of marketing for OraMetrix, the Texas company that owns SureSmile. From those pictures, computers create a 3-D image.

A cone-beam scanner is quicker, and he says that about a third of his

customers either own or have access to one.

Dr. Lin estimates that all of his roughly 800 SureSmile patients received cone-beam scans, some as many as four scans. Dr. Lin said he uses several techniques to keep the radiation as low as possible.

Dr. Lin said he started using the nonradiation method, but found that it took a half-hour or more to complete and could be uncomfortable for the patient. He says his i-CAT scanner takes only seconds, offers a better view of roots and often detects hidden problems that might complicate treatment. “It’s not the exception,” he said. “It happens on a routine basis.”

One of Dr. Lin’s satisfied patients is Tomek Miaskowski, 18, who just had his braces removed. “Today was probably the greatest day of my teenage life,” the patient said.

Mr. Miaskowski said he got two cone-beam scans. Radiation was not an issue for him. “I trust the doctor— that’s what you have to do,” he said.

Shorter treatment time makes the patients, their parents and the orthodontist happy. “We now attribute a significant portion of our revenue to the frequent use of our cone-beam machine for diagnostics, records and our SureSmile scans,” Dr. Lin said in a 2009 article he wrote for a dental publication.

In the article, Dr. Lin broke down the economics of his scanner, which cost about $200,000. “We calculated the value of each clinical minute at our practice at approximately $5,” he wrote, and using the cone beam instead of the camera cut each appointment by at least 30 minutes. “That’s $150 in savings,” he wrote. “For 1,000 possible new appointments for braces yearly, that’s $150,000 in savings.”

Using the cone-beam scanner, Dr. Lin wrote, he treats the same number of patients “in a three-day clinical week that we used to in a four-day week, which reduces our staff requirements.”

Little Regulation

Cone-beam CT scanners, like most radiological devices in medicine, are lightly regulated.

“Some states have in effect no inspections of dental X-ray units,” said Dr. G. Donald Frey, professor of radiology at the Medical University of South Carolina and a past president of the American Association of Physicists in Medicine. While inspectors generally evaluate machine performance, few attempt to measure the overall radiation risk to the patient’s organs.

“States tend not to want to regulate the practice of medicine or dentistry,” Dr. Frey said.

Most states require dentists to earn continuing education credits for re-licensure, but for the most part do not assess the content of the courses, trusting dentists to select and complete suitable courses.

The quality of these courses varies widely, The Times has found.

Dentists, for example, can earn two continuing education credits by reading about cone-beam technology in a new magazine, Orthodontic Practice — US, and then answering 10 simple questions appended to the end.

The article’s author is Dr. Lin, who said he has been a paid lecturer for Imaging Sciences for three years. He said the company did not pay him to write the article or to appear in its full-page advertisement in the same issue.

Dr. Lin said he speaks on behalf of the company because he believes the i-CAT is the best machine around.

Imaging Sciences has benefited from other favorable coverage by the magazine’s publisher, MedMark of Scottsdale, Ariz. A recent issue of MedMark’s “Implant Practice — US” included continuing education articles and a corporate profile of Imaging Sciences, titled “A company of innovation, quality and service.”

The article’s praise was hardly surprising. According to the publisher, Imaging Sciences wrote it.

Sarah E. Fitzpatrick and Kristina Rebelo contributed reporting.

A version of this article appears in print on November 23, 2010, on page A1 of the New York edition with the headline: THE RADIATION BOOM; Radiation Worries Rise With 3-D Dental Images.

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Image Gently During Dental Procedures

Introduction

One size does not fit all…

When using radiography during pediatric dental procedures remember:

.

- Select x rays for individual's needs, not merely as a routine
- Use the fastest image receptor possible: E- or F-speed film or digital sensors
- Collimate beam to area of interest
- Always use thyroid collars
- Child-size the exposure time
- Use cone-beam CT only when necessary

So when we image, let us image gently: More is often not better.

Safety

Guidelines and Resources

Cone-Beam CT

Dental Professionals (http://www.imagegently.org/Roles-What-can-I-do/Parent/Dentist)

Publications

The Alliance for Radiation Safety in Pediatric Imaging (/FAQsMore/TheAlliance.aspx)is comprised of over 80 imaging and health care organizations reaching over 500,000 professionals committed to imaging excellence and safety. The Dental Organizations that led this Safety in Dental Imaging Initiative are:

- American Academy of Oral and Maxillofacial Pathology (AAOMP) (http://www.aaomp.org/)
- American Academy of Oral and Maxillofacial Radiology (AAOMR) (http://www.aaomr.org/)
- American Academy of Pediatric Dentistry (http://www.aapd.org/)
- American Academy of Periodontology (http://www.perio.org/)
- American Association of Endodontists (http://www.aae.org/)
- American Association of Oral and Maxillofacial Surgeons (http://www.aaoms.org/)
- American Association of Orthodontists (https://www.aaoinfo.org/)
- American Association of Orthodontists (https://mylifemysmile.org/) - For Patients or Consumer
- American Association of Public Health Dentistry (http://www.aaphd.org/)
- American Dental Association (http://www.ada.org/)
- American Dental Assistant Association (http://www.dentalassistant.org/)
- American Dental Hygienist Association (http://www.adea.org/)
- FDI World Dental Federation (http://www.fdiworldental.org/home.aspx)
- International Association of Dento-Maxillo-FacialRadiology (IADMFR (http://www.iadmfr2015.com/))

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Upcoming Meetings (/CurrentEvents/Meetings.aspx)
Posters (/LinkClick.aspx?link=893&tabid=227&portalid=6&mid=1279)

Referring Physician (/WhatcanIdoasa/ReferringPhysician.aspx) (/WhatcanIdoasa/ReferringPhysician.aspx)
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Medical Physicist (/LinkClick.aspx?link=759&tabid=759&portalid=6&mid=1279)

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Login (http://www.imagegently. org/Login?returnurl=%2fProcedures%2fDental)

What Parents Should Know about the Safety of Dental Radiology.

There are many different types of x-ray images (pictures) that can be taken of children in the dental office to assist in diagnosis. These include the panoramic and orthodontic (cephalometric) extraoral images, intraoral images such as bitewings and periapicals (little films that go inside the mouth) and cone beam computed tomography (CBCT). All of these dental images use ionizing radiation (x-rays), and therefore parents may be concerned about the increased cancer risk (because of the x-rays) to their children. The following provides information on the risks of dental images in relation to their benefits.

What are X-rays?

X-rays are invisible beams of ionizing radiation. X- rays that are directed to the body do not pass through without changes but are absorbed differently by various tissues of the body. Once they pass through a body part, they are captured by the film and produce images in tones of gray showing calcified structures such as the jaw bones, teeth, and other bony structures. The use of x-rays to create dental images is not painful, but during the procedure, the child must stay still or else the image may be fuzzy. In some circumstances, parents may be asked to help keep their children still while dental images are taken. Depending on the area of the jaw imaged and the type of dental image, a lead body apron or thyroid shield may be used to reduce radiation exposure to other body areas not being imaged.

What is a panoramic film?

Panoramic films belong to the extraoral category of dental x-rays because the film is outside the mouth. The panoramic film provides to the dentist a good view of the maxilla and mandible as well as the whole dentition. Panoramic films also provide a partial view of the temporo-mandibular joint. One of the major advantages of the panoramic films is the short time required to acquire the image. Panoramic films are widely used by dentist because it provides a comprehensive “panoramic” view of the maxilla and mandible. It is commonly used for evaluation of the wisdom teeth or for the evaluation of potential fractures in trauma cases. [Figure 1]

Figure 1. Panoramic film

What is a periapical film?

Periapical films belong to the intraoral category of dental x-rays because the film is inside the mouth. The name “periapical “means that this film is designed to evaluate the root and crown of the teeth. The dentist usually takes periapicals of the back and anterior teeth. [Figure 2]

Figure 2. Periapical film of the front teeth (they are both fractured)

What is a bitewing film?

The name "bitewing" refers to a little tab of paper or plastic situated in the center of the x-ray film, which when bite on, allows the film to hover so that it captures an even amount of the maxillary and mandibular teeth. Bitewings are designed to evaluate the crowns and the most superior part of the bone around the teeth. They do not provide information of the roots of the teeth. Dentist usually uses bitewings for evaluation of the area in-between teeth looking for caries. [Figure 3] The American Dental Association (ADA) recommends bitewings for children (until the eruption of the first permanent molars) only if the spaces between teeth cannot visualized in the clinical exam. For children with high risk of decay, the recommendation is to take bitewings every 6 to 12 months (if the spaces between teeth cannot be visualized in the clinical exam). For children with low risk of decay, the recommendation is every 12 to 24 months. The clinical judgment of the dentist is at the end, the most important criteria.

Figure 3. Bitewing of the left side of the mouth

What is Cone Beam Computed Tomography (CBCT)?

Over the past 10 years, cone beam computed tomography (CBCT) has become increasing available for use in dental offices. CBCT produces images similar to computed tomography (CT) used in medicine except that CBCT may expose a child to less radiation dose. In CBCT an x-ray device rotates around the head to create many individual pictures of the child's jaw and teeth, and these individual images are used to build a virtual three-dimensional (3D) representation (main advantage of CBCT vs. other dental radiographs). [Figure 4] This virtual image may contain diagnostically important information that is not present in other dental images such as a bitewing or panoramic image. However, taking a CBCT image results in more radiation dose to the child than other commonly used dental images.

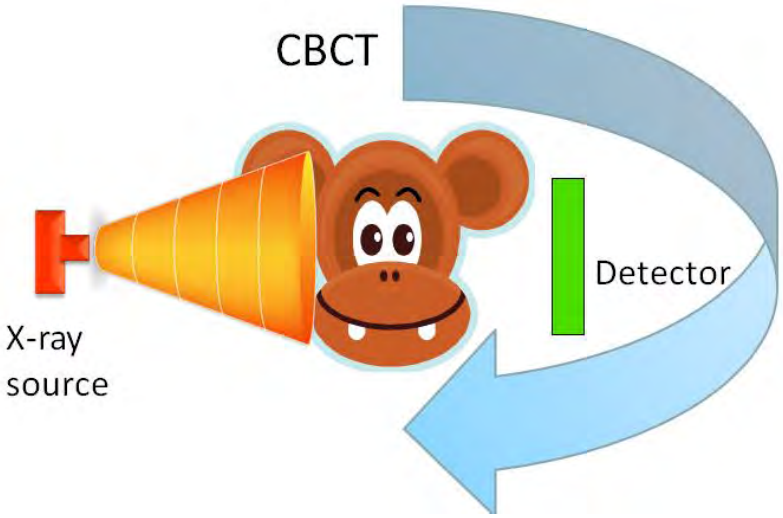

Figure 4. CBCT rotates 360 degrees around the patient head

There are many different types of machines used to take a CBCT image [Figure 5]. These machines may be called a scanner, and while some may look similar to medical CT scanners, others are similar to panoramic x-ray units. Depending on the type of scanner used, the child may sit, stand, or lie down while the scanner moves around the head. The CBCT procedure is quick and painless, with nothing touching the child. Some children may be apprehensive of the procedure because of the size of the scanner and its motion. [Figures 6 and 7]

Figure 5. Different CBCT machines

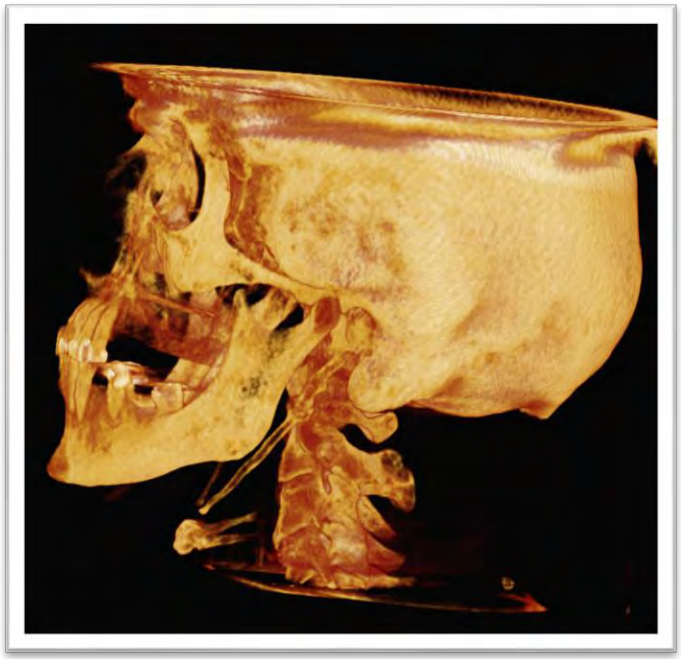

Figure 6. 3D reconstruction of the skull using a CBCT machine

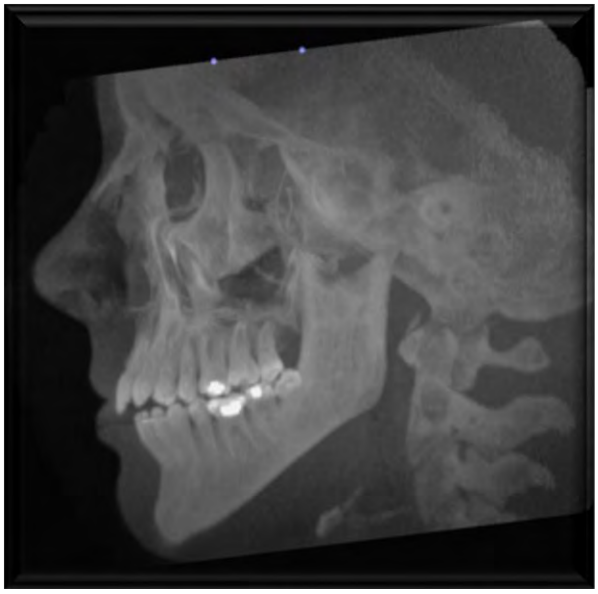

Figure 7. CBCT showing of the left side of the face

How Much Radiation is a Child Exposed to during Dental Radiography.

Every day we are exposed to small amounts of radiation from our environment. This radiation comes from outer space, the ground, building materials, air, and water. This is called natural background radiation. The amount of this radiation to which we are exposed depends upon where we live. For example, those who live in higher elevations (such as Denver, Colorado) are exposed to more radiation from outer space than people who live at sea level. To minimize the amount of radiation used to create a dental image, the settings on the X-ray device should be adjusted depending upon the child's size. The millisievert (mSv) is a measure of effective radiation dose to the body. One way of assessing the dental radiation risks is to compare the radiation doses that result from dental images with estimates of equivalent amounts of natural background radiation (Table 1).

Table 1. Comparison of Radiation Effective Dose from Various Dental and Medical Image Procedures to Natural Background Radiation

	Estimated effective dose	*Equivalent Amount of Background Radiation*
Natural background radiation	3 mSv/yr	
1 Panoramic X-ray	0.02 mSv	up to 3 days
4 bitewing X-rays	0.005 mSv	0.6 day
Cephalometric X-ray	0.006 mSv	up to 1 day
CBCT (both jaws)	up to 0.6 mSv	up to 30 days
Chest X-ray (single view)	up to 0.01 mSv	1 day
Chest X-ray (2 view)	up to 0.1 mSv	10 days
Head CT	up to 2 mSv	up to 8 months
Chest CT	up to 3 mSv	up to 12 months
Abdominal CT	up to 5 mSv	up to 20 months

What are the Risks to a Child from Radiation from Dental Radiography?

There is no conclusive evidence that radiation from dental diagnostic x-rays causes cancer. However, major national and international organizations responsible for evaluating radiation risks agree that we should act as if even low doses of radiation may potentially cause harm and should always try to minimize radiation exposure. This is particularly important in children as they are at an approximately 3 to 5 times higher radiation-induced cancer mortality risk than adults. This is because their developing tissues are inherently more radiosensitive and because they have more remaining years of life during which a radiation-induced cancer could develop.

It is estimated that approximately 1 in 1,000 individuals will develop cancer from an exposure of 10 mSv. Therefore a relative radiation level (RRL) can be provided when considering the risk for a single x-ray exposure or a course of treatment involving multiple images.

Table 2. Relative radiation level (RRL) designations for children and adults (after ACR)

Relative Radiation Level	***Effective Dose Estimate Range (mSv)***	
	Adult	***Child***
None	0	0
Minimal	< .1	< .03
Low	.1 – 1	.03 - .3
Medium	1 – 10	.3 – 3.0

Despite several limitations of estimating radiation dose risk, comparison of the radiation Effective Dose from various dental Imaging Procedures (Table 1) to the RRL (Table 2) shows that for children all dental radiographic procedures have minimal risk. For CBCT the risk can vary from low to medium depending on the scanner used.

How can Radiation Risk to a Child be Minimized?

The Image Gently Campaign provides guidance to dental practitioners to minimize radiation exposure to children. These involve numerous strategies and include:

- Only perform imaging when there is a clear medical or dental benefit to the child.
- Use the lowest amount of radiation for adequate imaging based on the size of the child.
- Only take images on the indicated area and always using the thyroid collar
- Avoid multiple unnecessary images.
- Use alternative diagnostic studies (such as ultrasound or MRI), if possible.

If a child's dentist requests a dental image should the parent allow it to be done?

As with any dental procedure, the benefit of the procedure should always outweigh the risk. Dental images can improve diagnoses and dental care. Dental images can help determine the best treatment option, avoid other tests or surgery, and improve health outcome. With any dental imaging procedure, it is appropriate to ask that appropriate low dose techniques be used to minimize radiation exposure.

How can I be sure that the imaging facility or dental office is using appropriate radiation reduction techniques?

The dentist or his/her staff should be able to provide information about how radiation dose is minimized in their specific facility. If requested, they should be able to provide information about the facility's accreditation by the state's radiation safety office (or equivalent) or board of dentistry.

Are there alternatives to CBCT?

For many years prior to the use of CBCT, conventional dental techniques provided images that in many cases were adequate for diagnoses of most dental conditions. CBCT is not a replacement for conventional dental techniques and should be used to provide additional information that would be necessary to choose appropriate treatments. While ultrasound and magnetic resonance imaging (MRI) are imaging techniques that do not use radiation, there are few situations in childrens' dentistry where these would be appropriate alternatives to CBCT. MRI usually takes a long time (compared with CBCT) and because of this, children may require sedation, which involves risk. The dentist should be asked whether or not alternative examinations would be appropriate.

If no abnormality is detected with a dental image does this mean the image was unnecessary?

Dental x-ray images should be considered only after a thorough clinical examination of the child. Dental images are taken either to confirm a clinical suspicion of a certain condition or to eliminate it from further consideration. In the latter case the dental image does not provide a positive result but is of value in that it may avoid additional tests or procedures.

Whom should I contact if I have further concerns regarding radiation exposure?

The clinician who originally ordered or performed the x-ray examination on your child should always be the first person you should approach with any questions regarding the procedure. If this individual is unable to answer satisfactorily your questions, you can request that your dentist consult with an oral and maxillofacial radiologist, or you can ask to be referred to one. Oral and maxillofacial radiologists are specialist dentists who have received additional training (beyond dental school) and expertise in dental radiography.

Image Gently

The information contained in this publication is provided through *Image Gently*, the educational and awareness campaign created by the Alliance for Radiation Safety in Pediatric Imaging, formed in July 2007. It is a coalition of healthcare organizations dedicated to providing safe, high quality pediatric imaging nationwide. The Society for Pediatric Radiology as well as over 33 other societies (including the American Academy of Oral and Maxillofacial Radiology) are members of this coalition representing more than 500,000 health care professionals in radiology, dentistry, pediatrics, medical physics, and radiation safety.

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Policy on Patient Safety

Originating Council
Council on Clinical Affairs

Review Council
Council on Clinical Affairs

Adopted
2008s

Revised
2013

Purpose
The American Academy of Pediatric Dentistry (**AAPD**) recognizes patient safety as an essential component of quality oral health care for infants, children, adolescents, and those with special health care needs. The AAPD encourages dentists to consider thoughtfully the environment in which they deliver health care services and to implement practices that decrease a patient's risk of injury or harm during the delivery of care. This policy is not intended to duplicate safety recommendations for medical facilities accredited by national commissions such as the Joint Commission on Accreditation of Healthcare Organizations or those related to workplace safety such as Occupational Safety & Health Administration.

Methods
This policy is based on a review of current dental and medical literature, including a systematic literature search of the MEDLINE/PubMed® electronic data base using the following parameters: Terms: patient safety AND dentistry, Fields: all; Limits: within the last 10 years, humans, English. Ten articles matched these criteria. Papers for review were chosen from this list and from the references within selected articles.

Background
All health care systems should be designed to promote patient health and protection. Dental practices must be in compliance with federal laws that help protect patients from misuse of personal information [eg, Health Insurance Portability and Accountability Act (**HIPAA**)][1-4] and potential dangers such as the transmission of disease. State and local laws help regulate potential chemical and environmental (eg, radiation) hazards and facilities (eg, fire prevention systems, emergency exits). Furthermore, state dental practice acts are intended to regulate the competency of and provision of services by dental health professionals.

Designing health care systems that focus on preventing errors and being more efficient and patient-family centered is critical to assuring patient safety.[5,6] Some possible sources of error in the dental office are miscommunication, failure to review the patient's medical history (eg, current drugs and medications), and lack of standardized records, abbreviations, and processes.[5] Standardization helps assure clerical and clinical personnel execute their responsibilities in a safe and effective manner. Policy and procedure manuals that describe each facility's established protocols serve as a valuable training tool for new employees and reinforce a consistent approach for safe, quality patient care. Identifying deviations from such protocols and studying patterns of occurrence can help reduce the likelihood of adverse events.[7] Reducing clinical errors requires a careful examination of adverse events, including 'near misses', and root cause analysis of how the event could be avoided in the future so that safety practices can be implemented. Safety demands a culture in which communication does not depend on hierarchy; a non-punitive or 'no blame' culture encourages all personnel to report errors.[6,8]

The environment in which dental care is delivered impacts patient safety. In addition to structural issues regulated by state and local laws, other design features should be planned and periodically evaluated for patient safety, especially as they apply to young children. Play structures, games, and toys are possible sources for accidents and infection.

Scientific knowledge and technology continually advance, and patterns of care evolve due, in part, to recommendations by organizations with recognized professional expertise and stature. Some recommendations can be based only on suggestive evidence or theoretical rationale (eg, infection control); other concerns of clinical practice remain in flux (eg, materials utilized in restorative dentistry). Consequently, the dental patient would benefit from a practitioner who follows current literature and participates in professional continuing education courses to increase awareness and knowledge of best current practices.

The AAPD emphasizes safe, age-appropriate, nonpharmacological or pharmacological behavior guidance techniques for use with pediatric dental patients. It is important to base behavior guidance on each patient's individual needs with goals of fostering a positive dental attitude, safety, and providing quality dental care.[9] Appropriate diagnosis of behavior and safe and effective implementation of advanced behavior guidance techniques (ie, protective stabilization, sedation, general

anesthesia) necessitate knowledge and experience that generally are beyond the core knowledge that students receive during predoctoral education.[9,10]

Policy statement

To promote patient health and protection, the AAPD encourages:

1. Patient safety instruction in dental curricula to promote safe, patient-centered care.[11]
2. Professional continuing education by all licensed dental professionals to maintain familiarity with current regulations, technology, and clinical practices.
3. Compliance with federal laws such as HIPAA to protect patients against misuse of information identifiable to them.[1]
4. Compliance and recognition of the importance of infection control policies, procedures, and practices in dental health care settings in order to prevent disease transmission from patient to care provider, from care provider to patient, and from patient to patient.[2-4]
5. Routine inspection of physical facility in regards to patient safety. This would include development of office emergency and fire safety protocols and routine inspection and maintenance of clinical equipment.
6. Recognition that informed consent by the parent is essential in the delivery of health care and effective relationship/communication practices can help avoid problems and adverse events.[12] The parent should be encouraged to be an active participant in the child's care.
7. Accuracy of patient identification with the use of at least two patient identifiers, such as name and date of birth, when providing care, treatment, or services.[5]
8. An accurate and complete patient chart that can be interpreted by a knowledgeable third party.[13] Standardizing abbreviations, acronyms, and symbols throughout the record is recommended.
9. An accurate, comprehensive, and up-to-date medical/dental history including medications and allergy list to ensure patient safety during each visit.[13] Ongoing communication with health care providers, both medical and dental, who manage the child's health helps ensure comprehensive, coordinated care of each patient.
10. A pause before an invasive procedure to confirm the patient, planned procedure(s), and tooth/surgical site(s) are correct.
11. Appropriate staffing and supervision of patients treated in the dental office.
12. Adherence to AAPD recommendations on behavior guidance, especially as they pertain to use of advanced behavior guidance techniques (ie, protective stabilization, sedation, general anesthesia).[9,10]
13. Standardization and consistency of processes within the practice. A policies and procedures manual, with ongoing review and revision, could help increase employee awareness and decrease the likelihood of untoward events. Dentists should emphasize procedural protocols that protect the patient's airway (eg, rubber dam isolation)[14] and minimize opportunity for injury during delivery of care (eg, protective eyewear).
14. Minimizing exposure to nitrous oxide by maintaining the lowest practical levels in the dental environment. This would include routine inspection and maintenance of nitrous oxide delivery equipment as well as adherence to clinical guidelines for patient selection and delivery of inhalation agents.[15]
15. Minimizing radiation exposure through adherence to ALARA (as low as reasonably achievable) principle, equipment inspection and maintenance, and patient selection criteria.[16]
16. All facilities performing sedation for diagnostic and therapeutic procedures to maintain records that track adverse events. Such events then can be examined for assessment of risk reduction and improvement in patient safety.[17]
17. Dentists who utilize in-office anesthesia care providers take all necessary measures to minimize risk to patients. Prior to delivery of sedation/general anesthesia, appropriate documentation shall address rationale for sedation/general anesthesia, informed consent, instructions to parent, dietary precautions, preoperative health evaluation, and any prescriptions along with the instructions given for their use. The dentist and anesthesia care provider must communicate during treatment to share concerns about the airway or other details of patient safety.[18]
18. Ongoing quality improvement strategies. Routine assessment of risk, adverse events, and mistakes with a plan for reduction and improvement in patient safety and satisfaction is imperative for such strategies.[5,6]

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Attachment 8

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Guideline on Prescribing Dental Radiographs for Infants, Children, Adolescents, and Persons with Special Health Care Needs

Originating Committee
Ad Hoc Committee on Pedodontic Radiology

Review Council
Council on Clinical Affairs

Adopted
1981

Revised
1992, 1995, 2001, 2005, 2009

Reaffirmed
1997, 2012

Purpose

The American Academy of Pediatric Dentistry (**AAPD**) intends this guideline to help practitioners make clinical decisions concerning appropriate selection of dental radiographs as part of an oral evaluation of infants, children, adolescents, and persons with special health care needs. The guideline can be used to optimize patient care, minimize radiation burden, and allocate health care resources responsibly.

Methods

The American Dental Association (**ADA**) initiated a review of "The Selection of Patients for X-ray Examinations: Dental Radiographic Examinations"[1] in 2002. The AAPD, along with other dental specialty organizations, participated in the review and revision of these guidelines. The Food and Drug Administration (**FDA**) accepted them in November 2004.[2] This review included a new systematic literature search of the MEDLINE/PubMed® electronic database using the following parameters: Terms: "dental radiology", "dental radiographs", "dental radiography", "cone beam computed tomography" AND "guidelines", "recommendations"; Fields: all; Limits: within the last 10 years, humans, and English. In 2006, the ADA Council on Scientific Affairs published an update to their recommendations for dental radiographs.[3] The AAPD continues to endorse the ADA/FDA's recommendations.

Background

Radiographs are valuable aids in the oral health care of infants, children, adolescents, and persons with special health care needs. They are used to diagnose oral diseases and to monitor dentofacial development and the progress of therapy. The recommendations in the ADA/FDA guidelines were developed to serve as an adjunct to the dentist's professional judgment. The timing of the initial radiographic examination should not be based upon the patient's age, but upon each child's individual circumstances. Because each patient is unique, the need for dental radiographs can be determined only after reviewing the patient's medical and dental histories, completing a clinical examination, and assessing the patient's vulnerability to environmental factors that affect oral health.

Radiographs should be taken only when there is an expectation that the diagnostic yield will affect patient care. The AAPD recognizes that there may be clinical circumstances for which a radiograph is indicated, but a diagnostic image cannot be obtained. For example, the patient may be unable to cooperate or the dentist may have privileges in a health care facility lacking intraoral radiographic capabilities. If radiographs of diagnostic quality are unobtainable, the dentist should confer with the parent to determine appropriate management techniques (eg, preventive/restorative interventions, advanced behavior guidance modalities, deferral, referral), giving consideration to the relative risks and benefits of the various treatment options for the patient.

Because the effects of radiation exposure accumulate over time, every effort must be made to minimize the patient's exposure. Good radiological practices (eg, use of lead apron, thyroid collars, and high-speed film; beam collimation) are important. The dentist must weigh the benefits of obtaining radiographs against the patient's risk of radiation exposure.

New imaging technologies [ie, cone beam computed tomography (**CBCT**)] have added three-dimensional capabilities that have many applications in dentistry. Evidence-based guidelines and policies currently are under development by organizations such as the American Academy of Oral and Maxillofacial Radiology (**AAOMR**).[4] The usefulness and future of CBCT have been reviewed with an introduction to issues

Guidelines for Prescribing Dental Radiographs

	Patient Age and Dental Developmental Stage				
Type of Encounter	**Child with Primary Dentition** (prior to eruption of first permanent tooth)	**Child with Transitional Dentition** (after eruption of first permanent tooth)	**Adolescent with Permanent Dentition** (prior to eruption of third molars)	**Adult, Dentate or Partially Edentulous**	**Adult, Edentulous**
New patient* being evaluated for dental diseases and dental development	Individualized radiographic exam consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be visualized or probed. Patients without evidence of disease and with open proximal contacts may not require a radiographic exam at this time.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images. A full mouth intraoral radiographic exam is preferred when the patient has clinical evidence of generalized dental disease or a history of extensive dental treatment.		Individualized radiographic exam, based on clinical signs and symptoms.
Recall patient* with clinical caries or at increased risk for caries**	Posterior bitewing exam at 6-12 month intervals if proximal surfaces cannot be examined visually or with a probe.			Posterior bitewing exam at 6-18 month intervals.	Not applicable
Recall patient* with no clinical caries and not at increased risk for caries**	Posterior bitewing exam at 12-24 month intervals if proximal surfaces cannot be examined visually or with a probe.		Posterior bitewing exam at 18-36 month intervals.	Posterior bitewing exam at 24-36 month intervals.	Not applicable
Recall patient* with periodontal disease	Clinical judgment as to the need for and type of radiographic images for the evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be identified clinically.				Not applicable
Patient for monitoring of growth and development	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development.		Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development. Panoramic or periapical exam to assess developing third molars.	Usually not indicated	
Patient with other circumstances including, but not limited to, proposed or existing implants, pathology, restorative/endodontic needs, treated periodontal disease and caries remineralization	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring in these circumstances.				

*** Clinical situations for which radiographs may be indicated include but are not limited to:**

A. Positive Historical Findings

1. Previous periodontal or endodontic treatment
2. History of pain or trauma
3. Familial history of dental anomalies
4. Postoperative evaluation of healing
5. Remineralization monitoring
6. Presence of implants or evaluation for implant placement

B. Positive Clinical Signs/Symptoms

1. Clinical evidence of periodontal disease
2. Large or deep restorations
3. Deep carious lesions
4. Malposed or clinically impacted teeth
5. Swelling
6. Evidence of dental/facial trauma
7. Mobility of teeth
8. Sinus tract ("fistula")
9. Clinically suspected sinus pathology
10. Growth abnormalities
11. Oral involvement in known or suspected systemic disease
12. Positive neurologic findings in the head and neck
13. Evidence of foreign objects
14. Pain and/or dysfunction of the temporomandibular joint
15. Facial asymmetry
16. Abutment teeth for fixed or removable partial prosthesis
17. Unexplained bleeding
18. Unexplained sensitivity of teeth
19. Unusual eruption, spacing or migration of teeth
20. Unusual tooth morphology, calcification or color
21. Unexplained absence of teeth
22. Clinical erosion

**** Factors increasing risk for caries may include but are not limited to:**

1. High level of caries experience or demineralization
2. History of recurrent caries
3. High titers of cariogenic bacteria
4. Existing restoration(s) of poor quality
5. Poor oral hygiene
6. Inadequate fluoride exposure
7. Prolonged nursing (bottle or breast)
8. Frequent high sucrose content in diet
9. Poor family dental health
10. Developmental or acquired enamel defects
11. Developmental or acquired disability
12. Xerostomia
13. Genetic abnormality of teeth
14. Many multisurface restorations
15. Chemo/radiation therapy
16. Eating disorders
17. Drug/alcohol abuse
18. Irregular dental care

*** From: American Dental Association, US Food & Drug Administration. The Selection of Patients for Dental Radiograph Examinations. Available at: "http://www.ada.org/sections/advocacy/pdfs/topics_radiography_examinations(1).pdf".**

Attachment 8

related to criteria, ramifications, and medico-legal considerations.[5] Certain principles clearly are emerging and point to the need for standards of provisions of care. Because this technology has potential to produce vast amounts of data and imaging information beyond initial intentions, it is important to interpret all information obtained, including that which may be beyond the immediate diagnostic needs of the practitioner.

Recommendations

The recommendations of the ADA/FDA guidelines are contained within the accompanying table. "The recommendations in this chart are subject to clinical judgment and may not apply to every patient. They are to be used by dentists only after reviewing the patient's health history and completing a clinical examination. Because every precaution should be taken to minimize radiation exposure, protective thyroid collars and aprons should be used whenever possible. This practice is strongly recommended for children, women of childbearing age, and pregnant women."[2]

Although standards are not officially developed for the use of CBCT, this advance in orofacial dental imaging is an excellent adjunct for improvements in dental care. The executive opinion statement of the AAOMR provides initial guidance for the use of this technology.[4] Their recommendations relate to the need for practices of qualified individuals to use this technology with selection criteria which include clear indications that minimize radiation exposure while maximizing diagnostic information obtained. When using CBCT, the resulting imaging is required to be supplemented with a written report placed in the patient's records that includes full interpretation of the findings.

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DENTAL RADIOGRAPHIC EXAMINATIONS: RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE

REVISED: 2012

AMERICAN DENTAL ASSOCIATION
Council on Scientific Affairs

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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DENTAL RADIOGRAPHIC EXAMINATIONS: RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE

BACKGROUND

The dental profession is committed to delivering the highest quality of care to each of its individual patients and applying advancements in technology and science to continually improve the oral health status of the U.S. population. These guidelines were developed to serve as an adjunct to the dentist's professional judgment of how to best use diagnostic imaging for each patient. Radiographs can help the dental practitioner evaluate and definitively diagnose many oral diseases and conditions. However, the dentist must weigh the benefits of taking dental radiographs against the risk of exposing a patient to x-rays, the effects of which accumulate from multiple sources over time. The dentist, knowing the patient's health history and vulnerability to oral disease, is in the best position to make this judgment in the interest of each patient. For this reason, the guidelines are intended to serve as a resource for the practitioner and are not intended as standards of care, requirements or regulations.

The guidelines are not substitutes for clinical examinations and health histories. The dentist is advised to conduct a clinical examination, consider the patient's signs, symptoms and oral and medical histories, as well as consider the patient's vulnerability to environmental factors that may affect oral health. This diagnostic and evaluative information may determine the type of imaging to be used or the frequency of its use. Dentists should only order radiographs when they expect that the additional diagnostic information will affect patient care.

Based on this premise, the guidelines can be used by the dentist to optimize patient care, minimize radiation exposure and responsibly allocate health care resources.

This document deals only with standard dental imaging techniques of intraoral and common extraoral examinations, excluding cone-beam computed tomography (CBCT). At this time the indications for CBCT examinations are not well developed. The ADA Council on Scientific Affairs has developed a statement on use of CBCT.[1]

INTRODUCTION

The guidelines titled, "The Selection of Patients for X-Ray Examination" were first developed in 1987 by a panel of dental experts convened by the Center for Devices and Radiological Health of the U.S. Food and Drug Administration (FDA). The development of the guidelines at that time was spurred by concern about the U.S. population's total exposure to radiation from all sources. Thus, the guidelines were developed to promote the appropriate use of x-rays. In 2002, the American Dental Association, recognizing that dental technology and science continually advance, recommended to the FDA that

the guidelines be reviewed for possible updating. The FDA welcomed organized dentistry's interest in maintaining the guidelines, and so the American Dental Association, in collaboration with a number of dental specialty organizations and the FDA, published updated guidelines in 2004. This report updates the 2004 guidelines and includes recommendations for limiting exposure to radiation.

PATIENT SELECTION CRITERIA

Radiographs and other imaging modalities are used to diagnose and monitor oral diseases, as well as to monitor dentofacial development and the progress or prognosis of therapy. Radiographic examinations can be performed using digital imaging or conventional film. The available evidence suggests that either is a suitable diagnostic method.[2-4] Digital imaging may offer reduced radiation exposure and the advantage of image analysis that may enhance sensitivity and reduce error introduced by subjective analysis.[5]

A study of 490 patients found that basing selection criteria on clinical evaluations for asymptomatic patients, combined with selected periapical radiographs for symptomatic patients, can result in a 43 percent reduction in the number of radiographs taken without a clinically consequential increase in the rate of undiagnosed disease.[6,7] The development and progress of many oral conditions are associated with a patient's age, stage of dental development, and vulnerability to known risk factors. Therefore, the guidelines in Table 1 are presented within a matrix of common clinical and patient factors, which may determine the type(s) of radiographs that is commonly needed. The guidelines assume that diagnostically adequate radiographs can be obtained. If not, appropriate management techniques should be used after consideration of the relative risks and benefits for the patient.

Along the horizontal axis of the matrix, patient age categories are described, each with its usual dental developmental stage: child with primary dentition (prior to eruption of the first permanent tooth); child with transitional dentition (after eruption of the first permanent tooth); adolescent with permanent dentition (prior to eruption of third molars); adult who is dentate or partially edentulous; and adult who is edentulous.

Along the vertical axis, the type of encounter with the dental system is categorized (as "New Patient" or "Recall Patient") along with the clinical circumstances and oral diseases that may be present during such an encounter. The "New Patient" category refers to patients who are new to the dentist, and thus are being evaluated by the dentist for oral disease and for the status of dental development. Typically, such a patient receives a comprehensive evaluation or, in some cases, a limited evaluation for a specific problem. The "Recall Patient" categories describe patients who have had a recent comprehensive evaluation by the dentist and, typically, have returned as a patient of record for a periodic evaluation or for treatment. However, a "Recall Patient" may also return for a limited evaluation of a specific problem, a detailed and extensive evaluation for a specific problem(s), or a comprehensive evaluation.

Both categories are marked with a single asterisk that corresponds to a footnote that appears below the matrix; the footnote lists "Positive Historical Findings" and "Positive Clinical Signs/Symptoms" for which radiographs may be indicated. The lists are not intended to be all-inclusive, rather they offer the clinician further guidance on clarifying his or her specific judgment on a case.

The clinical circumstances and oral diseases that are presented with the types of encounters include: clinical caries or increased risk for caries; no clinical caries or no increased risk for caries; periodontal disease or a history of periodontal treatment; growth and development assessment; and other circumstances. A few examples of "Other Circumstances" proposed are: existing implants, other dental and craniofacial pathoses, endodontic/restorative needs and remineralization of dental caries. These examples are not intended to be an exhaustive list of circumstances for which radiographs or other imaging may be appropriate.

The categories, "Clinical Caries or Increased Risk for Caries" and "No Clinical Caries and No Increased Risk for Caries" are marked with a double asterisk that corresponds to a footnote that appears below the matrix; the footnote contains links to the ADA Caries Risk Assessment Forms (0 – 6 years of age and over 6 years of age). It should be noted that a patient's risk status can change over time and should be periodically reassessed.[8]

The panel also has made the following recommendations that are applicable to all categories:

1. Intraoral radiography is useful for the evaluation of dentoalveolar trauma. If the area of interest extends beyond the dentoalveolar complex, extraoral imaging may be indicated.
2. Care should be taken to examine all radiographs for any evidence of caries, bone loss from periodontal disease, developmental anomalies and occult disease.
3. Radiographic screening for the purpose of detecting disease before clinical examination should not be performed. A thorough clinical examination, consideration of the patient history, review of any prior radiographs, caries risk assessment and consideration of both the dental and the general health needs of the patient should precede radiographic examination.[9-15]

In the practice of dentistry, patients often seek care on a routine basis in part because oral disease may develop in the absence of clinical symptoms. Since attempts to identify specific criteria that will accurately predict a high probability of finding interproximal carious lesions have not been successful for individuals, it was necessary to recommend time-based schedules for making radiographs intended primarily for the detection of dental caries. Each schedule provides a range of recommended intervals that are derived from the results of research into the rates at which interproximal caries progresses through tooth enamel. The recommendations also are modified by criteria that place an individual at an increased risk for dental caries. Professional judgment

should be used to determine the optimum time for radiographic examination within the suggested interval.

RECOMMENDATIONS FOR PRESCRIBING DENTAL RADIOGRAPHS

These recommendations are subject to clinical judgment and may not apply to every patient. They are to be used by dentists only after reviewing the patient's health history and completing a clinical examination. Even though radiation exposure from dental radiographs is low, once a decision to obtain radiographs is made it is the dentist's responsibility to follow the ALARA Principle (As Low as Reasonably Achievable) to minimize the patient's exposure.

Table 1.

TYPE OF ENCOUNTER	PATIENT AGE AND DENTAL DEVELOPMENTAL STAGE				
	Child with Primary Dentition (prior to eruption of first permanent tooth)	**Child with Transitional Dentition** (after eruption of first permanent tooth)	**Adolescent with Permanent Dentition** (prior to eruption of third molars)	**Adult, Dentate or Partially Edentulous**	**Adult, Edentulous**
New Patient* being evaluated for oral diseases	Individualized radiographic exam consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be visualized or probed. Patients without evidence of disease and with open proximal contacts may not require a radiographic exam at this time.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images. A full mouth intraoral radiographic exam is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.		Individualized radiographic exam, based on clinical signs and symptoms.
Recall Patient* with clinical caries or at increased risk for caries**	Posterior bitewing exam at 6-12 month intervals if proximal surfaces cannot be examined visually or with a probe			Posterior bitewing exam at 6-18 month intervals	Not applicable
Recall Patient* with no clinical caries and not at increased risk for caries**	Posterior bitewing exam at 12-24 month intervals if proximal surfaces cannot be examined visually or with a probe		Posterior bitewing exam at 18-36 month intervals	Posterior bitewing exam at 24-36 month intervals	Not applicable

TYPE OF ENCOUNTER (continued)	**Child with Primary Dentition** (prior to eruption of first permanent tooth)	**Child with Transitional Dentition** (after eruption of first permanent tooth)	**Adolescent with Permanent Dentition** (prior to eruption of third molars)	**Adult, Dentate and Partially Edentulous**	**Adult, Edentulous**
Recall Patient* with periodontal disease	Clinical judgment as to the need for and type of radiographic images for the evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be demonstrated clinically.				Not applicable
Patient (New and Recall) for monitoring of dentofacial growth and development, and/or assessment of dental/skeletal relationships	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development or assessment of dental and skeletal relationships		Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships. Panoramic or periapical exam to assess developing third molars	Usually not indicated for monitoring of growth and development. Clinical judgment as to the need for and type of radiographic image for evaluation of dental and skeletal relationships.	
Patient with other circumstances including, but not limited to, proposed or existing implants, other dental and craniofacial pathoses, restorative/endodontic needs, treated periodontal disease and caries remineralization	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of these conditions				

***Clinical situations for which radiographs may be indicated include, but are not limited to:**

A. Positive Historical Findings

1. Previous periodontal or endodontic treatment
2. History of pain or trauma
3. Familial history of dental anomalies

4. Postoperative evaluation of healing
5. Remineralization monitoring
6. Presence of implants, previous implant-related pathosis or evaluation for implant placement

B. Positive Clinical Signs/Symptoms

1. Clinical evidence of periodontal disease
2. Large or deep restorations
3. Deep carious lesions
4. Malposed or clinically impacted teeth
5. Swelling
6. Evidence of dental/facial trauma
7. Mobility of teeth
8. Sinus tract ("fistula")
9. Clinically suspected sinus pathosis
10. Growth abnormalities
11. Oral involvement in known or suspected systemic disease
12. Positive neurologic findings in the head and neck
13. Evidence of foreign objects
14. Pain and/or dysfunction of the temporomandibular joint
15. Facial asymmetry
16. Abutment teeth for fixed or removable partial prosthesis
17. Unexplained bleeding
18. Unexplained sensitivity of teeth
19. Unusual eruption, spacing or migration of teeth
20. Unusual tooth morphology, calcification or color
21. Unexplained absence of teeth
22. Clinical tooth erosion
23. Peri-implantitis

∗∗Factors increasing risk for caries may be assessed using the ADA Caries Risk Assessment forms (0 – 6 years of age and over 6 years of age).

EXPLANATION OF RECOMMENDATIONS FOR PRESCRIBING DENTAL RADIOGRAPHS

The explanation below presents the rationale for each recommendation by type of encounter and patient age and dental developmental stages.

New Patient Being Evaluated for Oral Diseases

Child (Primary Dentition)
Proximal carious lesions may develop after the interproximal spaces between posterior primary teeth close. Open contacts in the primary dentition will allow a dentist to visually inspect the proximal posterior surfaces. Closure of proximal contacts requires radiographic assessment.[16-18] However, evidence suggests that many of these lesions will remain in the enamel for at least 12 months or longer depending on fluoride exposure, allowing sufficient time for implementation and evaluation of preventive interventions.[19-21] A periapical/anterior occlusal examination may be indicated because of the need to evaluate dental development, dentoalveolar trauma, or suspected pathoses. Periapical and bitewing radiographs may be required to evaluate pulp pathosis in primary molars.

Therefore, an individualized radiographic examination consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be examined visually or with a probe is recommended. Patients without evidence of disease and with open proximal contacts may not require radiographic examination at this time.

Child (Transitional Dentition)
Overall dental caries in the primary teeth of children from 2-11 years of age declined from the early 1970s until the mid 1990s.[22-24] From the mid 1990s until the 1999-2004 National Health and Nutrition Examination Survey, there was a small but significant increase in primary decay. This trend reversal was larger for younger children. Tooth decay affects more than one-fourth of U.S. children aged 2–5 years and half of those aged 12-15 years; however, its prevalence is not uniformly distributed. About half of all children and two-thirds of adolescents aged 12–19 years from lower-income families have had decay.[25]

Children and adolescents of some racial and ethnic groups and those from lower-income families have more untreated tooth decay. For example, 40 percent of Mexican American children aged 6–8 years have untreated decay, compared with 25 percent of non-Hispanic whites.[25] It is, therefore, important to consider a child's risk factors for caries before taking radiographs.

Although periodontal disease is uncommon in this age group,[26] when clinical evidence exists (except for nonspecific gingivitis), selected periapical and bitewing radiographs are indicated to determine the extent of aggressive periodontitis, other forms of uncontrolled periodontal disease and the extent of osseous destruction related to metabolic diseases.[27,28]

A periapical or panoramic examination is useful for evaluating dental development. A panoramic radiograph also is useful for the evaluation of craniofacial trauma.[15,29,30] Intraoral radiographs are more accurate than panoramic radiographs for the evaluation of dentoalveolar

trauma, root shape, root resorption[31,32] and pulp pathosis. However, panoramic examinations may have the advantage of reduced radiation dose, cost and imaging of a larger area.

Occlusal radiographs may be used separately or in combination with panoramic radiographs in the following situations: 1. unsatisfactory image in panoramic radiographs due to abnormal incisor relationship, 2. localizations of tooth position, and 3. when clinical grounds provide a reasonable expectation that pathosis exists.[32-34]

Therefore, an individualized radiographic examination consisting of posterior bitewings with panoramic examination or posterior bitewings and selected periapical images is recommended.

Adolescent (Permanent Dentition)
Caries in permanent teeth declined among adolescents, while the prevalence of dental sealants increased significantly.[35] However, increasing independence and socialization, changing dietary patterns, and decreasing attention to daily oral hygiene can characterize this age group. Each of these factors may result in an increased risk of dental caries. Another consideration, although uncommon, is the increased incidence of periodontal disease found in this age group compared to children.[36]

Panoramic radiography is effective in dental diagnosis and treatment planning.[30,37,38] Specifically, the status of dental development can be assessed using panoramic radiography.[39] Occlusal and/or periapical radiographs can be used to detect the position of an unerupted or supernumerary tooth.[40-42] Third molars also should be evaluated in this age group for their presence, position, and stage of development.

Therefore, an individualized radiographic examination consisting of posterior bitewings with panoramic examination or posterior bitewings and selected periapical images is recommended. A full mouth intraoral radiographic examination is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.

Adult (Dentate or Partially Edentulous)
The overall dental caries experience of the adult population has declined from the early 1970s until the most recent (1999-2004) National Health and Nutrition Examination Survey.[43] However, risk for dental caries exists on a continuum and changes over time as risk factors change.[44] Therefore, it is important to evaluate proximal surfaces in the new adult patient for carious lesions. In addition, it is important to examine patients for recurrent dental caries.

The incidence of root surface caries increases with age.[45] Although bitewing radiographs can assist in detecting root surface caries in proximal areas, the usual method of detecting root surface caries is by clinical examination.[46]

The incidence of periodontal disease increases with age.[47] Although new adult patients may not have symptoms of active periodontal disease, it is important to evaluate previous experience with periodontal disease and/or treatment. Therefore, a high percentage of adults may require selected intraoral radiographs to determine the current status of the disease.

Taking posterior bitewing radiographs of new adult patients was found to reduce the number of radiological findings and the diagnostic yield of panoramic radiography.[48,49] In addition, the following clinical indicators for panoramic radiography were identified as the best predictors for useful diagnostic yield: suspicion of teeth with periapical pathologic conditions, presence of partially erupted teeth, caries lesions, swelling, and suspected unerupted teeth.[50]

Therefore, an individualized radiographic examination, consisting of posterior bitewings with selected periapical images or panoramic examination when indicated is recommended. A full mouth intraoral radiographic examination is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.

Adult (Edentulous)

The clinical and radiographic examinations of edentulous patients generally occur during an assessment of the need for prostheses. The most common pathological conditions detected are impacted teeth and retained roots with and without associated disease.[51] Other less common conditions also may be detected: bony spicules along the alveolar ridge, residual cysts or infections, developmental abnormalities of the jaws, intraosseous tumors, and systemic conditions affecting bone metabolism.

The original recommendations for this group called for a full-mouth intraoral radiographic examination or a panoramic examination for the new, edentulous adult patient. Firstly, this recommendation was made because examinations of edentulous patients generally occur during an assessment of the need for prostheses. Secondly, the original recommendation considered edentulous patients to be at increased risk for oral disease.

Studies have found that from 30 to 50 percent of edentulous patients exhibited abnormalities in panoramic radiographs.[51-55] In addition, the radiographic examination revealed anatomic considerations that could influence prosthetic treatment, such as the location of the mandibular canal, the position of the mental foramen and maxillary sinus, and relative thickness of the soft tissue covering the edentulous ridge.[51,53,55] However, in studies that considered treatment outcomes, there was little evidence to support screening radiography for new edentulous patients. For example, one study reported that less than 4 percent of such findings resulted in treatment modification before denture fabrication, and another showed no difference in post-denture delivery complaints in patients who did not receive screening pretreatment radiographs.[54,56]

This panel concluded that prescription of radiographs is appropriate as part of the initial assessment of edentulous areas for possible prosthetic treatment. A full mouth series of periapical radiographs or a combination of panoramic, occlusal or other extraoral radiographs may be used to achieve diagnostic and therapeutic goals. Particularly with the option of dental implant therapy for edentulous patients,[57] radiographs can be an important aid in diagnosis, prognosis, and the determination of treatment complexity.

Therefore, an individualized radiographic examination, based on clinical signs, symptoms, and treatment plan is recommended.

Recall Patient with Clinical Caries or Increased Risk for Caries

Child (Primary and Transitional Dentition) and Adolescent (Permanent Dentition)
Clinically detectable dental caries may suggest the presence of proximal carious lesions that can only be detected with a radiographic examination. In addition, patients who are at increased risk for developing dental caries because of such factors as poor oral hygiene, high frequency of exposure to sucrose-containing foods, and deficient fluoride intake (see caries risk assessment forms, 0 – 6 years of age and over 6 years of age) are more likely to have proximal carious lesions.

The bitewing examination is the most efficient method for detecting proximal lesions.[16,18,58] The frequency of radiographic recall should be determined on the basis of caries risk assessment.[15,59,60] It should be noted that a patient's caries risk status may change over time and that an individual's radiographic recall interval may need to be changed accordingly.[61]

Therefore, a posterior bitewing examination is recommended at 6 to 12 month intervals if proximal surfaces cannot be examined visually or with a probe.

Adult (Dentate and Partially Edentulous)
Adults who exhibit clinical dental caries or who have other increased risk factors should be monitored carefully for any new or recurrent lesions that are detectable only by radiographic examination. The frequency of radiographic recall should be determined on the basis of caries risk assessment.[15,59,60] It should be noted that a patient's risk status can change over time and that an individual's radiographic recall interval may need to be changed accordingly.[61]

Therefore, a posterior bitewing examination is recommended at 6 to 18 month intervals.

Recall Patient (Edentulous Adult)

A study that assessed radiographs of edentulous recall patients showed that previously detected incidental findings did not progress and that no intervention was indicated.[62] The data suggest that patients who receive continuous dental care do not exhibit new findings that require treatment.

An examination for occult disease in this group cannot be justified on the basis of prevalence, morbidity, mortality, radiation dose, and cost.[53-55]

Therefore, no radiographic examination is recommended without evidence of disease.

Recall Patient with No Clinical Caries and No Increased Risk for Caries

Child (Primary and Transitional Dentition)
Despite the general decline in dental caries activity, recent data show that subgroups of children have a higher caries experience than the overall population.[63,64] The identification of

patients in these subgroups may be difficult on an individual basis. For children who present for recall examination without evidence of clinical caries and who are not considered at increased risk for the development of caries, it remains important to evaluate proximal surfaces by radiographic examination. In primary teeth the caries process can take approximately one year to progress through the outer half of the enamel and about another year through the inner half.[20,65-68] Considering this rate of progression of carious lesions through primary teeth, a time-based interval of radiographic examinations from one to two years for this group appears appropriate. The prevalence of carious lesions has been shown to increase during the stage of transitional dentition.[25,69] Children under routine professional care would be expected to be at a lower risk for caries. Nevertheless, newly erupted teeth are at risk for the development of dental caries.

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 12 to 24 months if proximal surfaces cannot be examined visually or with a probe.

Adolescent (Permanent Dentition)
Adolescents with permanent dentition, who are free of clinical dental caries and factors that would place them at increased risk for developing dental caries, should be monitored carefully for development of proximal carious lesions, which may only be detected by radiographic examination. The caries process, on average, takes more than three years to progress through the enamel.[20,65-68] However, evidence suggests that the enamel of permanent teeth undergoes posteruptive maturation and that young permanent teeth are susceptible to faster progression of carious lesions.[70-73]

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 18 to 36 months.

Adult (Dentate and Partially Edentulous)
Adult dentate patients, who receive regularly scheduled professional care and are free of signs and symptoms of oral disease, are at a low risk for dental caries. Nevertheless, consideration should be given to the fact that caries risk can vary over time as risk factors change. Advancing age and changes in diet, medical history and periodontal status may increase the risk for dental caries.

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 24 to 36 months.

<u>Recall Patient with Periodontal Disease</u>

Child (Primary and Transitional Dentition), Adolescent (Permanent Dentition), and Adult (Dentate and Partially Edentulous)
The decision to obtain radiographs for patients who have clinical evidence or a history of periodontal disease/treatment should be determined on the basis of the anticipation that important diagnostic and prognostic information will result. Structures or conditions to be assessed should include the level of supporting alveolar bone, condition of the interproximal bony crest, length and shape of roots, bone loss in furcations, and calculus deposits. The

frequency and type of radiographic examinations for these patients should be determined on the basis of a clinical examination of the periodontium and documented signs and symptoms of periodontal disease. The procedure for prescribing radiographs for the follow-up/recall periodontal patient would be to use selected intraoral radiographs to verify clinical findings on a patient-by-patient basis.[28,74]

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be identified clinically.

Patient (New and Recall) for Monitoring of Dentofacial Growth and Development, and/or Assessment of Dental/Skeletal Relationships

Child (Primary and Transitional Dentition)
For children with primary dentition, before the eruption of the first permanent tooth, radiographic examination to assess growth and development in the absence of clinical signs or symptoms is unlikely to yield productive information. Any abnormality of growth and development suggested by clinical findings should be evaluated radiographically on an individual basis. After eruption of the first permanent tooth, the child may have a radiographic examination to assess growth and development. This examination need not be repeated unless dictated by clinical signs or symptoms. Cephalometric radiographs may be useful for assessing growth, and/or dental and skeletal relationships.

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships.

Adolescent (Permanent Dentition)
During adolescence there is often a need to assess the growth status and/or the dental and skeletal relationships of patients in order to diagnose and treat their malocclusion. Appropriate radiographic assessment of the malocclusion should be determined on an individual basis.

An additional concern relating to growth and development for patients in this age group is to determine the presence, position and development of third molars. This determination can best be made by the use of selected periapical images or a panoramic examination, once the patient is in late adolescence (16 to 19 years of age).

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships. Panoramic or periapical examination may be used to assess developing third molars.

Adult (Dentate, Partially Edentulous and Edentulous)
In the absence of any clinical signs or symptoms suggesting abnormalities of growth and development in adults, no radiographic examinations are indicated for this purpose.

Therefore, in the absence of clinical signs and symptoms, no radiographic examination is recommended.

Patients with Other Circumstances
(including, but not limited to, proposed or existing implants, other dental and craniofacial pathoses, restorative/endodontic needs, treated periodontal disease and caries remineralization)

All Patient Categories
The use of imaging, as a diagnostic and evaluative tool, has progressed beyond the longstanding need to diagnose caries and evaluate the status of periodontal disease. The expanded technology in imaging is now used to diagnose other orofacial clinical conditions and evaluate treatment options. A few examples of other clinical circumstances are the use of imaging for dental implant treatment planning, placement, or evaluation; the monitoring of dental caries and remineralization; the assessment of restorative and endodontic needs; and the diagnosis of soft and hard tissue pathoses.

Therefore it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring in these circumstances.

LIMITING RADIATION EXPOSURE

Dental radiographs account for approximately 2.5 percent of the effective dose received from medical radiographs and fluoroscopies.[75] Even though radiation exposure from dental radiographs is low, once a decision to obtain radiographs is made it is the dentist's responsibility to follow the ALARA Principle (As Low as Reasonably Achievable) to minimize the patient's exposure. Examples of good radiologic practice include

- use of the fastest image receptor compatible with the diagnostic task (F-speed film or digital);
- collimation of the beam to the size of the receptor whenever feasible;
- proper film exposure and processing techniques;
- use of protective aprons and thyroid collars, when appropriate; and
- limiting the number of images obtained to the minimum necessary to obtain essential diagnostic information.

RECEPTOR SELECTION
The American National Standards Institute and the International Organization for Standardization have established standards for film speed.[76,77] Film speeds available for dental radiography are D-speed, E-speed and F-speed, with D-speed being the slowest and F-speed the fastest. According to the U.S. Food and Drug Administration, switching from D to E speed can produce a 30 to 40 percent reduction in radiation exposure.[78] The use of F-speed film can reduce exposure 20 to 50 percent compared to use of E-speed film, without compromising diagnostic quality.[79-85]

Exposure of extraoral films such as panoramic radiographs requires intensifying screens to minimize radiation exposure to patients. The intensifying screen consists of layers of phosphor crystals that fluoresce when exposed to radiation. In addition to the radiation incident on the film, the film is exposed primarily to the light emitted from the intensifying screen. Previous generations of intensifying screens were composed of phosphors such as calcium tungstate. However, rare-earth intensifying screens are recommended because they reduce a patient's radiation exposure by 50 percent compared with calcium tungstate-intensifying screens.[86-89] Rare-earth film systems, combined with a high-speed film of 400 or greater, can be used for panoramic radiographs.[86] Older panoramic equipment can be retrofitted to reduce the radiation exposure to accommodate the use of rare-earth, high-speed systems.

Digital imaging provides an opportunity to further reduce the radiation dose by 40 to 60 percent.[90-93] In digital radiography, there are three types of receptors that take the place of conventional film: charge-coupled device (CCD), complementary-metal-oxide-semiconductor (CMOS), and photo-stimulable phosphor (PSP) plates. Systems that use CCD and CMOS-based, solid-state detectors are called "direct." When these sensors receive energy from the x-ray beam, the CCD or CMOS chip sends a signal to the computer and an image appears on the monitor within seconds. Systems that use PSP plates are called "indirect." When these plates are irradiated, a latent image is stored on them. The plate is then scanned and the scanner transmits the image to the computer.

RECEPTOR HOLDERS

Holders that align the receptor precisely with the collimated beam are recommended for periapical and bitewing radiographs. Heat-sterilizable or disposable intraoral radiograph receptor-holding devices are recommended for optimal infection control.[94] Dental professionals should not hold the receptor holder during exposure.[86] Under extraordinary circumstances in which members of the patient's family (or other caregiver) must provide restraint or hold a receptor holder in place during exposure, such a person should wear appropriate shielding.[86]

COLLIMATION

Collimation limits the amount of radiation, both primary and scattered, to which the patient is exposed. An added benefit of rectangular collimation is an improvement in contrast as a result of a reduction in fogging caused by secondary and scattered radiation.[89] The x-ray beam should not exceed the minimum coverage necessary, and each dimension of the beam should be collimated so that the beam does not exceed the receptor by more than 2 percent of the source-to-image receptor distance.[86] Since a rectangular collimator decreases the radiation dose by up to fivefold as compared with a circular one, [86,95,96] radiographic equipment should provide rectangular collimation for exposure of periapical and bitewing radiographs.[86] Use of a receptor-holding device minimizes the risk of cone-cutting (non-exposure of part of the image receptor due to malalignment of the x-ray beam). The position-indicating device should be open ended and have a metallic lining to restrict the primary beam and reduce the tissue volume exposed to radiation.[86] Use of long source-to-skin distances of 40 cm, rather than short distances of 20 cm, decreases exposure by 10 to 25 percent.[86,97] Distances between 20 cm and 40 cm are appropriate, but the longer distances are optimal.[86]

OPERATING POTENTIAL AND EXPOSURE TIME

The operating potential of dental x-ray units affects the radiation dose and backscatter radiation. Lower voltages produce higher-contrast images and higher entrance skin doses, and lower deep-tissue doses and levels of backscatter radiation. However, higher voltages produce lower contrast images that enable better separation of objects with differing densities. Thus, the diagnostic purposes of the radiograph should be used to determine the selection of kilovolt setting. A setting above 90 kV(p) will increase the patient dose and should not be used.[89] The optimal operating potential of dental x-ray units is between 60 and 70 kVp.[86,89]

Filmless technology is much more forgiving to overexposure often resulting in unnecessary radiation exposure. Facilities should strive to set the x-ray unit exposure timer to the lowest setting providing an image of diagnostic quality. If available, the operator should always confirm that the dose delivered falls within the manufacturer's exposure index. Imaging plates should be evaluated at least monthly and cleaned as necessary.

PATIENT SHIELDING AND POSITIONING

The amount of scattered radiation striking the patient's abdomen during a properly conducted radiographic examination is negligible.[98] The thyroid gland is more susceptible to radiation exposure during dental radiographic exams given its anatomic position, particularly in children.[93,99,100] Protective thyroid collars and collimation substantially reduce radiation exposure to the thyroid during dental radiographic procedures.[101,102] Because every precaution should be taken to minimize radiation exposure, protective thyroid collars should be used whenever possible. If all the recommendations for limiting radiation exposure are put into practice, the gonadal radiation dose will not be significantly affected by use of abdominal shielding.[86] Therefore, use of abdominal shielding may not be necessary.

Protective aprons and thyroid shields should be hung or laid flat and never folded, and manufacturer's instructions should be followed. All protective shields should be evaluated for damage (e.g. tears, folds, and cracks) monthly using visual and manual inspection.

Proper education and training in patient positioning is necessary to ensure that panoramic radiographs are of diagnostic quality.

OPERATOR PROTECTION

Although dental professionals receive less exposure to ionizing radiation than do other occupationally exposed health care workers,[75,86] operator protection measures are essential to minimize exposure. Operator protection measures include education, the implementation of a radiation protection program, occupational radiation exposure limits, recommendations for personal dosimeters and the use of barrier shielding.[103] The maximum permissible annual dose of ionizing radiation for health care workers is 50 millisieverts (mSv) and the maximum permissible lifetime dose is 10 mSv multiplied by a person's age in years.[86] Personal dosimeters should be used by workers who may receive an annual dose greater than 1 mSv to monitor their exposure levels. Pregnant dental personnel operating x-ray equipment should use personal dosimeters, regardless of anticipated exposure levels.[86]

Operators of radiographic equipment should use barrier protection when possible, and barriers should ideally contain a leaded glass window to enable the operator to view the patient during exposure.[86] When shielding is not possible, the operator should stand at least two meters from the tube head and out of the path of the primary beam.[103] The National Council on Radiation Protection & Measurements report "Radiation Protection in Dentistry" offers detailed information on shielding and office design.[86] State radiation control agencies can help assess whether barriers meet minimum standards.

HAND-HELD X-RAY UNITS

Hand-held, battery-powered x-ray systems are available for intra-oral radiographic imaging. The hand-held exposure device is activated by a trigger on the handle of the device. However, dosimetry studies indicate that these hand-held devices present no greater radiation risk than standard dental radiographic units to the patient or the operator. No additional radiation protection precautions are needed when the device is used according to the manufacturer's instructions. These include: 1. holding the device at mid-torso height, 2. orienting the shielding ring properly with respect to the operator, and 3. keeping the cone as close to the patient's face as practical. If the hand-held device is operated without the ring shield in place, it is recommended that the operator wear a lead apron.

All operators of hand-held units should be instructed on their proper storage. Due to the portable nature of these devices, they should be secured properly when not in use to prevent accidental damage, theft, or operation by an unauthorized user. Hand-held units should be stored in locked cabinets, locked storage rooms, or locked work areas when not under the direct supervision of an individual authorized to use them. Units with user-removable batteries should be stored with the batteries removed. Records listing the names of approved individuals who are granted access and use privileges should be prepared and kept current.

FILM EXPOSURE AND PROCESSING

All film should be processed following the film and processer manufacturer recommendations. Once this is achieved, the x-ray operator can adjust the tube current and time and establish a technique that will provide consistent dental radiographs of diagnostic quality. Poor processing technique, including sight-developing, most often results in underdeveloped films, forcing the x-ray operator to increase the dose to compensate, resulting in patient and personnel being exposed to unnecessary radiation.

A safelight does not provide completely safe exposure for an indefinite period of time. Extraoral film is much more sensitive to fogging. The length of time for which a film can be exposed to the safelight should be determined for the specific safelight/film combination in use.

QUALITY ASSURANCE

Quality assurance protocols for the x-ray unit, imaging receptor, film processing, dark room, and patient shielding should be developed and implemented for each dental health care setting.[86] All quality assurance procedures, including date, procedure, results, and corrective action, should be logged for documentation purposes. A qualified expert should survey all x-ray units on their placement and should resurvey the equipment every four years or after any

changes that may affect the radiation exposure of the operator and others.[86] Surveys typically are performed by state agencies, and individual state regulations should be consulted regarding specific survey intervals. The film processor should be evaluated at its initial installation and on a monthly basis afterward. The processing chemistry should be evaluated daily, and each type of film should be evaluated monthly or when a new box or batch of film is opened.[86] Abdominal shielding and thyroid collars should be inspected visually for creases or clumping that may indicate voids in their integrity on a monthly basis.[86] Damaged abdominal shielding and collars should be replaced. Table 2 lists specific methods of quality assurance procedures, covering not only inspection of the x-ray unit itself but also of the film processor, the image receptor devices, the darkroom and abdominal shielding and collars.[103,104]

It is imperative that the operator's manual for all imaging acquisition hardware is readily available to the user, and that the equipment is operated and maintained following the manufacturer's instructions, including any appropriate adjustments for optimizing dose and image quality.

TECHNIQUE CHARTS/PROTOCOLS

Size-based technique charts/protocols with suggested parameter settings are important for ensuring that radiation exposure is optimized for all patients. Technique charts should be used for all systems with adjustable settings, such as tube potential, tube current, and time or pulses. The purpose of using the charts is to control the amount of radiation to the patient and receptor. Technique charts are tables that indicate appropriate settings on the x-ray unit for a specific anatomical area and will ensure the least amount of radiation exposure to produce a consistently good-quality radiograph.

Technique charts for intraoral and extraoral radiography should list the type of exam, the patient size (small, medium, large) for adults and a pediatric setting. The speed of film used, or use of a digital receptor, should also be listed on the technique chart. The chart should be posted near the control panel where the technique is adjusted for each x-ray unit. A technique chart that is regularly updated should be developed for each x-ray unit. The charts will also need to be updated when a different film or sensor, new unit, or new screens are used.

RADIATION RISK COMMUNICATION

Dentists should be prepared to discuss with their patients the benefits and risks of the x-ray exam.[105] To help answer patient and parent questions about dental radiology radiation safety, the American Academy of Oral and Maxillofacial Radiology and the Alliance for Radiation Safety in Pediatric Imaging partnered to create a brochure targeted at parents and patients.[106]

Table 2.

Quality Assurance Procedures for Assessment of Radiographic Equipment		
The following procedures for periodic assessment of the performance of radiographic equipment, film processing, equipment, image receptor devices, dark room integrity, and abdominal and thyroid shielding are adapted from the National Council for Radiation Protection and Measurements report, "Radiation Protection in Dentistry."[86] Please refer to state guidelines for specific regulations.		
Equipment	**Frequency**	**Method**
X-ray Machine	On installation At regular intervals as recommended by state regulations Whenever there are any changes in installation workload or operating conditions	Inspection by qualified expert (as specified by government regulations and manufacturers recommendations).
Film Processor	On installation Daily	**Method 1: Sensitometry and Densitometry** A sensitometer is used to expose a film, followed by standard processing of the film. The processed film will have a defined pattern of optical densities. The densities are measured with a densitometer. The densitometer measurements are compared to the densities of films exposed and processed under ideal conditions. A change in densitometer values indicates a problem with either the development time, temperature or the developer solutions. *Advantages* Accuracy Speed *Disadvantage* Expense of additional equipment **Method 2: Reference Film** A film exposed and processed under ideal conditions is attached to the corner of a view box as a reference film. Subsequent films are compared with the reference film. *Advantage* Cost effectiveness *Disadvantage* Less sensitive
Image Receptor Devices Intensifying Screen and	Monthly With each new batch of film Every six months	**Method 1: Sensitometry and Densitometry** (as described above) **Method 2: Reference Image** (as described above) Visual inspection of cassette integrity Examination of intensifying screen for

Extraoral Cassettes		scratches Development of an unexposed film that has been in the cassette exposed to normal lighting for one hour or more
Darkroom Integrity	On installation Monthly After a change in the lighting filter or lamp	While in a darkroom with the safelight on, place metal object (such as a coin) on unwrapped film for a period that is equivalent to the time required for a typical darkroom procedure Develop film Detection of the object indicates a problem with the safelight or light leaks in the darkroom
Abdominal and Thyroid Shielding	Monthly (visual and manual inspection)	All protective shields should be evaluated for damage (e.g., tears, folds, and cracks) monthly using visual and manual inspection. If a defect in the attenuating material is suspected, radiographic or fluoroscopic inspection may be performed as an alternative to immediately removing the item from service. Consideration should be given to minimizing the radiation exposure of inspectors by minimizing unnecessary fluoroscopy.

TRAINING AND EDUCATION

Where permitted by law, auxiliary dental personnel can perform intraoral and extraoral imaging.[103] Personnel certified to take dental radiographs should receive appropriate education. Practitioners should remain informed about safety updates and the availability of new equipment, supplies and techniques that could further improve the diagnostic quality of radiographs and decrease radiation exposure. Free training materials are available for limiting radiation exposure in dental imaging through the International Atomic Energy Agency.[107]

CONCLUSION

Dentists should conduct a clinical examination, consider the patient's oral and medical histories, as well as consider the patient's vulnerability to environmental factors that may affect oral health before conducting a radiographic examination. This information should guide the dentist in the determination of the type of imaging to be used, the frequency of its use, and the number of images to obtain. Radiographs should be taken only when there is an expectation that the diagnostic yield will affect patient care.

Dentists should develop and implement a radiation protection program in their offices. In addition, practitioners should remain informed on safety updates and the availability of new equipment, supplies, and techniques that could further improve the diagnostic ability of radiographs and decrease exposure.

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Medical Physicists Should Join the Movement—

Image Gently… in Dentistry

Safe, Effective Dental X Rays for Children—

There is no question: X Rays help dentists care for children.

As imaging professionals we know radiation matters! Children are more sensitive to radiation. What we do now lasts their lifetime. So when we image, let's Image Gently!

We should encourage our dental colleagues:

- Select x rays for individual's needs, not merely as a routine
- Use the fastest image receptor possible: E- or F-speed film or digital sensors
- Collimate the beam to the area of interest—Use rectangular collimation (White and Pharoah)
- Child-size the exposure time
- Use cone-beam CT only when necessary
- Always use thyroid collars

The following pages provide information for medical physicists regarding dental imaging technology—

What a medical physicist needs to know when surveying a dental facility

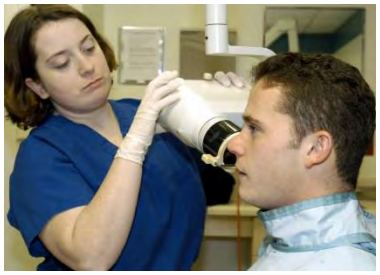
Many medical physicists are highly experienced with multiple advanced imaging modalities, such as mammography, multi-detector computer tomography (MDCT), interventional fluoroscopy, and other imaging modalities in medicine. But providing medical physics services to a dental office requires attention to a different set of issues. This document reviews the major areas of focus for a medical physics survey of a dental office, and addresses relevant image quality and radiation safety principles.

1. **The effective doses are so low, why do we worry about dental offices?**
    a. Remember that many dental patients are children and some offices image asymptomatic patients. Image Gently is committed to helping professionals provide the necessary imaging at the lowest radiation dose consistent with meeting those clinical imaging objectives. The medical physicist is the ideal professional to guide the dental practitioner to methods of reducing dose while providing essential image quality.

    Effective doses are low but skin doses for intraoral radiography are relatively high due to the use of direct x-ray film exposure, i.e., no intensifying screens. A full mouth survey may include up to 20 radiographs, each at approximately 200 mrad each resulting in a skin dose on the order of a CT scan, although to a smaller volume.

What a medical physicist needs to know when surveying a dental facility

2. **To refresh your memory, here are the most common types of dental images produced:**
   a. **Bitewing** images of the chewing surfaces of the teeth with the patient biting down, and typically show four teeth: two maxillary (upper) and two lower (mandibular). These images can be acquired using either small dental film packets or a reusable digital image receptor. (White, 2009) There are two types of digital receptors—computed radiographic (CR) plates and direct digital radiography (DR).



   b. **Full Mouth Series** consists of 16 to 20 films, taken to show all teeth. The actual number of films required varies slightly depending on practitioner preference and the number and size of the teeth in the patient's mouth. The same equipment used for bitewings is used for all the images in a full mouth series.

   c. **Cephalometric** images are full size radiographs of the skull, typically 8x10-inch, taken either AP or Lateral. Film images are taken in an 8x10-inch cassette with a phosphorescent screen. Digital images are acquired with a digital image receptor, not unlike those used in general radiography.

What a medical physicist needs to know when surveying a dental facility

d. **Panoramic** radiographs use an aperture that allows a thin slit of radiation to expose the patient and image receptor as the x-ray tube and image receptor rotate around the patient, with the image receptor translating at the same time. (White, 2009) Panoramic images are used to show the relationship between all teeth and the relevant bones. These images are acquired with a special sized sheet of dental film (15x30 cm or 5x12 inches), placed in a flexible light tight cassette, designed to provide intimate contact with the phosphorescent screen. Digital dental panoramic units may use a slot digital image receptor.

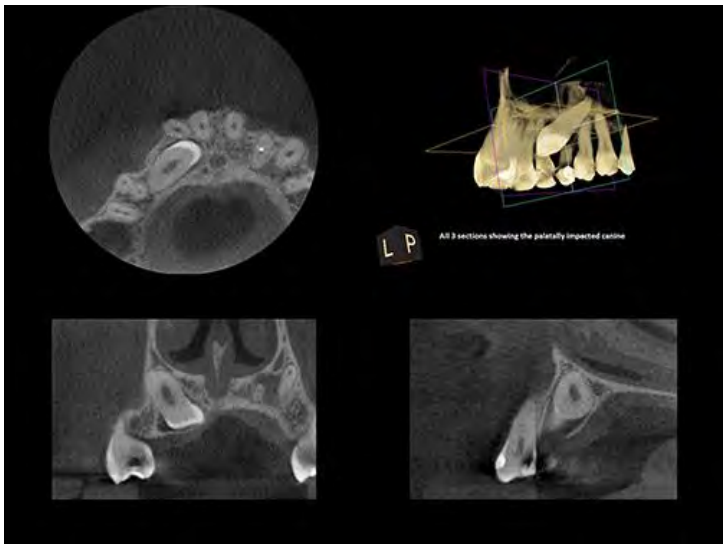
What a medical physicist needs to know when surveying a dental facility

e. **Cone beam CT (CBCT)** has become increasingly popular in dental specialty offices and is now appearing in general dentistry practices. CBCT systems appear visually similar to panoramic x-ray units, but instead of a slit aperture, the beam is collimated to the 8x10-inch digital image receptor. The CBCT images provide excellent image quality and are being utilized for an increasing number of diagnostic purposes in dentistry. The effective dose may be an order of magnitude higher than from a bitewing, primarily because more organs are exposed. Combined panoramic-CBCT systems have been introduced that utilize a slot shaped image receptors for panoramic imaging and a 2D digital image receptor for CBCT. Some systems have become available with multiple-use selectable collimation that allow the user to reduce the field to the area of interest, but with an associated potential for operator error.

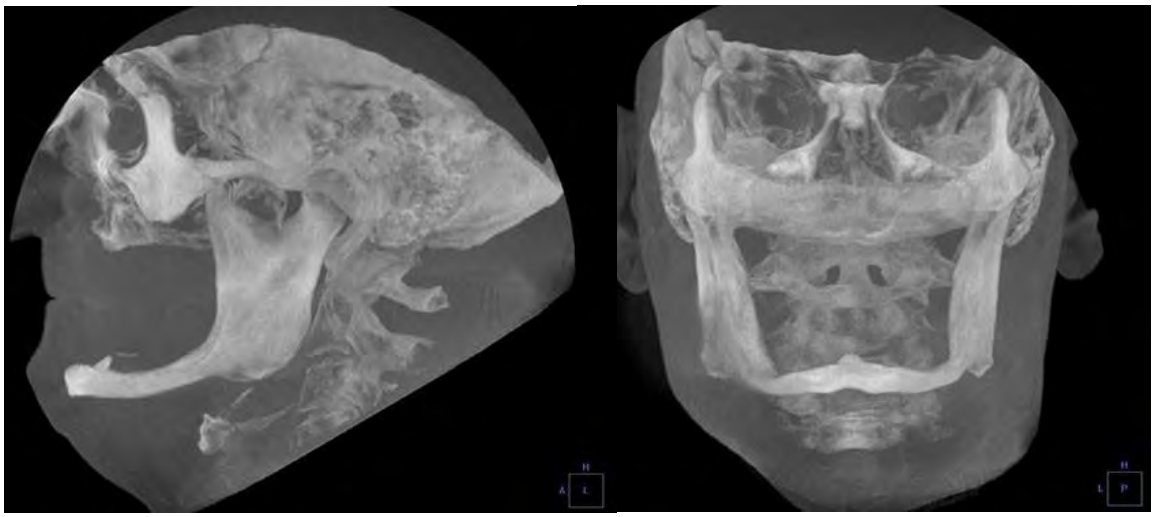
Large Volume CBCT Images

What a medical physicist needs to know when surveying a dental facility

CBCT Images



Small Volume CBCT



Large Volume CBCT: Three-dimensional on left; Coronal on right

What a medical physicist needs to know when surveying a dental facility

3. **First, evaluate the image receptor and dose.**
   a. If the facility is using dental film, check to see that they are using E-speed film, F-speed film , or what is referred to as "E- F speed" film. This may require some detective work, if the film is purchased by mail in bulk. While many facilities have converted to digital image receptors, recent data shows that 31% to ***64% continue to use D speed film***. (Gray, personal communication; also Table 1) The image quality for E-, F-, and E-F-speed films is similar to that obtained with D-speed film (Bernstein, 2003; FDA, 2014; Ludlow, 2001; Syriopoulos, 2001) at approximately one-half of the radiation dose. (Table 1) More information on the different speed films and image quality can be found here.

   This table also provides some other insights. The average exposure for D-speed film is about 260 mR. This is much higher the necessary. D-speed film exposures should be on the order of 175 to 225 mR. (Table 2) In other words, there is no need for dental exposures in excess of 225 mR for D-speed film. For histograms showing the wide range of bitewing exposures in use today see Pages 5 and 6 of this PowerPoint presentation.

Table 1

Dental Bitewing X-Ray Exposures (mR)

(Courtesy New York State Department of Health)

Dental Bitewing for 2009 (N=7,205)					
Type	Total	% of Total	Average	SD	Highest
D	3,483	55%	256	99	2,150
E	1,001	16%	162	72	1,320
F	774	12%	148	63	520
Digital	1,947	31%	105	59	693
Dental Bitewing for 2005 (N=6,325)					
Type	Total	% of Total	Average	SD	Highest
D	3,084	49%	258	93	860
E	1,118	18%	162	70	786
F	500	8%	140	67	952
Digital	1,623	26%	106	58	712
Dental Bitewing for 2001 (N=8,600)					
Type	Total	% of Total	Average	SD	Highest
D	5,127	81%	262	106	3,308
E	1,674	26%	161	68	675
F	510	8%	148	58	650
Digital	1,289	20%	110	64	560

What a medical physicist needs to know when surveying a dental facility

Table 1 also provides insight relative to radiation exposure over time. As can be seen the exposures from 2001 to 2009 remain virtually unchanged, although these exposures all could be much lower. This indicates that there is a significant amount of work to be done on educating the practitioners about radiation exposure, and how to optimize image quality and radiation dose.

Table 2 provides suggested exposure ranges for dental bitewing x-ray exposures. As can be seen, the average exposures in Table 1 typically exceeds the suggest exposure ranges in Table 2. For film imaging, this is usually caused by under-processing film due to depleted chemicals. More information can be found here.

Table 2
Suggested Dental Bitewing Exposure Ranges

Type	Suggested Exposure Range (mR)
D	175 to 225
E-F or F	100 to 125
Digital-CR	60 to 120*
Digital-DR CMOS	50 to 100*
Digital-DR CCD	40 to 60*

*Based on 25th and 75th percentile of optimal exposure from Table II from Udupa, H., et al., Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116:774-783. Note—Required exposure for optimal image quality varies with digital sensor type. Table 2 should be considered as a starting point for image quality and dose optimization.

b. Using the posted technique chart, measure and evaluate the dose. Compare with references. (NCRP, 2003; NCRP 2012) Ask the staff open ended questions like “What techniques do you use for bitewings? Do you have different techniques for children?” If you choose to make alternate technique recommendations, provide a written technique chart for each unit, for adult and pediatric patients. For facilities with multiple x-ray units of different manufacturers or models, it may be beneficial to provide an additional single technique chart showing the differences for all x-ray systems in the suite.

What a medical physicist needs to know when surveying a dental facility

c. Digital image receptors require less radiation skin dose than film imaging. CR (photostimulable phosphor) receptors require a dose similar to E-, F-, or E-F-speed film. DR image receptors can provide clinical images in the 40 to 100 mR range, dependent on the type of digital receptors. Image and radiation dose optimization should be carried out using the data in Table 2 as a starting point. (It is not uncommon to find significantly higher doses being delivered for digital imaging.)

d. Digital imaging has eliminated the need for film processing and all of the associated issues. However, there are issues associated with digital imaging which should be investigated during an evaluation. The medical physicist's experience with digital imaging in general radiography, dose creep, and challenges associated with the conversion to digital imaging will be fully applicable here. For more information click here.

4. **Radiographic film processing conditions and quality** vary considerably in the dental imaging community. Verify that proper time-temperature developing is being used. Film processing tips are included in Link B. Film processing is usually the weakest link in the imaging chain, with under-processing resulting in low contrast radiographs and increased patient doses. The histograms on Pages 5 and 6 in this PowerPoint presentation clearly demonstrate the broad range of patient doses and suboptimal photographic processing (approximately one-third of the facilities produce films with inferior contrast) in use today. To assist with testing processing conditions, inexpensive devices are available for dental film processing quality control. These are also helpful in assuring appropriate initial film exposure technique selection and processing conditions.

What a medical physicist needs to know when surveying a dental facility

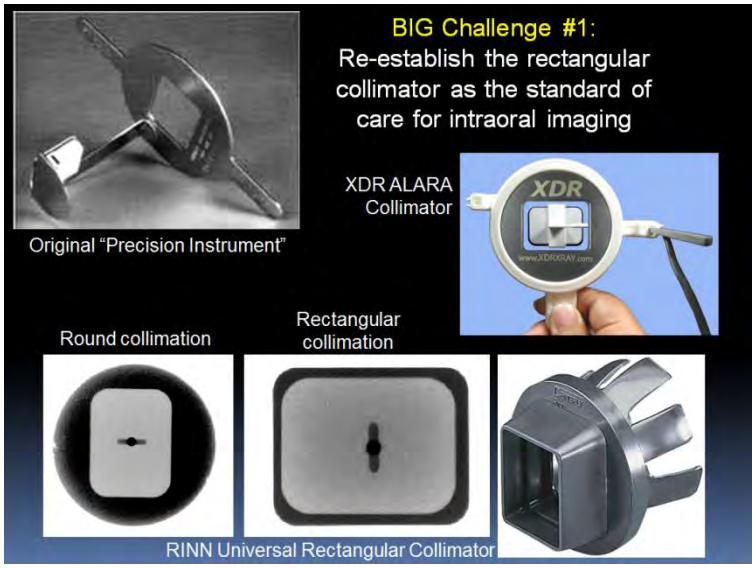
5. **Evaluate the x-ray generator and output** using standard techniques. Be sure that your radiation detector is properly positioned, and sized appropriately to include the complete x-ray beam. Modern units typically operate at only a single kVp and mA.

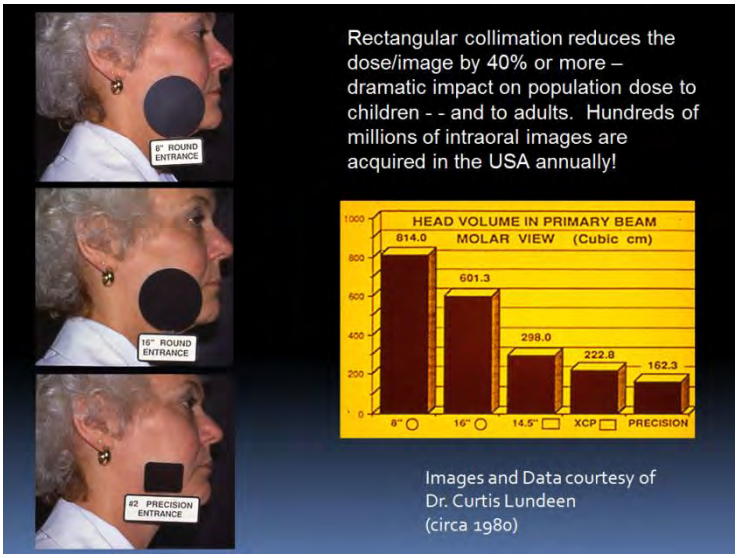
6. **Carefully evaluate beam collimation.** For intraoral radiographic units, consider recommending a rectangular aperture, which has been shown to significantly reduce effective dose by providing an x-ray beam that more closely approximates the rectangular image receptor. (White and Pharoah) The diagnostic medical physicist's experience with the benefits (image quality and radiation safety) derived from collimating the x-ray beam to the image receptor in body radiography and fluoroscopy (for example), will be directly applicable here. Evaluating collimation for panoramic or CBCT systems requires some pre-planning, and may be accomplished using GAF Chromic Film and the manufacturer's specifications for geometry.

The photo on the left shows self-developing x-ray film taped to the surface of the x-ray tube cover. The mages at the right show two strips, following exposure.

What a medical physicist needs to know when surveying a dental facility

Rectangular beam collimation reduces patient radiation dose by 60%. The following two PowerPoint slides provide some excellent visuals to demonstrate this point:





See Progress and Challenges in Diagnostic Imaging for Children.

What a medical physicist needs to know when surveying a dental facility

7. **Radiation Safety** should be evaluated based on integrated exposure measurements using a dosimeter, taken at various locations within and near the x-ray source. Inquire about workload with the staff, and verify by reviewing representative patient logs. These should be readily available on digital systems. Be sure to account for any effect of very short radiographic exposure times. It may be necessary to increase the mAs to obtain a reading on your survey instrument.

   Be aware that CBCT systems are often located where panoramic units were previously installed. However, the scattered radiation dose from CBCT is substantially higher than for panoramic units (about an order of magnitude), due to the significantly larger field of view exposed in CBCT systems. Calculate the exposure to persons in the vicinity of the x-ray source following the principles of NCRP Report 147 (NCRP, 2004). While exposures and workloads may remain consistent from year to year for intraoral x-ray units, increased utilization of CBCT systems in recent years make it essential for the medical physicist to evaluate personnel exposure during each annual survey. At the very least the medical physicist should recalculate estimated weekly exposures using ***initial*** area survey measurements and ***recent*** workload data. Results should be compared with requirements from the local jurisdiction. Pay particular attention to personnel who may be working within line of sight of a CBCT unit or in an adjacent room, and make appropriate recommendations to assure ALARA.

8. **Occupational Dosimetry**. While many dental offices are not required to use personnel dosimetry, potentially increased utilization in a digital and CBCT imaging environment may warrant a renewed assessment of occupational exposure with personnel dosimetry. The associated exposure reports are useful to many facilities as a risk mitigation method where many personnel are young females of child-bearing age.

What a medical physicist needs to know when surveying a dental facility

9. **Hand-Held Dental X-Ray Units** are being used in many offices. One x-ray unit can be used in more than one room. These units must be appropriately shielded by the manufacturer at the x-ray tube and with a leaded-acrylic disk at the front of the position indicating device (PID) to reduce backscatter. Several papers have been published on the safety and image quality of these systems. (Brooks, 2009; Gray, 2012; Phillips, 2012; Thatcher, 2013)

10. **Remember that a medical physicist can contribute** to the quality of care delivered by a dental facility and personnel safety by following established imaging physics principles for both traditional and newer digital imaging technology. By speaking with the dentist and staff and understanding how x-rays are used in each practice setting the medical physicist's recommendations can impact a very large number of patients.

Check out these dental imaging tip sheets for further helpful information—

A. **D- versus E-F- or F-Speed Dental Films**

B. **Radiographic Film Processing Tips**

C. **Digital Imaging Tip Sheet**

What a medical physicist needs to know when surveying a dental facility

General References and Suggested Reading

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Hand-held Dental X-Ray Units

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U.S. Food and Drug Administration

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Dental Cone-beam Computed Tomography

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- Description
- Uses
- Benefits/Risks
- Information for Patients and Parents
- Information for Dental Professionals
- Industry Guidance

On this webpage, the FDA is providing:

- information about the use of cone-beam computed tomography in dentistry particularly in the pediatric population,
- information for patients, parents and health care providers to help reduce unnecessary radiation exposure from dental cone-beam computed tomography, and
- resources for manufacturers of dental cone-beam computed tomography devices.

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Attachment 8

Description

Cone-beam computed tomography systems (CBCT) are a variation of traditional computed tomography (CT) systems. The CBCT systems used by dental professionals rotate around the patient, capturing data using a cone-shaped X-ray beam. These data are used to reconstruct a three-dimensional (3D) image of the following regions of the patient's anatomy: dental (teeth); oral and maxillofacial region (mouth, jaw, and neck); and ears, nose, and throat ("ENT").

Cone-beam computed tomography system.

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Uses

Dental CBCT systems have been sold in the United States since the early 2000s and are increasingly used by radiologists and dental professionals for various clinical applications including dental implant planning, visualization of abnormal teeth, evaluation of the jaws and face, cleft palate assessment, diagnosis of dental caries (cavities), endodontic (root canal) diagnosis, and diagnosis of dental trauma.

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Benefits/Risks

X-ray imaging, including dental CBCT, provides a fast, non-invasive way of answering a number of clinical questions. Dental CBCT images provide three-dimensional (3-D) information, rather than the two-dimensional (2-D) information provided by a conventional X-ray image. This may help with the diagnosis, treatment planning and evaluation of certain conditions.

Attachment 8

Although the radiation doses from dental CBCT exams are generally lower than other CT exams, dental CBCT exams typically deliver more radiation than conventional dental X-ray exams. Concerns about radiation exposure are greater for younger patients because they are more sensitive to radiation (i.e., estimates of their lifetime risk for cancer incidence and mortality per unit dose of ionizing radiation are higher) and they have a longer lifetime for ill effects to develop.

The FDA has launched a pediatric X-ray imaging website that provides specific recommendations for parents and health care providers to help reduce unnecessary radiation exposure to children. The FDA's Center for Devices and Radiological Health defines the ages of the pediatric population as birth through 21 years.

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Information for Patients and Parents

The American Dental Association (ADA) and the FDA recommend that clinicians perform dental X-ray examinations, including dental CBCT, only when necessary for the diagnosis or treatment of disease. The clinical benefit of a medically appropriate X-ray imaging exam outweighs the small radiation risk. However, efforts should be made to help minimize this risk.

The FDA also recommends that for all X-ray imaging procedures, including dental CBCT, patients and parents of children should:

- Talk with their health care provider.
  - Review the benefits and risks of the procedure before it is performed.
  - Discuss if the imaging exam is necessary and if there are equally useful alternative exams that use no or less ionizing radiation.
  - Ask if the facility uses radiation reduction techniques such as size-based protocols for children.
- Keep a record of your family's medical-imaging histories.
  - The Image Wisely/FDA My Medical Imaging History and Image Gently "My Child's Medical Imaging Record" cards provide a format for patients and parents to track all imaging exams as part of a discussion with the referring physician when a new exam is recommended.
- Resources for patients and parents about the benefits and risks of dental CBCT and other X-ray imaging include:
  - FDA Medical Imaging: Pediatric X-ray Imaging
  - The Alliance for Radiation Safety in Pediatric Imaging in partnership with the American Academy of Oral and Maxillofacial Radiology: "What is Pediatric Dental Radiography?" and "What Parents Should Know about the Safety of Dental Radiology"
  - The Radiological Society of North America's and the American College of Radiology's patient information webpage: RadiologyInfo: Dental Cone Beam CT

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Information for Dental Professionals

Dental CBCT should be performed only when necessary to provide clinical information that cannot be provided using other imaging modalities.

As stated in FDA's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, the FDA recommends imaging professionals follow the principles of justification and optimization in the protection of patients undergoing radiological examinations. The FDA recommends that dental professionals:

- Discuss the rationale for the examination with the patient and/or parent to ensure a clear understanding of benefits and risks.
- Reduce the number of inappropriate referrals (i.e., justify X-ray imaging exams) by:
  - determining if the examination is needed to answer a clinical question,
  - considering alternate exams that use less or no radiation exposure, and
  - reviewing the patient's medical imaging history to avoid duplicate exams.
- Use exposure settings for dental CBCT exams that are optimized to provide the lowest radiation dose that yields an image quality adequate for diagnosis (i.e., radiation doses should be "As Low as Reasonably Achievable"). The technique factors used should be chosen based on the clinical indication, patient size, and anatomical area scanned, and the equipment should be properly maintained and tested.

Additional information for health care providers on appropriate and safe use of dental X-ray imaging exams includes:

- The use of cone-beam computed tomography in dentistry: An advisory statement from the American Dental Association Council on Scientific Affairs (August 2012).
- The joint FDA and American Dental Association Guidelines for the Selection of Patients for Dental Radiographic Examinations-2004 provides information on how to determine if X-rays are appropriate (justified) for a given patient. While these guidelines do not mention CBCT specifically, many of the general recommendations apply to dental CBCT.
- Recommendations specific to the use of dental CBCT can be found in the Joint Position Statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology USE OF CONE-BEAM COMPUTED TOMOGRAPHY IN ENDODONTICS.
- Position statement of the American Academy of Oral and Maxillofacial Radiology on selection criteria for the use of radiology in dental implantology with emphasis on cone beam computed tomography (2012)
- Based on data from many countries, including the U.S., the European Commission's SEDENTEXCT project has developed a training program and "Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology; Evidence Based Guidelines 2011".

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- Academy of Dental Therapeutics and Stomatology's: A Clinician's Guide to Understanding Cone Beam Volumetric Imaging (CBVI)
- The International Atomic Energy Agency (IAEA)'s Dental Radiology- X Rays contains information for health professionals to help protect patients from unnecessary radiation exposure in dental imaging including CBCT.
- The American Academy of Pediatric Dentistry (AAPD) Policy on Patient Safety gives general guidelines on safe use of dental imaging.
- FDA Medical Imaging: Pediatric X-ray Imaging

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Information for Industry

Dental CBCT systems are medical devices that are also radiation-emitting electronic products. The FDA regulates manufacturers of dental CBCT devices through the Electronic Product Radiation Control (EPRC) and medical device provisions of the Federal Food, Drug, and Cosmetic Act. Dental CBCT systems are classified under 21 CFR 892.1750.

For more information on bringing an X-ray imaging system to market and for post-market requirements see:

- Getting a Radiation Emitting Product to Market
- Device Advice: Complementary Regulatory Assistance
- Post-market Requirements (Devices)

FDA's webpages on Computed Tomography and Medical X-Rays provide more detailed lists of industry resources relevant to dental CBCT systems.

On May 10, 2012, the FDA issued Draft Guidance: Pediatric Information for X-ray Imaging Device Premarket Notifications to encourage manufacturers to consider the radiation safety of pediatric populations in the design of new X-ray imaging devices, including dental CBCT systems. On July 16, 2012, the FDA held a public workshop to discuss the draft guidance. Participants provided recommendations specific to dental cone-beam CT scanners. More information about the meeting (including archived webcast and presentation slides) are available on the workshop website, Device Improvements for Pediatric X-ray Imaging.

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Required Reports for Industry

- Diagnostic X-Ray CT Products Radiation Safety Report (PDF) (PDF - 836KB)

Attachment 8

- Guide for Filling Annual Reports for X-Ray Components and Systems (PDF) (PDF - 871KB)

More in Medical X-ray Imaging

- Radiography
- Computed Tomography (CT)
- **Dental Cone-beam Computed Tomography**
- Fluoroscopy
- Mammography

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Attachment 8

Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and Maxillofacial Radiology

American Academy of Oral and Maxillofacial Radiology

Aims. To summarize the potential benefits and risks of maxillofacial cone beam computed tomography (CBCT) use in orthodontic diagnosis, treatment and outcomes and to provide clinical guidance to dental practitioners.
Methods. This statement was developed by consensus agreement of a panel convened by the American Academy of Oral and Maxillofacial Radiology (AAOMR). The literature on the clinical efficacy of and radiation dose concepts associated with CBCT in all aspects of orthodontic practice was reviewed.
Results. The panel concluded that the use of CBCT in orthodontic treatment should be justified on an individual basis, based on clinical presentation. This statement provides general recommendations, specific use selection recommendations, optimization protocols, and radiation-dose, risk-assessment strategies for CBCT imaging in orthodontic diagnosis, treatment and outcomes.
Conclusions. The AAOMR supports the safe use of CBCT in dentistry. This position statement is periodically revised to reflect new evidence and, without reapproval, becomes invalid after 5 years. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116: 238-257)

Malocclusions and craniofacial anomalies adversely affect quality of life. Orthodontics and dentofacial orthopedic treatment address the correction of malocclusions and facial disproportions due to dental/skeletal discrepancies to provide esthetic, psychosocial, and functional improvements. For almost a century, two-dimensional (2D) planar radiographic imaging and cephalometry have been used to assess the interrelationships of the dentition, maxillofacial skeleton, and soft tissues in all phases of the management of orthodontic patients, including diagnosis, treatment planning, evaluation of growth and development, assessment of treatment progress and outcomes, and retention. However, the limitations of 2D imaging have been realized for decades as many orthodontic and dentofacial orthopedic problems involve the lateral or "third dimension."[1-3] For instance, relapse of and unfavorable responses to orthodontic therapy remain poorly understood despite implications that considerations in the transverse plane are important factors in stability.[4] For years, multiple radiographic projections were obtained to attempt to display complex anatomic relationships and surrounding structures; however, interpreting multiple-image inputs is challenging. With the increasing availability of multi-slice computed tomography (CT) and, more recently, cone beam computed tomography (CBCT), visualization of these relationships in three dimensions is now feasible.

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SCOPE AND PURPOSE OF THE RECOMMENDATIONS AND CONCLUSIONS

This position statement was developed by board-certified orthodontists and oral and maxillofacial radiologists convened by the American Academy of Oral and Maxillofacial Radiology (AAOMR). Their objectives were to 1) review and evaluate critically the current science, guidance and other resources available from professional organizations on the clinical benefits and potential limitations of the use of CBCT in orthodontics, and 2) develop consensus derived, orthodontic-specific clinical guidelines. Imaging selection recommendations, optimization protocols and radiation-dose, risk-assessment strategies were developed to assist professional clinical judgment on the use of CBCT in orthodontics. The panel concluded that there is no clear evidence to support the routine use of ionizing radiation in standard orthodontic diagnosis and treatment planning, including the use of CBCT.

BACKGROUND

Imaging considerations in orthodontic therapy

One purpose of radiographic imaging in orthodontics is to supplement clinical diagnosis in the pretreatment assessment of the orthodontic patient. Radiographic imaging may also be performed during treatment to assess the effects of therapy and posttreatment to monitor stability and outcome. Imaging for a specific orthodontic patient occurs in at least three 3 stages: 1) selection of the most appropriate radiographic imaging technique, 2) acquisition of appropriate images, and 3) interpretation of the images obtained. In some instances, these steps need to be repeated. Selection of the appropriate radiographic imaging technique (or techniques) is

based on the principle that practitioners who use imaging with ionizing radiation have a professional responsibility of beneficence—that imaging is performed to "serve the patient's best interests." This requires that each radiation exposure is justified clinically and that procedures are applied that minimize patient radiation exposure while optimizing maximal diagnostic benefit. The extension of this principle, referred to as the "as low as reasonably achievable" (ALARA),[5] to CBCT imaging is supported by the American Dental Association.[6] Justification of every radiographic exposure must be based primarily on the individual patient's presentation including considerations of the chief complaint, medical and dental history, and assessment of the physical status (as determined with a thorough clinical examination) and treatment goals.[6]

In 1987, a panel of representatives from general dentistry and various academic disciplines in the United States was convened by the Food and Drug Administration. This panel published broad selection recommendations for intraoral radiographic examinations.[7] These were updated in 2004.[8,9] The guidelines suggest that for monitoring growth and development of children and adolescents, "clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring of dentofacial growth and development." In both the European Union[10-12] and the United Kingdom[13] orthodontic imaging guidelines state that there is neither an indication for taking radiographs routinely before clinical examinations nor for taking a standard series of radiographic images for all orthodontic patients. The latter document provides clinical decision algorithms based on the ages of the patients (less than or over 9 years of age) and clinical presentation (delayed or ectopic eruption, crowding, or anteroposterior discrepancies such as overjet or overbite, etc.).

CBCT imaging in orthodontics

There has been a dramatic increase in the use of CBCT in dentistry over the last decade. This technology has found particular applications in orthodontics for diagnosis and treatment planning for both adult and pediatric patients.[14-20] CBCT imaging provides two unique features for orthodontic practice. The first is that numerous linear (e.g., lateral and posteroanterior cephalometric images) or curved planar projections (e.g., simulated panoramic images) currently used in orthodontic diagnosis, cephalometric analysis, and treatment planning can be derived from a single CBCT scan. This provides for greater clinical efficiency. The second, and most important, is that CBCT data can be reconstructed to provide unique images previously unavailable in orthodontic practice. Innately CBCT data are presented as inter-relational undistorted images in three orthogonal planes (i.e., axial, sagittal, and coronal); however, software techniques are readily available (e.g., maximum intensity projection and surface or volumetric rendering) that provide three-dimensional visualization of the maxillofacial skeleton, airway space and soft tissue boundaries such as the facial outline. The current diagnostic uses of CBCT are summarized in Appendix A.[21-158]

Evidence based assessments

The potential for extracting additional diagnostic information from volumetric imaging and the technical ease of obtaining scans has led some clinicians and manufacturers to advocate the replacement of current conventional imaging modalities with CBCT for standard orthodontic diagnosis and treatment.[15,18,159,160] Although CBCT imaging increases clinician confidence in orthodontic diagnosis[161] and has demonstrated clinical efficacy in altering treatment planning for impacted maxillary canines,[37,43,161] unerupted teeth, severe root resorption, and severe skeletal discrepancies,[161] no benefit has been demonstrated for patients specifically referred for abnormalities of the temporomandibular joint, airway assessment or dental crowding.[161] Despite the number of publications on the use of CBCT for specific orthodontic applications, most are observational studies of diagnostic performance and efficacy with wide ranging methodological soundness.[162] Few authors have presented higher levels of evidence and measured the impact of CBCT on orthodontic diagnosis and treatment planning decisions.

Fundamentals to guideline development are systematic reviews of the published literature. Systematic reviews use well-defined and reproducible literature search strategies to identify evidence focused on a specific research question. Evidence is graded according to its level of methodological rigor (or quality), relevance and strength. There is a lack of CBCT-orthodontic systematic reviews. There is a need for rigorous investigation on the efficacy of CBCT imaging for all aspects of orthodontics related to its influence on therapy decisions and ultimately patient outcome.[163] Because of the lack of CBCT-orthodontic systematic reviews, the panel used consensus and published criteria.[164-168] to develop three hierarchical recommendations for CBCT imaging in orthodontics (Table I). An important consideration in the use of CBCT is that ionizing radiation is a risk to patient health.

Radiation dose considerations in orthodontics

There are two broad potential harmful effects of ionizing radiation in orthodontics. The first is deterministic effects that cause the death of cells from high doses over short periods of time and usually occur only after thresholds are reached. Below these thresholds no clinical change has been reported. These levels are never reached for a single exposure in the diagnostic range

Table I. Panel consensus recommendations for use of CBCT imaging*

Recommendation	*Consensus level*	*Definition*
Likely indicated	I	The use of CBCT imaging is indicated in most circumstances for this clinical condition. There is an adequate body of evidence to indicate a favorable benefit from the procedure relative to the radiation risk in the majority of situations.
Possibly indicated	II	The use of CBCT imaging may be indicated in certain circumstances for this clinical condition. There is a sufficient body of evidence to indicate a possible favorable benefit from the procedure relative to the radiation risk in many situations.
Likely not indicated	III	The use of CBCT imaging is not indicated in the majority of circumstances for this clinical condition. There is an insufficient body of evidence to indicate a benefit from the procedure relative to the radiation risk in most situations.

*In the future, if CBCT imaging radiation levels are equivalent to conventional modalities, this table may be less relevant.

used in conventional oral and maxillofacial radiology. They do, however, occur in dental patients who have cancer and undergo radiotherapy to the head and neck region. One example of this is radiation-induced oral mucositis. The second effect is a stochastic effect that irreversibly alters the cells, usually by damaging cellular DNA. Such damage can result in cancer. The long-term risk associated with diagnostic radiographic imaging is radiation-induced carcinogenesis. Unlike deterministic effects, stochastic effects can result from low levels of radiation that are cumulative over time.

Assessment of the risks associated with the use of ionizing radiation for diagnostic imaging is an important public health issue. Recent reports have increased concerns over the potential association between radiation exposure and cancer. In one article, a relationship was found between intracranial meningiomas and dental radiographic procedures[169]; however, numerous rebuttal articles have highlighted limitations in this study.[170-173] Most recently, the results of a retrospective cohort study provide evidence of a link between exposure to radiation from medical CT and cancer risk in children.[174] It was found that children and young adults who received radiation doses from the equivalent of 2 or 3 medical CT scans of the head have almost triple the risk of developing leukemia or brain cancer later in life. Medical CT head scans may have an effective dose of up to 2000 μSv[175]; however, for CT examinations with dental protocols, substantial reductions to less than 1000 μSv have been reported.[159,176-184] Most CBCT examinations impart a fraction of medical CT effective dose; however, doses vary considerably among CBCT units.[90,137,159,176-196]

Low-dose radiographic procedures (including maxillofacial CBCT) are those that result in doses below about 1,00,000 μSv. The risk of cancer induction caused by low-dose radiographic procedures is difficult to assess. While there is lack of agreement among radiation epidemiologists and radiobiologists, there is consensus among the four authoritative agencies in the United States responsible for developing public-health, radiation-safety directives that for stochastic risks, such as carcinogenesis, the risks should be considered to be linearly related to doses, down to the lowest doses.[197-200] The assessment of risk is, however, confounded in that people are exposed to background radiation, including cosmic radiation from airline flights and/or living at high altitudes. For this position statement, the panel reviewed information on the potential health effects of exposure to diagnostic ionizing radiation. There is neither convincing evidence for carcinogenesis at the level of dental exposures, nor the absence of evidence of such damage. This situation is unlikely to change in the near future. In the absence of evidence of a threshold dose, it is prudent, from a patient-policy perspective, to assume that such a risk exists. This implies that there is no safe limit or "safety zone" for ionizing radiation exposure in diagnostic imaging. Every exposure cumulatively increases the risk of cancer induction. Consequently, to be cautious, the guidelines presented in this position statement are focused on minimizing or eliminating unnecessary radiation exposure in diagnostic imaging.

The overall biological effect of exposure to ionizing radiation, expressed as the risk of cancer development over a lifetime, is determined from absorbed radiation dose to specific organs in combination with weighting factors that account for differences in exposed-tissue sensitivity and patient susceptibility factors such as gender and age. For this position statement, the International Commission on Radiological Protection (ICRP)'s effective dose (E) method was used to estimate whole body dose and measure stochastic radiation risks to patients based on evidence of biological effects currently available.[201] Effective dose is calculated by multiplying organ doses by risk weighting factors (which are the organs' relative radiosensitivities to developing cancers). The sum of the products for all of the organs is

the effective whole-body dose (effective dose).[201] The estimated risk weighting factors have recently been revised, and a number of additional tissues found in the head and neck region have been included (most importantly the salivary glands, lymphatic nodes, muscle, and oral mucosa).[197] These modifications have resulted in substantial increases (ranging from 32% to 422%) in effective doses for specific maxillofacial radiographic procedures.[177]

The effective dose for CBCT radiographic imaging used for orthodontic records is of particular concern, especially as the modal age for initiating orthodontic treatment represents a pediatric population. The radiation risk to ionizing radiation is greater for young children than for adolescents and adults because: 1) the rate of cellular growth and organ development (when radiosensitivity is highest) is greater in young children; 2) children have longer life expectancies, so the cumulative effects of radiation exposures have longer time periods in which they can cause cancers; 3) with CBCT imaging, specific organ and effective doses, (particularly the salivary glands) are, on average, 30% higher for young children than for adolescents[183]; and 4) unless specific, pediatric, exposure−reduction techniques are incorporated, the radiation doses for children (small patients) may exceed typical adult radiation levels (with some currently available CBCT units, it is not possible to implement exposure−reduction techniques). In sum, it is estimated that children may be two to ten times or more prone to radiation-induced carcinogenesis than mature adults.[175,200-202] Because it is important to consider the increased risks associated with exposing children to ionizing radiation, the American College of Radiology (ACR) has incorporated pediatric, effective-dose estimates in relative radiation level (RRL) designations for specific imaging procedures (Table II).[203] In addition, there are at least two national radiation safety initiatives to raise awareness of using lower radiation doses to image children: Image Gently[204] and the National Children's Dose Registry.[205] The AAOMR sought, and received, permission to adopt the ACR, relative-radiation-level designations for several reasons: First, this scheme provides a relative assessment of radiation dose risk based on the premise that with an exposure of 10,000 μSv, there is a risk of 1 in 1000 individuals developing cancer; second, the risk is related to diagnostic imaging only (and is unrelated to considerations of background radiation exposure); and three, risk assessment incorporates increased pediatric radiation sensitivity considerations.

For all imaging procedures using ionizing radiation, the clinical benefits should be balanced against the potential radiation risks, which are determined by the relative radiosensitivity of those being imaged and the abilities of the operators to control radiation exposures.

Table II. Estimations of relative radiation level designations for children and adults for orthodontic imaging (*with permission from* ACR,* 2011)

	Effective dose estimate range (μSv)	
Relative radiation level	*Adult*	*Child*†
0	0	0
☢	<100	<30
☢☢	100-1000	30-300
☢☢☢	1000-10,000	300-3000
☢☢☢☢	10,000-30,000	3,000-10,000

*Some of the information in this document was provided with permission from the American College of Radiology (ACR) and taken from the ACR Appropriateness Criteria. The ACR is not responsible for any deviations from original ACR Appropriateness Criteria content.
†Child is defined as any individual less than 18 years of age.

GUIDELINES FOR CBCT IN ORTHODONTICS

The choice of modality used for imaging an orthodontic patient is based on a risk/benefit assessment (i.e., the risk to the patient attributable to radiation exposure in relationship to the benefit to the patient from imaging procedure). Assessment of clinical benefit is primarily patient and practitioner dependent but should be based on the application of sound imaging selection principles. As part of this position statement, the following guidelines are suggested for the use of CBCT in orthodontics:

1. Image appropriately according to clinical condition
2. Assess the radiation dose risk
3. Minimize patient radiation exposure
4. Maintain professional competency in performing and interpreting CBCT studies

1. Image appropriately according to clinical condition

Recently the American Dental Association Council on Scientific Affairs issued an advisory statement on the use of CBCT in dentistry. The AAOMR contributed to the statement,[6] which is based on the ALARA principle and acknowledges the increased sensitivity of pediatric patients to ionizing radiation and recognizes that patients present with varying degrees of orthodontic complexity. The panel recommends the following general strategies for the use of CBCT in orthodontics:

Recommendation 1.1. The decision to perform a CBCT examination is based on the patient's history, clinical examination, available radiographic imaging, and the presence of a clinical condition for which the benefits to the diagnosis and/or treatment plan outweigh the potential risks of exposure to radiation, especially in the case of a child or young adult.

Recommendation 1.2. Use CBCT when the clinical question for which imaging is required cannot be answered adequately by lower-dose conventional

dental radiography or alternate non-ionizing imaging modalities.

Recommendation 1.3. Avoid using CBCT on patients to obtain data that can be provided by alternate non-ionizing modalities (e.g., to produce virtual orthodontic study models).

Recommendation 1.4. Use a CBCT protocol that restricts the field of view (FOV), minimizes exposure (mA and kVp), the number of basis images, and resolution yet permits adequate visualization of the region of interest.

Recommendation 1.5. Avoid taking a CBCT scan solely to produce a lateral cephalogram and/or panoramic view if the CBCT would result in higher radiation exposure than would conventional imaging.

Recommendation 1.6. Avoid taking conventional 2D radiographs if the clinical examination indicates that a CBCT study is indicated for proper diagnosis and/or treatment planning or if a recent CBCT study is available.

To assist clinicians in defining the scope of orthodontic conditions and the most appropriate CBCT imaging in each circumstance, specific imaging selection recommendations for the use of CBCT in orthodontics are given in Table III. The proposed recommendations include the phase of treatment (pre-, during-, or post-treatment), the treatment difficulty and the presence of additional skeletal and dental conditions. The table rows list orthodontic phases of treatments and treatment difficulty categories and columns list dental and skeletal clinical conditions. Within each cell, the overall suitability of the CBCT procedure (Table I) and most appropriate FOV are provided. Table IV describes the three FOV ranges most commonly encountered in orthodontic imaging. The concerns in selecting a CBCT FOV are the inclusion of the region of clinical importance and the collimation of the radiation beam to that specific region. The rational for orthodontic image selection recommendations is in Appendix B.

2. Assess the radiation dose risk

Orthodontists must be knowledgeable of the radiation risk of performing CBCT and be able to communicate this risk to their patients. Radiation risk has most often been estimated by calculating the effective dose[201] of a CBCT scan and comparing this value to; 1) measurements obtained from comparable imaging modalities (e.g., multiples of typical panoramic images or a multi-slice medical CT), 2) background equivalent radiation time (e.g., days of background), or 3) radiation detriment [e.g., probability of x cancers per million scans (stochastic-cancer rate)]. Often the base unit of these comparisons (typical panoramic dose, background radiation, weighted probabilities of fatal and nonfatal cancers) is variable and not absolute. This means, for example, that depending on the panoramic

Table III. Imaging selection recommendations for the use of cone beam computed tomography in orthodontics

Presentation		*Dental and skeletal clinical conditions*								
Primary	*Treatment difficulty*	*None*	*Dental structure anomalies*	*Anomalies in dental position*	*Compromised dento-alveolar boundaries*	*Asymmetry*	*Anteroposterior discrepancies*	*Vertical discrepancies*	*Transverse discrepancies*	*TMJ signs and/or symptoms*
Pretreatment	Mild	III	FOV_S (I)	FOV_S (I)	$FOV_{s,m}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{s,m}$ (III)
	Moderate	$FOV_{m,l}$ (II)	FOV_S (I)	FOV_S (I)	$FOV_{s,m}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)
	Severe	FOV_l (II)	FOV_S (I)	FOV_S (I)	$FOV_{s,m}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)
During treatment		III	FOV_S (III)	FOV_S (II)	$FOV_{s,m}$ (II)	Presurgical $FOV_{m,l}$ (I)	Presurgical $FOV_{m,l}$ (II)	Presurgical $FOV_{m,l}$ (II)	Presurgical $FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)
Posttreatment		III	FOV_S (III)	FOV_S (III)	$FOV_{s,m}$ (III)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)	$FOV_{m,l}$ (II)

CBCT, cone beam computed tomography; Field of View (FOV): FOV_s = Small FOV CBCT imaging; FOV_m = Medium FOV CBCT imaging; FOV_l = Large FOV CBCT imaging. Consensus Recommendations: I = Likely Indicated; II = Possibly Indicated; III = Likely Not Indicated.

Table IV. Definition of cone beam computed tomography field of view (FOV) ranges for orthodontic imaging

FOV	*Abbreviation*	*Definition*
Small	FOV_s	A region of radiation exposure that is limited to a few teeth, a quadrant, and up to two dental arches and that has a spherical volume diameter or cylinder height ≤10 cm.
Medium	FOV_m	A region of radiation exposure that includes the dentition of at least one arch up to both dental arches and that has a spherical volume diameter or cylinder height >10 cm and ≤15 cm.
Large	FOV_l	A region of radiation exposure that includes the TMJ articulations and anatomic landmarks necessary for quantitative cephalometric and/or airway assessment and that has a spherical volume diameter or cylinder height >15 cm.

image dose used for the comparison (e.g., equipment manufacturer and model, film vs. digital acquisition) the risk for CBCT may be reported either conservatively or liberally compared to panoramic radiography.

To standardize comparison of radiation dose risk between various imaging procedures, this position statement recommends the use of RRLs (Table II). The RRL for various imaging examinations used either as an isolated procedure or for a course of orthodontics can be determined for adults and children using published effective dose calculations (Table VI).[90,159,176-196,206,207] Calculations of RRL levels in millisieverts (mSv; 1mSv = 1000 μSv) were made with methods described elsewhere,[197] and data from the 7th Biological Effects of Ionizing Radiation report.[208] The estimate in the report, and the basis for subsequent levels of radiation risk, is that approximately 1 in 1000 individuals develop cancer from an exposure of 10,000 μSv.[197] RRL assignments are based on reviews of current literature. These assignments are revised periodically, as practice evolves and further information becomes available.

Based on these considerations, the following recommendations are suggested for assessing patient radiation dose risk for CBCT in orthodontics:

Recommendation 2.1. Consider the RRL (Table II) when assessing the imaging risk for imaging procedures over a course of orthodontic treatment. Table V contains the effective doses for specific orthodontic protocols and various modalities. Appendix C provides an example of the calculation of RRL for Orthodontic Imaging.

Recommendation 2.2. Because CBCT exposes patients to ionizing radiation that may pose elevated risks to some patients (pregnant or younger patients), explain and disclosure to patients radiation exposure risks, benefits and imaging modality alternatives and document this in the patients' records.

3. Minimize patient radiation exposure

Depending on the equipment type and operator preferences, operators can alter radiation doses to patients by adjusting various exposure (e.g., milliamperage, kilovoltage), image-quality (e.g., number of basis images, resolution, arc of trajectory) and beam-collimation (e.g., FOV) settings. CBCT units from different manufacturers vary in dose by as much as 10-fold for an equivalent FOV examination (Table V).[184] In addition, adjustments of exposure factors to improve image quality are available in many CBCT units and can cause as much as 7-fold differences in patient doses (Table V).[184] If CBCT imaging is warranted, appropriate selection of the FOV to match the region of interest (ROI) may provide a substantial dose savings.

Based on these considerations, the following specific recommendations are made to minimize patient radiation exposure for CBCT in orthodontics:

Recommendation 3.1. Perform CBCT imaging with acquisition parameters adjusted to the nominal settings consistent with providing appropriate images of task-specific diagnostic quality for the desired diagnostic information required: 1) Use a pulsed exposure mode of acquisition, 2) Optimize exposure settings (mA, kVp), 3) Reduce the number of basis projection images, and 4) Employ dose reduction protocols (e.g., reduced resolution) when possible.

Recommendation 3.2. When other factors remain the same, reduce the size of the FOV to match the ROI; however, selection of FOV may result in automatic or default changes in other technical factors (e.g., mAs) that should be considered because these concomitant changes can result in an increase in dose.

Recommendation 3.3. Use patient protective shielding (such as, lead torso aprons and consider the use of thyroid shields) when possible (e.g., maxillary only scan), to minimize exposure to radiosensitive organs outside the FOV of the exposure.

Recommendation 3.4. Ensure that all CBCT equipment is properly installed, routinely calibrated and updated, and meets all governmental requirements and regulations.

Appendix C provides an example of the calculation of the RRL for both adults and children with and

Table V. Selected published effective doses ($E_{ICRP,\ 2007}$) in microSieverts [μSv] for various field of view (FOV) cone beam computed tomography devices used in orthodontics in comparison with multi-slice computed tomography (MSCT), rotational panoramic and cephalometric radiography

Examination	*CBCT unit*	*Scanning volume (cm²)*	*Protocol*	E *(μSv)*[Reference]
Large FOV CBCT (>15 cm height/diameter)	3DeXAM	17 × 23	0.4 mm resolution	72[196]
	3D Accuitomo 170	17 × 12	Adolescent; 10 years old	216[183]; 282[183]
	CB MercuRay	15 × 15	Maxillofacial/TMJ	436[184]; 569[184]; 680[195]; 511[180]/436[90]
		20 × 20	SR/HR/TMJ	558[177]; 761[195]/1025[177]; 1073[184]/916[90]
	Galileos	15 × 15	High/low dose	128[184]/70[184]
	Galileos Comfort	15 × 15	Adult; adolescent; 10 years old	84[191]; 71[183]; 70[183]
	i-CAT Classic	16 × 22	Low/high resolution	65-69[192]; 193[177]; 82[178]; 206[186]; 110[181]/127-131[192]
	i-CAT Next Generation	23 × 17		74[184]; 78[190]
	Iluma	19 × 19	Standard/ultra	98[184]/498[184]
	Iluma Elite	21 × 14		368[191]
	KODAK 9500	18 × 20	With; without filtration	136[191]; 166[188]/260[188]
	NewTom 3G	15 × 15/20 × 20		57[178]/59[177]; 68[184]
	NewTom 9000	15 × 15		56[159]; 95[193]; 52[184]
	Newtom VGi	15 × 15		194[191]
	Skyview 3D	17 × 17	Adult; adolescent; 10 years old	87[191]; 90[183]; 105[183]
Medium FOV CBCT (>10 cm and ≤15 cm height/diameter)	3DeXAM	13 × 16	0.3 mm resolution	107[196]
	3D Accuitomo 170	10 × 14	Adolescent; 10 years old	188[183]; 237[183]
	CB Mercuray	10 × 10	Maxillofacial/TMJ imaging	283[177]; 407[184]; 603[195]/283[90]
	i-CAT Classic	13 × 16		61[159]; 105[177]; 134[186]; 69[184]
	i-CAT Next Generation	13 × 16	Adult; adolescent; 10 years old	87[184]; 83[191]; 77[190]; 82[183]; 134[183]
	NewTom VG	11 × 15	Adult; adolescent; 10 years old	83[191]; 81[183]; 114[183]
	Scanora 3D	13.5 × 14.5	Adult; adolescent; 10 years old	68[191]; 74[183]; 85[183]
Small FOV CBCT (≤10 cm height/diameter)	3DeXAM	5 × 10	Man	111[182]
		8 × 16	0.25; 0.30 resolution	170[196]; 45[196]
		4 × 16	Max 0.125 mm; 0.3 mm resolution/man 0.125 mm; 0.3 mm resolution	68[196]; 33[196]/76[196]; 38[196]
		8 × 8	0.125 mm; 0.3 mm resolution	122[196]; 62[196]
	3D Accuitomo IID	3 × 4		27[179]
	3D Accuitomo FPD	4 × 4/6 × 6		102[180]; 20[185]/43[185]; 50[180]; 166[179]

Table V. Continued

Examination	*CBCT unit*	*Scanning volume (cm^2)*	*Protocol*	E *(μSv)*[Reference]
	3D Accuitomo 170	4 × 4	Man adult; adolescent; 10 year old	43[191]; 32[183]; 28[183]
		5 × 10	Max	54[191]
		5 × 14	Max adolescent; 10 years old	70[183]; 214[183]
	AZ3000CT	7.9 × 7.1		333[182]
	i-CAT Classic	6 × 16	Man SR; HR/Mx SR; HR	96[186]; 189[186]/59[186]; 93[186]
	i-CAT Next Generation	6 × 16	Man SR; HR/Max SR; HR	74[184]; 45[191]; 58[190]; 113[190]/32[190]; 60[190]
		6 × 16	Max adolescent; 10 year old/man adolescent; 10 year old	33[183]; 43[183]/49[183]; 63[183]
	Implagraphy	5 × 8		83[182]
	KODAK 9500	5 × 15/9 × 15	Without; with filtration	93[188]; 76[188]/92[191]; 163[188]; 98[188]
	KODAK 9000 3D	5 × 3.7	Max anterior adult; 10 years old/man molar adult; adolescent	19[191]; 16[183]/40[191]; 24[183]
	Newtom VGi	8 × 12		265[191]
	Pan eXam Plus 3D	4.1 × 6.1	Max 0.133 mm; 0.2 mm resolution/man 0.133 mm; 0.2 mm resolution	79[196]; 40[196]/115[196]; 49[196]
		7.8 × 6.4	Max 0.2 mm; 0.3 mm resolution/man 0.2 mm; 0.3 mm resolution	125[196]; 79[196]/184[196]; 110[196]
	Picasso Trio	7 × 12	Low/high dose	81[191]/123[191]
	PreXion	8.1 × 7.6	High/standard resolution	388[184]/189[184]
		6 × 16	Max adolescent; 10 years old/man adolescent, 10 years old	33[183]; 43[183]/49[183]; 63[183]
	ProMax 3D	8 × 8	High/standard/low	674[179]; 652[184]; 122[191]; 306[193]/197[193]/488[184]; 30[187]; 28[191]
		8 × 8	Adolescent; 10 years old	18[183]; 28[183]
	Pax-Uni3D	5 × 5	Max anterior	44[191]
	Scanora 3D	6 × 6		91[179]
		7.5 × 10	Max/man/both	46[191]/47[191]/45[191]
		7.5 × 10	Adolescent; 10 year old	52[183]; 67[183]
	Veraviewepocs 3D	4 × 4/4 × 8/6 × 6/8 × 8		31[185]/40[185]/40[185]/73[191]

(*continued on next page*)

Table V. Continued

Examination	*CBCT unit*	*Scanning volume (cm^2)*	*Protocol*	E *(μSv)*[Reference]
MSCT	Siemens Somatom	Lower jaw/head	Head sensation 16; volume zoom 4	474[178]; 494[178]/995[178]; 1110[178]
		Lower jaw	Sensation 10; emotion 6	426[182]; 199[182]
		10 × 12	Sensation 64	430[159]; 860-534[177]
		20 × 12.8/11.7	Sensation 64 adolescent; 10 years old	1047[183]; 605[183]
	Philips Mx8000IDT		Lower jaw; head	541[178]; 1160[178]
	GE 4 Slice CT	34.8 × 25		685[179]
	GE 64 Slice CT	25 × 41.25		1410[179]
	Toshiba Aquilion 64	9 × 4		990[181]
	HiSpeed QX/I	7.7 × 15		769[180]
Panoramic	Planmeca Promax	N/A	Film; CCD	26[207]; 24.3[184]
	Planmeca PM Proline 2000	N/A	High; low dose	38[207]; 12[207]
	Veraviewepocs	15 × 10	Adolescent	6[183]
	Sirona Orthophos	DS 15 × 11; XGplus 23 × 15		10[159]; 50[181]
	Instrumentarium OP100	30 × 15		21.5[192]
Cephalometric	PSP	N/A	Lat ceph	5.6[184]
	Orthophos DS	18 × 15	Lat ceph	10[159]
	Instrumentarium OC 100	24 × 18	Lat ceph	4.5[192]
	Veraviewepocs 2D	20 × 20	Lat ceph	2[183]
	Planmeca Promax PA	N/A	PA	5.1[184]

CBCT, cone beam computed tomography; *PSP*, photo-stimulable phosphor; *CCD*, charged coupled device-based technology; *Max*, maxillary; *Man*, mandibular; *TMJ*, temporomandibular joint; *MSCT*, multi-slice computed tomography; *HR*, high resolution; *SR*, standard resolution; *Lat ceph*, lateral cephalometric image; *PA*, posteroanterior cephalometric image; *N/A*, not available.

Product/Manufacturer details: 3DeXAM (KaVo Dental GmbH, Biberach/Riβ, Germany); 3D Accuitomo 170 (J. Morita Mfg. Corp., Kyoto, Japan); CB Mercuray (Hitachi Medical Systems, Kyoto, Japan); Galileos (Sirona Dental Systems GmbH, Bensheim Germany); Galileos Comfort (Sirona Dental Systems GmbH, Bensheim Germany); i-CAT Classic (Imaging Sciences International, Hatfield, PA); i-CAT Next Generation (Imaging Sciences International, Hatfield, PA); Iluma (Imtec (3M), Ardmore, OK); Iluma Elite (Imtec (3M), Ardmore, OK); KODAK 9500 (Kodak Dental Systems, Carestream Health, Rochester, NY); NewTom 3G (Quantitative Radiology, Verona, Italy); NewTom 9000 (Quantitative Radiology, Verona, Italy); Newtom VGi (Quantitative Radiology, Verona, Italy); Skyview 3D (MyRay, Cefla Dental Group, Imola, Italy); 3DeXAM (KaVo Dental GmbH, Biberach/Riβ, Germany); 3D Accuitomo 170 (J. Morita Mfg. Corp., Kyoto, Japan); CB Mercuray (Hitachi Medical Systems, Kyoto, Japan); i-CAT Classic (Imaging Sciences International, Hatfield, PA); i-CAT Next Generation (Imaging Sciences International, Hatfield, PA); NewTom VG (Quantitative Radiology, Verona, Italy); Scanora 3D (Soredex, Tuusula, Finland); 3DeXAM (KaVo Dental GmbH, Biberach/Riβ, Germany); 3D Accuitomo IID (J. Morita Mfg. Corp., Kyoto, Japan); 3D Accuitomo FPD (J. Morita Mfg. Corp., Kyoto, Japan); 3D Accuitomo 170 (J. Morita Mfg. Corp., Kyoto, Japan); AZ3000CT (Asahi Roentgen, Kyoto, Japan); i-CAT Classic (Imaging Sciences International, Hatfield, PA); i-CAT Next Generation (Imaging Sciences International, Hatfield, PA); Implagraphy (Vatech, E-WOO Technology Co, Ltd. Republic of Korea); KODAK 9500 (Kodak Dental Systems, Carestream Health, Rochester, NY); KODAK 9000 3D (Kodak Dental Systems, Carestream Health, Rochester, NY); Newtom VGi (Quantitative Radiology, Verona, Italy); Pan eXam Plus 3D (PaloDEx Group Oy, Tuusula, Finland); Picasso Trio (Vatech, Co, Ltd. Republic of Korea); PreXion 3D (PreXion Inc., San Mateo, CA); ProMax 3D (Planmeca OY, Helsinki, Finland); Pax-Uni3D (Vatech, Technology Co, Ltd. Republic of Korea); Scanora 3D (Soredex, Tuusula, Finland); Veraview epocs 3D (J. Morita Mfg. Corp., Kyoto, Japan); Siemens Somatom (Siemens Medical Solutions USA, Malvern, PA); Philips Mx8000IDT (Philips Medical Systems, Best, the Netherlands); GE 4 slice CT (GE Medical Systems, Little Chalfont, UK); GE 64 slice CT (GE Medical Systems, Little Chalfont, UK); Toshiba Aquilion 64 (Toshiba Medical Systems Corporation, Tochigi, Japan); HiSpeed QX/I (GE Medical Systems, Little Chalfont, UK); Planmeca Promax (Planmeca, Helsinki, Finland); Planmeca PM Proline 2000 (Planmeca, Helsinki, Finland); Veraview epocs (J. Morita Mfg. Corp., Kyoto, Japan); Sirona Orthophos (Sirona Dental Systems GmbH, Bensheim Germany); Instrumentarium OP100 (Instrumentarium Dental, Tuusula, Finland); Orthophos DS (Sirona Dental Systems GmbH, Bensheim Germany); Instrumentarium OC 100 (Instrumentarium Dental, Tuusula, Finland); Veraview epocs 2D (J. Morita Mfg. Corp., Kyoto, Japan); Planmeca Promax PA (Planmeca OY, Helsinki, Finland).

Table VI. Examples of the calculation of the RRL associated with specific imaging protocols used in orthodontics

		Stage of treatment			*Dose (μSv)*		*Relative radiation level**	
Protocol	*Modality*	*Initial diagnostic*	*Mid-treatment*	*Post-treatment*	*Sub-total*	*Total*	*Child*	*Adult*
Conventional imaging	Panoramic[†]	+	+	+	36	47.2	☢☢	☢
	Lateral cephalogram[‡]	+	−	+	11.2			
Conventional + small FOV CBCT	Panoramic[†]	+	+	+	36	107.2	☢☢	☢
	Lateral cephalogram[‡]	+	−	+	11.2			
	Small FOV CBCT[§]	+	−	−	60			
Large FOV CBCT + conventional imaging	Panoramic[†]	−	+	+	24	112.6	☢☢	☢☢
	Lateral cephalogram[‡]	−	−	+	5.6			
	Large FOV CBCT[‖]	+	−	−	83			
Large FOV CBCT	Large FOV CBCT[‖]	+	+	+	249	249	☢☢	☢☢

CBCT, cone beam computed tomography; *FOV*, field of view; *CCD*, charged coupled device technology; *Sub-total*, product of the times when the modality is used at each stage over a course of treatment by the average effective dose per modality exposure; *Total*, sum of subtotals for a particular orthodontic imaging protocol.

*American College of Radiology relative radiation level[203]; ☢, child (<30 μSv), adult (<100 μSv); ☢☢, child (<30-300 μSv), adult (100-1000 μSv).

[†]Planmeca PM Proline 2000 (low dose) − charged coupled device (12 μSv).[207]

[‡]Photostimulable storage phosphor (5.6 μSv).[177]

[§]i-CAT Next Generation − Maxilla 6 cm FOV height, high resolution (60 μSv).[190]

[‖]i-CAT Next Generation − 16 × 13 cm (83 μSv).[191]

without CBCT imaging for representative orthodontic imaging protocols (Table VI).

4. Maintain professional competency in performing and interpreting CBCT studies

Orthodontists must be able to exercise judgment by applying professional standards to all aspects of CBCT. Any radiographic image prescribed and/or performed by a dental practitioner may contain information that is important to the management or general health of the patient. Incidental findings in CBCT images of orthodontic patients are common,[209-213] and some are critical to patient health.[214] Clinicians who order or perform CBCT for orthodontic patients are responsible for interpreting the entire image volumes, just as they are responsible for interpreting all regions of other radiographic images that they order.[215,216]

Based on these considerations, the following recommendations are related to performing and interpreting CBCT studies:

Recommendation 4.1. Clinicians have an obligation to attain and improve their professional skills through lifelong learning in regards to performing CBCT examinations as well as interpreting the resultant images. Clinicians need to attend continuing education courses (such as those offered by the American Dental Association Continuing Education Recognition Program) to maintain familiarity with the technical and operational aspects of CBCT and to maintain current knowledge of scientific advances and health risks associated with the use of CBCT.

Recommendation 4.2. Clinicians have legal responsibilities when operating CBCT equipment and interpreting images and are expected to comply with all governmental and third party payer (e.g., Medicare) regulations.

Recommendation 4.3. It is important that patients/guardians know about the limitations of CBCT with regard to visualization of soft tissues, artifacts and noise.

EMERGING DEVELOPMENTS

CBCT acquisition technology continues to develop and a number of innovations are proposed to improve image quality, increase utility and reduce radiation output. These include the use of automatic exposure control with photon counting, added filtration, flat panel detectors with greater photon sensitivity, customizable FOV collimation, variable exposure parameters (mA, kVp) and image quality settings (e.g., scan trajectory options and number of basis images). The image quality and dose reductions purported by such innovations should be assessed critically and verified by independent published research.

SUMMARY

The recommendations provided for the use of CBCT in orthodontics are neither rigid guidelines nor do they represent or imply a standard of care. While it is the responsibility of each practitioner to make a decision, along with the patient/family, as to what imaging is considered to be in the patient's best interest, this

position statement is intended to assist the clinician in the decision making process.

This position statement supports and affirms the position of the American Dental Association Council on Scientific Affairs in that the selection of CBCT imaging should be based on initial clinical evaluation and must be justified based on individual need.[6] The perceived or actual benefits to the patient must outweigh the radiation risks. Exposure of patients to ionizing radiation must never be considered "routine." It is important to perform a thorough clinical examination prior to performing or ordering any radiographic study. This position statement provides four guidelines for CBCT use in orthodontic practice: 1) Image appropriately by applying imaging selection recommendations, 2) Assess the radiation dose risk, 3) Minimize patient radiation exposure and, 4) Maintain professional competency in performing and interpreting CBCT studies.

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APPENDIX A: DIAGNOSTIC USES OF CBCT IN ORTHODONTICS

Dental structural anomalies

These comprise assessments of variations in tooth morphology, hypodontia, retained primary teeth, supernumeraries/gemination/fusion, root abnormalities, and external and internal resorption.[21-32]

Anomalies in dental position

These include dental impactions, presence of unerupted and impacted supernumeraries, locations of molars in relation to the inferior alveolar canals, anomalies in eruption sequences, and ectopic eruptions (including teeth in clefts).[14,22,27,33-50]

Compromised dento-alveolar boundaries

The assessment of dento-alveolar volume (in addition to that which can be determined by clinical examination and study models) is needed when there is reduced buccal/lingual alveolar width, bimaxillary protrusion, compromised periodontal status, and/or clefts of the alveolus.[51-56]

Asymmetry

Clinically, asymmetry presents as chin or mandibular deviation, dental midline deviation, and/or occlusal cant discrepancies as well as other dental and craniofacial asymmetries.[57-64]

Anteroposterior discrepancies

These are skeletally based Class II and Class III malocclusions.[59,60,62,65-73]

Vertical discrepancies

Initial facial patterns assessed clinically or radiographically may suggest skeletal discrepancies related to vertical maxillary deficiency or excess and may present as anterior open bite or deep overbite.[67,74]

Transverse discrepancies

These anomalies may be present as either skeletal lingual or buccal crossbites or discrepancies without the

presence of crossbites in which there is excessive dental compensation of the bucco-lingual inclination of posterior teeth.[67,75,76]

Temporomandibular joint (TMJ) signs and/or symptoms

TMJ pathoses that result in alterations in the size, form, quality and spatial relationships of the osseous joint components may lead to skeletal and dental discrepancies in the three planes of space. In affected condyles, perturbed resorption and/or apposition can lead to progressive bite changes and compensations in the maxilla. In addition, tooth position, occlusion and the articular fossa of the non-affected side of the mandible can become involved. The sequelae of these changes are unpredictable orthodontic outcomes. Such TMJ conditions include developmental disorders such as condylar hyperplasia, hypoplasia, or aplasia, arthritic degeneration, persistently symptomatic joints, and bite changes including progressive bite opening and limitation or deviation upon opening or closing.[77-96]

Dentofacial deformities and craniofacial anomalies

CBCT imaging can facilitate analysis of these conditions and be used to simulate virtual treatments and plan orthopedic corrections and orthognathic surgeries. Computer-aided jaw surgery is increasing in use clinically because virtual plans accurately represent surgical procedures in the operating room.[65,66,68-73,97-109]

Conditions that affect airway morphology

A number of authors have used CBCT imaging to measure airway dimensions and reported changes over time with specific therapies including orthognathic surgery and particularly obstructive sleep apnea.[18,111-131] There are challenges in the use of CBCT clinically as the validity of such measurements may vary.[132,133] The boundaries of the nasopharynx with the maxillary/paranasal sinuses and of the oropharynx with the oral cavity are often not consistent among subjects and image acquisitions, and airway shapes and volumes vary markedly with dynamic processes such as breathing and head postures.

In addition, CBCT has been reported useful in preoperative assessment and/or postoperative evaluation of treatment outcomes for specific research applications including:

Specific surgical procedures

Research in the areas of craniofacial growth and development as well as assessments of the short- and long-term outcomes of various treatment regimens has the potential to benefit from CBCT assessments of longitudinal changes and diagnostic characterization of tooth and facial morphology of hard and soft tissues. Studies on the morphological basis for craniofacial growth and response to treatment can help elucidate clinical questions on variability of outcomes of treatment, as well as clarify treatment effects and areas of bone remodeling and displacement.

Orthodontic mini-implants used as temporary anchorage devices

Numerous authors have identified CBCT imaging as being clinically useful in identifying optimal site location for placement of orthodontic mini-implants.[67,75,134-151]

Maxillary expanders

CBCT imaging of maxillary transverse deficiencies treated with fixed and removable expanders has been reported of benefit in characterizing appliance specific skeletal displacement, associated dental effects and quantifying changes in skeletal dimensions of the nasal cavity and maxillary sinus volume.[51,152-158]

APPENDIX B: RATIONAL FOR ORTHODONTIC IMAGE SELECTION RECOMMENDATIONS

The recommendations in Table III are based upon the complexity of the orthodontic case. The following were considered in developing the recommendations.

Selection of clinical conditions for indications of CBCT use

The most common clinical dental and skeletal conditions in the orthodontic patient are presented as column headings in Table III.

Definition of orthodontic treatment difficulty criteria

The panel acknowledges the uniqueness of the facial form of each patient and the inherent difficulty in attempting to assess the severity of malocclusion and quantifying and categorizing orthodontic treatment need. For patients with severe malocclusions, there are, however, more choices with regard to appropriate orthodontic treatments, and there is an increased need for radiographic diagnostic input. For Table III, malocclusion severity was categorized and anticipated appropriateness of CBCT imaging was listed according to three levels of patient presentation:

Mild. Patients present with dental malocclusions, with or without minimal anteroposterior, vertical, or transverse skeletal discrepancies. These patients are treated usually with conventional biomechanics (with or without extraction). CBCT imaging is likely

inappropriate for these patients unless they present with the additional clinical conditions noted.

Moderate. Patients present with dental and skeletal discrepancies that are treated orthodontically and/or orthopedically only. These discrepancies include bimaxillary proclination, open bite, and compensated Class III malocclusion. CBCT imaging is possibly indicated for many of these patients as indicated.

Severe. Patients present with skeletal conditions including, but not limited to complicated skeletal discrepancies, craniofacial anomalies (e.g., cleft lip and palate, craniofacial synostosis, etc.), sleep apnea, speech disorders, and post oncology/trauma/resection/pathology. For patients in this group, a team approach for treatment is used including speech therapy, clinical psychology, orthodontic and surgical interventions. Advanced imaging, including CBCT, may be indicated for many of these patients.

Selection of FOV

There is limited published research on the many and varied technical issues associated with CBCT imaging in orthodontics including optimal fields of view (image sizes) for specific diagnostic tasks, optimal exposure settings (some tasks may require lower exposures than others), and variations in the levels of ionizing radiation used (for similar tasks) with various CBCT systems. More specific and additional issues and controversies related to CBCT use include: 1) the necessary diagnostic quality of images[205]; 2) imperfect superimposition of CBCT and surface-scan data; 3) differing levels of exposure needed to determine root and bone morphology related to appliance construction or for the diagnosis of pathology; 4) indications for use of multiple CBCT scans; 5) lack of and utility of 3D norms; 6) impact of CBCT for the assessment of treatment outcome; 7) responsibility for the identification of clinically significant incidental pathology; and 8) responsibility for calibration and maintenance of the equipment.[203]

Assessment of progress and treatment outcomes

In complex cases, follow-up CBCT acquisitions for growth observation, assessment of treatment progress, and posttreatment analysis may be helpful. Any imaging protocol for the longitudinal quantitative assessment of the craniofacial complex requires methods to: 1) minimize the radiation dose from sequential multiple CBCT exposures; 2) construct accurate three-dimensional surface models; 3) reliably image registration (non-rigid, elastic and deformable; or rigid registration) using stable structures of reference for cranial base or regional superimpositions; and 4) quantify changes over time.

Age considerations

The choice of radiographic imaging method of a patient with clinically determined dental and/or skeletal modifying factors is dependent on the stage of growth of the individual and age-related presentation of the condition; therefore, recommendations for CBCT for some dental/skeletal conditions are age dependent. These conditions include:

Tooth structural anomalies. A CBCT examination may be indicated when other diagnostic modalities indicate a problem with root morphology or resorption in the mixed and permanent dentitions.

Tooth positional or eruption anomalies. A possible indication for a CBCT examination (in addition to periapical, occlusal and/or panoramic images) exists when interceptive orthodontic treatment is being considered for children between the ages of 5-11. In such cases, a small FOV should be used. Another possible indication for a CBCT examination (usually restricted or small FOV) is for children more than 11 years of age if surgical exposure is being considered as a treatment option and the location of the crown cannot be determined clinically or with conventional 2D images (e.g., panoramic, occlusal and/or periapical images).

Craniofacial anomalies. An additional possible indication for CBCT is in children (0-4 years) prior to mandibular distraction or other craniofacial surgical treatments if the children can remain motionless during the scans. For children between 5 and 11 years of age, CBCT is useful for locating developing teeth prior to alveolar bone grafting and Phase I orthodontic treatment for children with oral clefts. For these cases, limited fields of views may suffice. For patients older than 11 and comprehensive orthodontic treatments are required in preparation for craniofacial surgical procedures, CBCT may provide a benefit at the diagnostic stage of orthodontic treatment as well as immediately before the surgical procedures. Such decisions are case specific.

APPENDIX C: CALCULATION OF RRL FOR ORTHODONTIC IMAGING

Table VI provides four orthodontic imaging protocols and provides RRLs[168,203] and published effective doses. For example, if a typical imaging protocol incorporates three digital (Planmeca PM Proline 2000 [low dose]) panoramic images (initial- diagnostic-, mid- and post-treatment; 12 μSv[207] for each exposure = 36 μSv) and two digital (photo-stimulable storage phosphor) lateral cephalometric images (initial- and post-treatment; 5.6 μSv[177] for each exposure = 11.2 μSv) the total equivalent dose for the orthodontic series is 47.2 μSv. For an adult this represents an RRL of ☮ whereas for

a child this represents an RRL of ☢☢. This can be compared to orthodontic imaging series incorporating a large FOV CBCT (i-CAT Next Generation [16 × 13 cm]) image (initial; 83 μSv[191]), two digital (Planmeca PM Proline 2000 [low dose][206]) panoramic images (mid- and post-treatment; 12 μSv[207] for each exposure = 24 μSv) and one digital (photo-stimulable storage phosphor) lateral cephalometric image (post-treatment; 5.6 μSv[177]). The equivalent dose for this orthodontic imaging series is 112.6 μSv. While radiation risk (RRL) using CBCT in this example is for both the adult and child is the same (☢☢), this protocol provides over twice the absolute dose than the conventional imaging series and elevates the risk of the adult into a higher category.

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Use of cone-beam computed tomography in endodontics

Joint Position Statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology

INTRODUCTION

The American Association of Endodontists (AAE) and the American Academy of Oral and Maxillofacial Radiology (AAOMR) have jointly developed this position statement. It is intended to provide scientifically based guidance to clinicians regarding the use of cone beam computed tomography (CBCT) in endodontic treatment as an adjunct to planar imaging. This document will be periodically revised to reflect new evidence.

Endodontic disease adversely affects quality of life and can produce significant morbidity in afflicted patients. Radiography is essential for the successful diagnosis of odontogenic and non-odontogenic pathoses, treatment of the pulp chamber and canals of a compromised tooth, biomechanical instrumentation, evaluation of final canal obturation, and assessment of healing.

Until recently, radiographic assessments in endodontic treatment have been limited to intraoral and panoramic radiography. These radiographic technologies provide two-dimensional representations of three-dimensional tissues. If any element of the geometric configuration is compromised, the image can demonstrate errors.[1] In more complex cases, radiographic projections with different beam angulations can allow parallax localization. However, complex anatomy and surrounding structures can make interpretation of planar "shadows" difficult.

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CONE BEAM COMPUTED TOMOGRAPHY

The advent of CBCT has made it possible to visualize the dentition, the maxillofacial skeleton, and the relationship of anatomic structures in three-dimensions.[2] Significantly increased use of CBCT is evidenced by a recent Web-based survey of active AAE members in the U.S. and Canada which found that 34.2% of 3,844 respondents indicated that they were utilizing CBCT. The most frequent use of CBCT among the respondents was for diagnosis of pathosis, preparation for endodontic treatment or endodontic surgery, and for assistance in the diagnosis of trauma related injuries.[3]

CBCT, as with any technology, has known limitations. There are also numerous CBCT equipment manufacturers and models available. In general, CBCT can be categorized into large, medium, and limited volume units based on the size of their "field of view."

Volume Size(s)

The size of the "field of view" or FOV describes the scan volume of CBCT machines and is dependent on the detector size and shape, beam projection geometry and the ability to collimate the beam. Beam collimation limits the x-radiation exposure to the region of interest and ensures that an optimal FOV can be selected based on disease presentation. Smaller scan volumes generally produce higher resolution images, and since endodontics relies on detecting disruptions in the periodontal ligament space measuring approximately 200μm, optimal resolution is necessary.[4]

The principal limitation of large FOV cone beam imaging is the size of the field irradiated. Unless the smallest voxel size is selected in these larger FOV machines, there is also reduced resolution compared to intraoral radiographs or limited-volume CBCT machines with inherent small voxel sizes. The limited volume CBCT imaging in endodontics is advantageous, but by irradiating only one site or area, projections acquired may not contain the entire region of interest. Reconstructed images may suffer from truncation artifacts[5] when comparing medical CT with CBCT reconstructed images; medical CT scans provide the most suitable images for tumor-derived alterations due to their capacity for soft tissue visualization.[6]

For most endodontic applications, limited volume CBCT is preferred over large volume CBCT for the following reasons:

1. Increased spatial resolution to improve the accuracy of endodontic-specific tasks such as the visualization of small features including accessory canals, root fractures, apical deltas, calcifications, etc.
2. Highest possible spatial resolution that provides a diagnostically acceptable signal-to-noise ratio for the task at hand.
3. Decreased radiation exposure to the patient.
4. Time savings due to smaller volume to be interpreted.

Dose Considerations

Every effort should be made to reduce the effective radiation dose to the patient for endodontic-specific tasks. Using the smallest possible FOV, the smallest voxel size, the lowest mA setting and the shortest exposure time in conjunction with a pulsed exposure mode of acquisition is recommended. If extension of pathology beyond the area surrounding the tooth apices or a multifocal lesion with possible systemic etiology is suspected, and/or a non-endodontic cause for devitalization of the tooth is established clinically, appropriate larger field of view protocols may be employed on a case-by-case basis. Interpretation of the entire acquired volume will be essential to justify the use of task-specific modification of acquisition protocol in such cases. CBCT has a significant advantage over medical grade CT as radiation doses from commonly used CBCT acquisition protocols are lower by an order of magnitude.[7] Selection of the most appropriate imaging protocol for the diagnostic task at hand is paramount.

Patient Selection Criteria

CBCT must not be used routinely for endodontic diagnosis or for screening purposes in the absence of clinical signs and symptoms. The patient's history and clinical examination must justify the use of CBCT by demonstrating that the benefits to the patient outweigh the potential risks. Clinicians should use CBCT only when the need for imaging cannot be answered adequately by lower dose conventional dental radiography or alternate imaging modalities.

Patient Consent

Significant risks, benefits and alternatives of special importance should be explained by disclosure and patient education and then documented in patient's record. The use of CBCT will expose the patient to ionizing radiation that may pose elevated risks to some patients (*e.g.*, cases of pregnancy, previous treatment with ionizing radiation and younger patients). Patients should be informed that CBCT volumes cannot be relied upon to show soft-tissue lesions unless they have caused changes in hard tissues (teeth and bone), and some of the images may contain artifacts that can make interpretation difficult.

A patient may understand the relevant facts and implications of not following a recommended diagnostic or therapeutic action and still refuse the proposed intervention. This is known as the medico-legal concept of "informed refusal" and is recognized in certain state laws and court decisions.[8] Should a patient be incapable of understanding or responding to an informed consent presentation or be a minor, the informed consent or informed refusal should be documented in the patient's record and signed by an individual legally responsible for the patient. If a legally responsible individual is not available, a witness should acknowledge in writing that the informed consent or refusal process took place.

Interpretation

Clinicians ordering a CBCT are responsible for interpreting the entire image volume, just as they are for any other radiographic image. Any radiograph may demonstrate findings that are significant to the health of the patient. There is no informed consent process that allows the clinician to interpret only a specific area of an image volume. Therefore, the clinician can be liable for a missed diagnosis, even if it is outside his/her area of practice.[9] Any questions by the practitioner regarding image data interpretation should promptly be referred to a specialist in oral and maxillofacial radiology.

Protection Of Patients and Office Personnel

At this time, all CBCT equipment produce dose levels and beam energies that are higher than conventional dental radiography, requiring extra practical pro-

tection measures for office personnel. Appropriate qualified experts should be consulted prior to and after installation to meet state and federal requirements, and manufacturer's recommended calibration routines should be conducted at the recommended intervals.

RECOMMENDATIONS

The decision to order a CBCT scan must be based on the patient's history and clinical examination, and justified on an individual basis by demonstrating that the benefits to the patient outweigh the potential risks of exposure to X-rays, especially in the case of children or young adults. CBCT should only be used when the question for which imaging is required cannot be answered adequately by lower dose conventional dental radiography or alternate imaging modalities. Initial studies regarding the use of CBCT for a variety of endodontic related imaging tasks have demonstrated the effectiveness and comparability of CBCT to conventional radiography.[10-16] In general, the use of CBCT in endodontics should be limited to the assessment and treatment of complex endodontic conditions such as:

- Identification of potential accessory canals in teeth with suspected complex morphology based on conventional imaging.
- Identification of root canal system anomalies and determination of root curvature.
- Diagnosis of dental periapical pathosis in patients who present with contradictory or nonspecific clinical signs and symptoms, who have poorly localized symptoms associated with an untreated or previously endodontically treated tooth with no evidence of pathosis identified by conventional imaging, and in cases where anatomic superimposition of roots or areas of the maxillofacial skeleton is required to perform task-specific procedures.
- Diagnosis of non-endodontic origin pathosis in order to determine the extent of the lesion and its effect on surrounding structures.
- Intra- or post-operative assessment of endodontic treatment complications, such as overextended root canal obturation material, separated endodontic instruments, calcified canal identification, and localization of perforations.
- Diagnosis and management of dento-alveolar trauma, especially root fractures, luxation and/or displacement of teeth, and alveolar fractures.
- Localization and differentiation of external from internal root resorption or invasive cervical resorption from other conditions, and the determination of appropriate treatment and prognosis.
- Pre-surgical case planning to determine the exact location of root apex/apices and to evaluate the proximity of adjacent anatomical structures.
- Dental implant case planning when cross-sectional imaging is deemed essential based on the clinical evaluation of the edentulous ridge.

SUMMARY

All radiographic examinations must be justified on an individual needs basis whereby the benefits to the patient of each exposure must outweigh the risks. In no case may the exposure of patients to X-rays be considered "routine," and certainly CBCT examinations should not be done without initially obtaining a thorough medical history and clinical examination. CBCT should be considered an adjunct to two-dimensional imaging in dentistry. Limited field of view CBCT systems can provide images of several teeth from approximately the same radiation dose as two periapical radiographs, and they may provide a dose savings over multiple traditional images in complex cases.

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EDITORIAL

Image gently: enhancing radiation protection during pediatric imaging

The amount of radiation that people receive from health care sources has been increasing, and this includes children. It also includes dental patients. While it is difficult to show directly that diagnostic radiation leads to cancer in a particular individual, x-radiation is a carcinogen according to the US Food and Drug Administration, and there are good population data to indicate that there are increased cancers in people who have been exposed to radiation at levels that can be encountered during diagnostic imaging procedures. This is particularly important for children, whose tissues are more radiosensitive and whose life expectancy provides a longer time to develop cancers resulting from radiation exposure. The risk is small in proportion to the natural risk of cancer of 1 in 5, and it is estimated to be in the range of 1 in 1000 for an abdominal CT in childhood that is beyond the upper limit of exposure from dental radiographic procedures. The risk is cumulative, however, and each subsequent exposure will increase the risk accordingly. While for any one individual the increased risk is very small, given the large number of diagnostic x-ray exposures performed, the risk to the population as a whole is worth considering.

For this reason, the Alliance for Radiation Safety in Pediatric Imaging was founded in 2008; it is more familiarly known as "Image Gently." The founding members were the Society for Pediatric Radiology, the American Association of Physicists in Medicine, the American College of Radiology, and the American Society of Radiologic Technologists. The Alliance now has more than 80 organizations as members. There are an increasing number of organizations in dentistry joining the alliance, the first being the American Academy of Oral and Maxillofacial Radiology, which joined during my presidency of that organization in 2010. Subsequently, the European Academy of DentoMaxillofacial Radiology and the Canadian Association of Oral and Maxillofacial Radiology signed up. The "Image Gently Alliance" is endorsed by the American Dental Association's Council on Scientific Affairs, and the ADA is an Image Gently Alliance member organization. Among the dental specialty organizations in addition to those in radiology, the Image Gently Alliance includes the American Academy of Pediatric Dentistry, the American Academy of Periodontology, the American Association of Endodontists, the American Association of Oral and Maxillofacial Surgeons, and the American Academy of Oral and Maxillofacial Pathology. The American Dental Education Association has also endorsed Image Gently and is participating in preparations for an Image Gently dental initiative that is set to be launched in September 2014. Any professional organization in dentistry that has not yet formally joined Image Gently is urged to do so. Individual dentists and dental specialists are urged to take the Image Gently pledge online at http://imagegently.dnnstaging.com/Home.aspx. There is no membership fee for professional societies in the health sciences to join the Alliance, and pledging to Image Gently is also free for individuals. The aforementioned website also provides educational materials for practitioners and for parents. It is a useful resource.

Radiation safety is a balancing act between risks and benefits. In situations where, according to the published evidence, there is unlikely to be a diagnostic benefit, the risks, however small, are still excessive. If an image or image volume is needed for diagnostic purposes, then it can also be used for secondary purposes. However, if there is no likely diagnostic benefit, then, for example, substituting ionizing radiation in cone beam computed tomography for impression materials or visible light scanning would be inappropriate.

There are 2 basic imaging principles. First, use professional judgment in selecting necessary imaging based on individual patient needs. These can only be defined once the practitioner has reviewed the patient health and dental history, reviewed the chief complaint, and then clinically examined the patient. Radiographs should not be made "routinely," nor without professional assessment and prescription. Second, use ionizing radiation dosages that are as low as reasonably achievable, but never so low that diagnostic quality is lost. If a radiograph or image volume is needed, then it should be made using parameters that do not inhibit the value of the resulting image for diagnosis. If there are suitable alternatives to using ionizing radiation, then these should be considered.

One size does not fit all…so when we image children, let's image gently! Sign the pledge and call upon your professional group to join the Image Gently Alliance if they have not yet done so.

Allan G. Farman
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NCRP SC 4-5
Radiation Protection in Dentistry: Cone Beam CT, Digital Imaging, and Hand-Held X-Ray Units

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Supplement vs Report

- Original concept– Supplement
- However—
  - NCRP 145 published in 2003
  - Some changes in all areas
    - Updates needed
  - Some areas continue to be problems, e.g., high speed film and photographic processing
- Recommending new report: revision with three new sections

Target Audience

- Primary care dentists
- Dental and maxillofacial radiologists
- Head and neck radiologists
- ENT physicians
- Medical physicists
- Radiographers and imaging technologists
- Dental assistants and hygienists
- Dental radiologic technicians
- Equipment manufacturers and suppliers
- State regulators
- Relevant federal agency representatives

Primary Topics

Need?

- CBCT, digital radiography, and hand-held x-ray units in wide use
- No formal guidelines on safe and effective use in US
- Every dental practitioner acts as an independent radiologist
- CBCT installed as "plug and play" devices
  - Perceived not as CT but exotic panoramic units
  - Many states classify same as intraoral units

Topics

- CBCT including patient selection criteria
- Digital radiography
- Hand-held x-ray units
- Use of high-speed film
- Under-processing of intraoral dental film
- New data from NEXT surveys
- Synopsis of current standards
- Organizations and their roles, e.g., Image Gently

CBCT, Digital Radiography, and Hand-Held X-Ray Units

- Executive summary
- General information
- Equipment and facilities, protection of patients and staff, measurements and dose
- Administrative and regulatory considerations
- Education and training
- Summary and conclusions
- References
- Glossary
- Appendices

Timing

18 to 24 months (Summer, 2015)
Influenced by availability of NEXT data

Cone Beam CT

Cone Beam CT Effective Dose

Modality	Effective Dose (μSv)
Intraoral	1.5
Panoramic	24
CBCT	48 – 1,073
CT Scan (dental program)	534 – 2,100

Concerns About CBCT

- Need referral criteria—being used inappropriately
- CBCT units in wide use— 5,000 today;
  - 15,000 projected in five years (only dental)
  - Others– ENT, extremity, ???
- No formal guidelines on safe and effective use in US
- Every dental practitioner acts as an independent radiologist
- CBCT installed as “plug and play” devices
  - Perceived not as CT but exotic panoramic units
  - Many states classify same as intraoral units

Computed Radiography

Photostimulable phosphor plate

Use similar to film

Plate placed in laser scanner to obtain digital image

One unit can support several rooms

Digital (or Direct) Radiography

Charge-coupled device (CCD) or complimentary metal oxide semiconductors (CMOS)

Digital data directly through USB cable to computer

Relatively costly, one or two rooms

Adoption of Digital Radiography

Digital radiography is *NOT* replacing *film* radiography as rapidly as in medical imaging

25% to 45% of dental facilities using digital intraoral imaging (depending on state)

5% to 35% of those using digital use CR (depending on state)

Hand-Held X-Ray Units

Minimal concerns with appropriate design and use

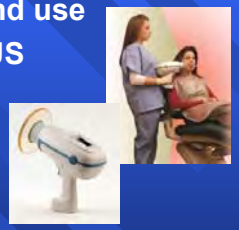
15,000 in use today in US

Original concern—

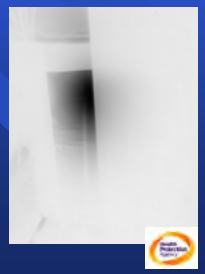
Holding x-ray tube

Not all hand-helds are created equal!

No formal guidelines on safe and effective use in US



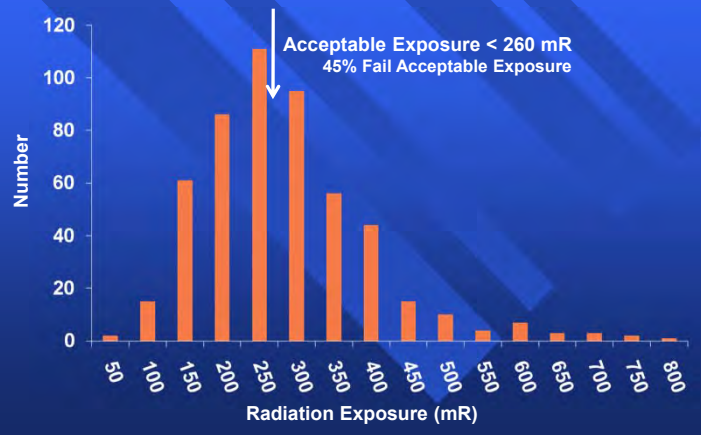
All Hand-Helds Not Created Equal



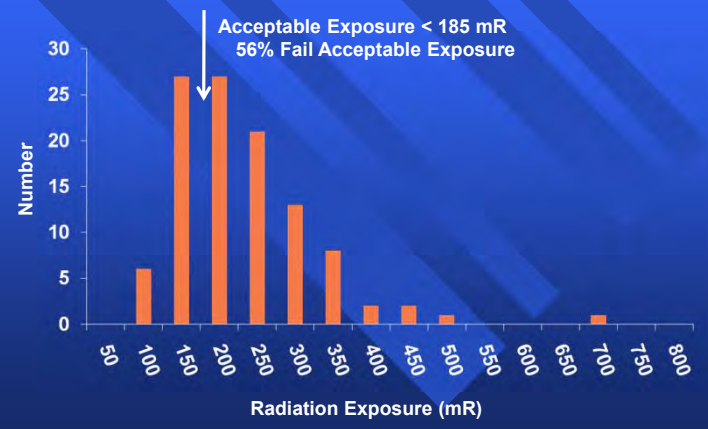
Dental Intraoral Skin Doses

D-speed film– 2 mGy
F-speed film– 1 mGy
Computed radiography (PSP) plates– 1 to 1.25 mGy
Direct radiography (CDC or CMOS)– 0.5 to 1.0 mGy

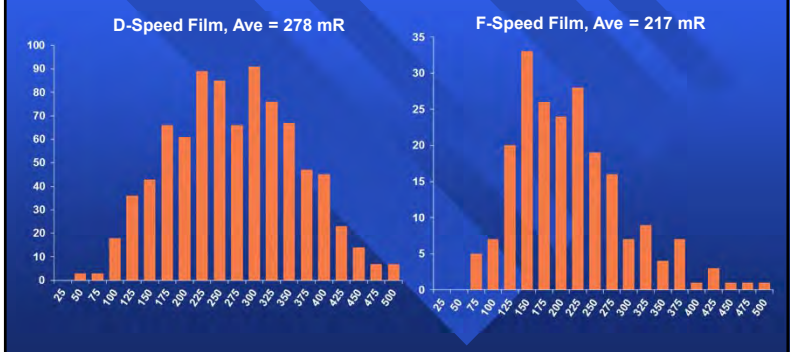
Patient Radiation Exposure (mR) D-Speed Film



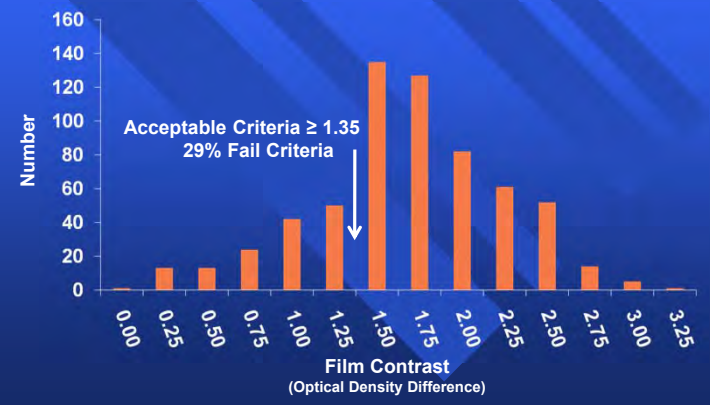
Patient Radiation Exposure (mR) E-F-Speed Film



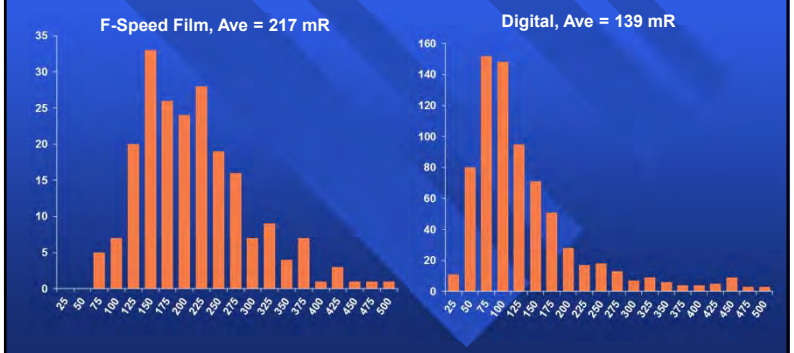
Entrance Exposure
D- vs F-Speed Film



Film Contrast



Entrance Exposure
F-Speed Film vs Digital



Funding

- American Academy of Oral and Maxillofacial Radiology (AAOMR)
- American Board of Radiology Foundation (ABRF)
- American Dental Education Association (ADEA)
- US Food and Drug Administration
- Solicitations for support being sought from other dental specialty groups and health care organizations

NCRP

National Council on Radiation Protection & Measurements

209 **Division 21**

210 **818-021-0011**

211

212 **Application for License to Practice Dentistry Without Further Examination**

213

214 (1) The Oregon Board of Dentistry may grant a license without further examination to a dentist
215 who holds a license to practice dentistry in another state or states if the dentist meets the
216 requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory
217 evidence of:
218 (a) Having graduated from a school of dentistry accredited by the Commission on Dental
219 Accreditation of the American Dental Association; or
220 (b) Having graduated from a dental school located outside the United States or Canada,
221 completion of a predoctoral dental education program of not less than two years at a dental
222 school accredited by the Commission on Dental Accreditation of the American Dental
223 Association or completion of a postdoctoral General Dentistry Residency program of not less
224 than two years at a dental school accredited by the Commission on Dental Accreditation of the
225 American Dental Association, and proficiency in the English language; and
226 (c) Having passed the dental clinical examination conducted by a regional testing agency or by
227 a state dental licensing authority; and
228 (d) Holding an active license to practice dentistry, without restrictions, in any state; including
229 documentation from the state dental board(s) or equivalent authority, that the applicant was
230 issued a license to practice dentistry, without restrictions, and whether or not the licensee is, or
231 has been, the subject of any final or pending disciplinary action; and
232 (e) Having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of
233 the United States, the United States Public Health Service or the United States Department of
234 Veterans Affairs for a minimum of 3,500 hours in the five years immediately prior to application.
235 **For dentists employed by a dental education program, documentation from the dean or**
236 **appropriate administration of the institution regarding length and terms of employment,**
237 **the applicant's duties and responsibilities, the actual hours involved in teaching all**
238 **disciplines of clinical dentistry, and any adverse actions or restrictions**; and
239 (f) Having completed 40 hours of continuing education in accordance with the Board's
240 continuing education requirements contained in these rules within the two years immediately
241 preceding application.
242 (2) Applicants must pass the Board's Jurisprudence Examination.

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(3) A dental license granted under this rule will be the same as the license held in another state; i.e., if the dentist holds a general dentistry license, the Oregon Board will issue a general (unlimited) dentistry license. If the dentist holds a license limited to the practice of a specialty, the Oregon Board will issue a license limited to the practice of that specialty. If the dentist holds more than one license, the Oregon Board will issue a dental license which is least restrictive.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.060, 679.065, 679.070, 679.080 & 679.090

Hist.: OBD 4-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 4-2001, f. & cert. ef. 1-8-01; OBD 12-2001(Temp), f. & cert. ef. 1-9-01 thru 7-7-01; OBD 14-2001(Temp), f. 8-2-01, cert. ef. 8-15-01 thru 2-10-02; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 1-2002(Temp), f. & cert. ef. 7-17-02 thru 1-12-03; Administrative correction 4-16-03; OBD 1-2003, f. & cert. ef. 4-18-03; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

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818-021-0025

Application for License to Practice Dental Hygiene Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dental hygienist who holds a license to practice dental hygiene in another state or states if the dental hygienist meets the requirements set forth in ORS 680.040 and 680.050 and submits to the Board satisfactory evidence of:

(a) Having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) ~~Evidence of h~~**Having** passed the clinical dental hygiene examination conducted by a regional testing agency or by a state dental or dental hygiene licensing authority; and

(d) Holding an active license to practice dental hygiene, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dental hygiene, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

(e) Having conducted licensed clinical practice in Oregon, in other states or in the Armed Forces of the United States, the United States Public Health Service, the United States Department of Veterans Affairs, or teaching all disciplines of clinical dental hygiene at a dental hygiene education program accredited by the Commission on Dental Accreditation of the American Dental Association for a minimum of 3,500 hours in the five years immediately preceding application. For dental hygienists employed by a dental hygiene program, documentation from the dean or appropriate administration of the institution regarding length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching all disciplines of clinical dental hygiene, and any adverse actions or restrictions; and

(f) Having completed 24 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

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Stat. Auth.: ORS 680

Stats. Implemented: ORS 680.040, 680.050, 680.060, 680.070 & 680.072

Hist.: OBD 4-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 4-2001, f. & cert. ef. 1-8-01; OBD 12-2001(Temp), f. & cert. ef. 1-9-01 thru 7-7-01; OBD 14-2001(Temp), f. 8-2-01, cert. ef. 8-15-01 thru 2-10-02; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 1-2002(Temp), f. & cert. ef. 7-17-02 thru 1-12-03; Administrative correction 4-16-03; OBD 1-2003, f. & cert. ef. 4-18-03; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 4-2011, f. & cert. ef. 11-15-11

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Division 42

818-042-0020

Dentist and Dental Hygienist Responsibility

(1) A dentist is responsible for assuring that a dental assistant has been properly trained, has demonstrated proficiency, and is supervised in all the duties the assistant performs in the dental office. Unless otherwise specified, dental assistants shall work under indirect supervision in the dental office.

(2) A dental hygienist who works under general supervision may supervise ~~a~~ dental assistant**s** in the dental office if the dental assistant**s** ~~is~~ **are** rendering assistance to the dental hygienist in providing dental hygiene services and the dentist is not in the office to provide indirect supervision. A dental hygienist with an Expanded Practice Permit may hire and supervise ~~a~~ dental assistant**s** who will render assistance to the dental hygienist in providing dental hygiene services.

(3) The supervising dentist or dental hygienist is responsible for assuring that all required licenses, permits or certificates are current and posted in a conspicuous place.

(4) Dental assistants who are in compliance with written training and screening protocols adopted by the Board may perform oral health screenings under general supervision.

Stat. Auth.: ORS 679 & 680

Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 2-2012, f. 6-14-12, cert. ef. 7-1-12

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818-042-0120

Certification by Credential

(1) Dental Assistants who wish to be certified by the Board in Radiologic Proficiency or as Expanded Function Dental Assistants, ~~or as~~ Expanded Function Orthodontic Dental Assistants**, or as Expanded Function Preventive Dental Assistants** shall:

(a) Be certified by another state in the functions for which application is made. The training and certification requirements of the state in which the dental assistant is certified must be substantially similar to Oregon's requirements; or

(b) Have worked for at least 1,000 hours in the past two years in a dental office where such employment involved to a significant extent the functions for which certification is sought; and

(c) Shall be evaluated by a licensed dentist, using a Board approved checklist, to assure that the assistant is competent in the expanded functions.

(2) Applicants applying for certification by credential in Radiologic Proficiency must obtain certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, of having successfully completed training equivalent to that required by OAR 333-106-0055 or approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.020, 679.025 & 679.250

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

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348 **818-042-XXXX**

349

350 **Expanded Functions - Preventive Dental Assistants (EFPDA)**

351

352 **The following duties are considered Expanded Function Preventive Duties and may be**
353 **performed only after the dental assistant complies with the requirements of 818-042-**
354 **XXXX:**
355 **(1) Polish the coronal surfaces of teeth with a brush or rubber cup as part of oral**
356 **prophylaxis to remove stains; and**
357 **(2) Apply pit and fissure sealants provided the patient is examined before the sealants**
358 **are placed. The sealants must be placed within 45 days of the procedure being**
359 **authorized by a dentist or dental hygienist.**

360

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361 **818-042-XXXX**

362

363 **Certification - Expanded Function Preventive Dental Assistants (EFPDA)**

364

365 **The Board may certify a dental assistant as an expanded function preventive dental**
366 **assistant:**
367 **(1) By credential in accordance with OAR 818-042-0120, or**
368 **(2) If the assistant submits a completed application, pays the fee and provides evidence**
369 **of;**
370 **(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory**
371 **completion of a course of instruction in a program accredited by the Commission on**
372 **Dental Accreditation of the American Dental Association; or**
373 **(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the**
374 **Oregon Basic or Certified Preventive Functions Dental Assistant (CPFDA) examination,**
375 **and the Expanded Function Dental Assistant examination, or equivalent successor**
376 **examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any**
377 **other testing entity authorized by the Board; and certification by an Oregon licensed**
378 **dentist that the applicant has successfully polished the coronal surfaces of teeth with a**
379 **brush or rubber cup as part of oral prophylaxis to remove stains on six patients; and**
380 **(c) Completion of a Board approved course in pit and fissure.**
381

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818-042-0130

Application for Certification by Credential

An applicant for certification by credential shall submit to the Board:

(1) An application form approved by the Board, with the appropriate fee;

(2) Proof of certification by another state and any other recognized certifications (such as CDA or COA certification) and a description of the examination and training required by the state in which the assistant is certified submitted from the state directly to the Board; or

(3) Certification that the assistant has been employed for at least 1,000 hours in the past two years as a dental assistant performing the functions for which certification is being sought.

(4) If applying for certification by credential as an EFDA**,** ~~or~~ EFODA **or EFPDA**~~,~~ certification by a licensed dentist that the applicant is competent to perform the functions for which certification is sought; and

(5) If applying for certification by credential in Radiologic Proficiency, certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, or the Oregon Board of Dentistry, that the applicant has met that agency's training requirements for x-ray machine operators, or other comparable requirements approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679

Stats. Implemented: ORS 679.020, 679.025 & 679.250

Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

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OREGON BOARD OF DENTISTRY

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BOARD APPROVED COURSE IN PLACING CORD SUBGINGIVALLY

INTRODUCTION

Board of Dentistry Administrative Rule 818-042-0090 allows Expanded Functions Dental Assistants (EFDAs) to place cord subgingivally under the following circumstances:

"Upon successful completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association, or other course of instruction approved by the Board, a certified Expanded Function Dental Assistant may perform the following functions under the indirect supervision of a dentist or dental hygienist providing the procedure is checked by the dentist or dental hygienist prior to the patient being dismissed."

"Indirect Supervision" means supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed. (ORS 679.010 (9))"

The Board approved course should offer instruction on the purpose, techniques and safety considerations of placing cord subgingivally and the Expanded Function Dental Assistant's role as the operator under indirect supervision of the dentist.

PREREQUISTIES

(1) The attendee must be an Oregon Expanded Function Dental Assistant.

(2) The attendee must provide a copy of their EFDA certification with course registration.

COURSE FORMAT

This course should be presented in a Lecture/clinical format for a total of at least (6) hours.

Lecture: To include the following regards to purpose, techniques and safety issues for placement of cord subgingivally.

(1) OAR Div. 42 rule regarding placement of sealants by an EFDA
(2) Patient health history review
- is the history current
- noted allergies
- medications
- other health considerations

(3) Infection control issues
- principles of disease transmission
- need for safety glasses for the patient
- universal precautions

(4) OSHA regulations
- operator injury
- spill cleanup

(5) Use of dental equipment and instruments
- use of appropriate fulcrum
- intra-oral hand mirror
- use of correct instruments

(6) Understanding anatomical tooth structures
- tooth surfaces
- tooth margins
- surrounding periodontium and gingival tissue
- anatomic terminology

(7) Indication/Contradictions for retraction cord
- tissue health
- isolation of the site
- correct type of retraction cord to be used
- depth and placement of gingival retraction cord

(8) Appropriate material and technique
- placement of cord subgingivally
- margins
- Type of retraction cord

Written Exam: Class participants must take a 25 question, multiple choice exam with a minimum passing score of 80% prior to commencing the lab portion of the course.

Clinical: After successfully completing the lecture and the written examination, attendees shall show proof of having placed cord subgingivally, on not less than ten (10) patients under the indirect supervision of a dentist. (Attached)

VERIFICATION OF PLACING
CORD SUBGINGIVALLY
ATTENDEE

Employer/Dentist **Oregon License No. _____**

Name:_____

Address: _____

City: _____ State: _____ Zip Code: _____

I hereby certify that _____
(Assistant's Name)

Has successfully placed cord subgingivally on _____ patients.

Date: _____ Dental Assistant's Signature: _____

Date: _____ Dentist's Signature: _____

(Use more than one form if necessary)

Return completed form(s) to Board Approved Instructor to receive Certificate of Completion of Course.

State regulations on the use of dental fillers. Information gathered from state dental board websites and provided by staff of those dental boards.

Alabama
Dentists are allowed to use Botox and Dermal fillers in any area of the face to treat maxillofacial trauma, and for the treatment of diagnosed dental and orofacial problems/pain and conditions and for cosmetic purposes following proper continuing education and certification. Found in July 2010 minutes.

Alaska
The Alaska Board has no rules or laws that address the items listed below. The Board has determined that a dentist can do any of the cosmetics required if they are part of the dental treatment plan, but cannot perform them as stand-alone procedures.

Arizona
Arizona's Substantive Policy Statement #15 states that it must be used in the context of a therapeutic dental treatment plan

Arkansas
The Arkansas State Board of Dental Examiners has been asked if the administration of Botox and dermal fillers for elective cosmetic procedures is allowed. The Board's response was, "If it fits the definition of dentistry." The definition of dentistry is as follows: **17-82-102**(1)(A) Practicing dentistry means: The evaluation, diagnosis, prevention and treatment by nonsurgical, surgical or related procedures of diseases, disorders and conditions of the oral cavity, maxillofacial area and the adjacent and associated structures and their impact on the human body, but not for the purpose of treating diseases, disorders and conditions unrelated to the oral cavity, maxillofacial area and the adjacent and associated structures.

California
Must have a special cosmetic surgery permit to administer botox and/or dermal fillers.

Connecticut
The dental board permits dentists only to perform procedures related to the mouth, structures in the mouth, and the jaw. Procedures outside the area of the mouth or jaw may not be performed by dentists.

Delaware
The Board of Dentistry and Dental Hygiene has responded to requests for recommendations on Botox and dermal fillers by stating that it is unauthorized to offer recommendations. The Board has observed that neither licensing law nor the Board's rules and regulations expressly discuss the treatments. Because the rules do not contain any provisions regarding these treatments, the Board has responded to requests by stating that determinations regarding whether use of Botox violates the law or the Board's rules and regulations must be made on a case by case basis based on facts of the alleged violation that are presented to the Board.

Florida
Currently there are no laws and rules that address who can and cannot administer Botox injections in the state of Florida.

Georgia

Rule 150-14-.04. Administration of Injectable Pharmacologics

(a) For purposes of this rule, the term below shall have the following meaning. "Injectable pharmacologic" means any medication classified as a neurotoxin, adjuvant or therapeutic agent including, but not limited to, hyaluronic acid (such as Restylane), fillers (such as collagen), Botulinum Toxin Type A (such as Botox) or similar products that have been approved by the Federal Food and Drug Administration.

(b) No dentist shall administer an injectable pharmacologic unless the minimum standards of training and procedure set forth in this section are satisfied.

(c) Administration of an injectable pharmacologic for the functional or cosmetic enhancement of the gums, cheeks, jaws, lips, the oral cavity and associated tissues is a procedure which can be performed by a dentist in connection with a dental procedure in a dental treatment setting.

(d) A dentist may administer an injectable pharmacologic only after having completed a Board-approved post-doctoral course that is sufficient to prepare a dentist to satisfactorily administer injectable pharmacologics safely and effectively, as provided in (f) below.

(e) Notwithstanding (d) above, a dentist licensed in Georgia who has successfully completed an ADA accredited oral and maxillofacial surgery advanced specialty education program shall not be required to complete the Board-approved course set forth in (f) below prior to administering injectable pharmacologics.

(f) In order to obtain Board approval for a course on injectable pharmacologics, a course provider shall submit a course outline, including course content and objectives and the curriculum vitae of the instructor(s), for Board review and approval. The course outline shall indicate whether the training is visual, hands-on or lecture. An approved course shall be at least 21 hours in length and shall include advanced instruction in the following:

1. Anatomy of head and neck;
2. Neurophysiology, including facial tissues, parasympathetic, sympathetic and peripheral nervous systems relative to peri-oral tissue, and facial architecture;
3. Patient selection, including indications and contraindications;
4. Pharmacological effects and contraindications, including potential drug interactions; and
5. Management of complications.

(g) The course administrator shall issue a certificate of completion to a dentist who successfully completes the approved course.

(h) A dentist who desires to administer injectable pharmacologics shall submit to the Board, within 30 days of completing the course, a certified true copy of the certificate of course completion provided to the dentist by the course administrator.

(i) Prior to administering injectable pharmacologics to a patient, the dentist shall conduct an appropriate physical examination within the scope of dental practice, obtain a complete medical history, including the patient's medications, allergies and sensitivities and comprehensively assess the dental needs of the patient. Specific notations on the use of

injectable pharmacologics, including the type of agent, dosage, duration and any untoward reactions, shall be recorded in the patient record.

(j) A dentist shall not delegate the administration of an injectable pharmacologic.

(k) The use of injectable pharmacologics without first having met the minimum standards for training and the procedures contained in this section shall constitute a deviation from the acceptable standards of practice required of a licensee and may subject a dentist to the penalties set forth in O.C.G.A. 43-11-47.

Hawaii

"The use of Botox is within the scope of practice of dentistry as defined in Chapter 448, Hawaii Revised Statutes ("HRS"). Licensed dentists in Hawaii are allowed to utilize Botox specifically for the treatment of TMD/myofacial pain or other conditions affecting the oral cavity and associated structures as specified in 448.1, HRS. Dental practitioners are advised to receive appropriate training and acquire the necessary knowledge, skills, and expertise to provide this service in a safe and efficacious manner. Additionally, they should confer with their dental insurance carrier to determine if malpractice coverage for this procedure exists.

The use and placement of dermal fillers by licensed dentists in Hawaii is also within the scope of practice of dentistry. Dermal fillers may be utilized to treat conditions affecting the oral cavity and associated structures. Licensed dentists should confer with their dental insurance carrier to determine if malpractice coverage for this procedure exists.

The use of Botox and placement of dermal fillers must be completed by the licensed dentist possessing the appropriate training, knowledge, and skill set. It cannot be delegated to a dental hygienist or dental assistant."

Idaho

After considering numerous questions regarding Botox and Derma Fillers, the Board has determined the statutory definition of the practice of dentistry in Idaho is sufficiently broad to allow a dentist to perform dermal filler or Botox procedures as long as those procedures fall within the scope of the practice of dentistry as defined in Idaho Code§54-901. Dentists have a professional responsibility to seek whatever training they deem necessary to assure competence when performing these procedures (or any dental procedures). Because the statutory definition of the practice of dental hygiene (Idaho Code §54-902) does not include reference to "adjacent tissues" the Board determined that injection by a dental hygienist of Botox into perioral tissue is not allowed.

Illinois

The procedures you list below may all be considered part of the practice of dentistry as defined in the Illinois Dental Practice Act, "'Dentistry' means the healing art which is concerned with the examination, diagnosis, treatment planning and care of conditions within the human oral cavity and its adjacent tissues and structures." 225 ILCS 25/4(k). A dentist performing any of these procedures must be qualified to do so through advanced education, training and experience.

Indiana

State Board of Dentistry Position Statement Use Of Botox And Other Dermal Fillers

The Indiana Dental Practice Act does not prohibit the use of Botox and other dermal fillers administered by a dentist Licensed in the state of Indiana. Dentists are limited to using these materials in the oral and maxillofacial area within the scope of dentistry. Dentists are further limited based by the Specific education and training received for providing these services.

Iowa
Botox or Dermal Fillers Iowa law limits dentists to providing services that are within the scope of dentistry, which is defined in Iowa Code section 153.13(2) as duties that include, "examination, diagnosis, treatment, and attempted correction by any medicine, appliance, surgery, or other appropriate method of any disease, condition, disorder, lesion, injury, deformity, or defect of the oral cavity and maxillofacial area, including teeth, gums, jaws, and associated structures and tissue, which methods by education, background experience, and expertise are common to the practice of dentistry. A dental license further extends the scope of authority of a dentist to prescribe, administer, or dispense prescription medications. However, such authority is granted only "if the use is directly related to the practice of dentistry within the scope of the dentist-patient relationship." 650-IAC16.2(1) Board rules further require that a dental exam be conducted and a medical history taken before a dentist prescribes, administers, or dispenses medication to a patient. The Board has determined that under these laws, a dentist may administer botox and other derma fillers if the use of those medications is directly related to the practice of dentistry, but only if the dentist has successfully completed appropriate education and training. The Board has determined that at this time, the only dentists who have completed appropriate education and training to use these medications in the practice of dentistry are dentists who have completed an ADA-accredited residency program which includes in the scope of its education and training the administration of Botox and other derma fillers.

Kansas
Facial Injections To Reduce Signs Of Aging Is Not The Practice Of Dentistry
All dental boards are facing the issue of whether or not a general dentist can use botulinum toxin type A, commonly called Botox, or dermal fillers, as a cosmetic remedy for facial aging. There are many continuing education programs that promote this procedure to physicians, nurses and dentists. Some of the courses have ADA/CERP approval. The Kansas Dental Board discussed this issue at the meeting of Oct 31, 2009 and adopted the following policy: the use of these products is to be "limited to the practice of dentistry, and the practice of dentistry is defined in the Dental Practices Act." When reading the definitions of dentistry, there is no mention of any facial enhancements, and in fact the closest portion of the definition of dentistry would be: **KSA 65-1422. Persons deemed to be practicing dentistry.** A person shall be deemed to be practicing dentistry:
(a) Who performs, or attempts or professes to perform, any dental operation or oral surgery or dental service of any kind, gratuitously or for a salary, fee, money or other remuneration paid, or to be paid directly or indirectly, to such person or to any other person or agency who is a proprietor of a place where dental operations, oral surgery or dental services are performed; or
(f) who diagnoses, or professes to diagnose, prescribe for, or professes to prescribe for, treats, or professes to treat, disease, pain, deformity, deficiency, injury or physical condition of the human teeth or jaws, or adjacent structure.

Kentucky
The use of Botox and other injectables falls within the scope of dentistry as long as it involves conditions surrounding the mouth.

Louisiana
§132. Administration of Botox and Dermal Fillers
A. The board does not issue permits for the administration of Botox or dermal fillers. The board does not regulate dental materials of any type. However, due to the rising utilization of these materials by dentists, the board sets forth the following requirements.
B. Before administering Botox or dermal fillers, a dentist must have either received satisfactory training in a dental institution accredited by the Commission on Dental Accreditation of the American Dental Association or successfully completed a continuing education course of instruction that includes at a minimum the following:
1. patient assessment and consultation for Botox and dermal fillers;
2. indications and contraindications for these techniques;

3. safety and risk issues for botulinum
4. proper preparation and delivery techniques for desired outcomes;
5. enhancing and finishing esthetic dentistry cases with dermal fillers;
6. botulinum neurotoxin treatment of temporomandibular joint syndrome and bruxism;
7. knowledge of adverse reactions and management and treatment of possible complications;
8. patient evaluation for best esthetic and therapeutic outcomes;
9. Integrating botulinum neurotoxin and dermal filler therapy into dental therapeutic and esthetic treatment plans;
10. live patient hands-on training including diagnosis, Treatment planning, and proper dosing and delivery of Botox And dermal fillers.
C. Botox and dermal fillers shall only be administered in dental offices using universal precautions as required by the Federal Centers for Disease Control.
D. All dental auxiliaries are prohibited from administering either Botox or dermal fillers.
E. Continuing education courses shall be approved or sponsored by one or more of the entities set forth in LAC 46:XXXIII.1615.

Maine
Dentist can administer Botox for dentally related procedures only.

Maryland
Use of Botox, Dermal Fillers and Similar Drugs
The Board has received a number of inquiries regarding the use of Botox, dermal fillers and similar drugs. Under Maryland law, the practice of dentistry is defined, in part in the following manner: "to diagnose, treat, or attempt to diagnose or treat any disease, injury, malocclusion, or malposition of a tooth, gum, or jaw, or structures associated with a tooth, gum, or jaw if the service, operation, or procedure is included in the curricula of an accredited dental school or in an approved dental residency program of an accredited hospital or teaching institution…." Annotated Code of Maryland, Health Occupations Article, § 4-101(l)(3). A dentist may, therefore, use any legally prescribed drugs to treat patients as long as the treatment is within the aforementioned scope of practice. A dentist must also be competently trained to administer Botox and similar drugs in accordance with the Code of Maryland Regulations (COMAR) 10.44.32 Competency.
The competency regulations state in relevant part: "A dentist shall limit their practice to the areas of competence by which proficiency has been gained through education, training, and experience." COMAR 10.44.32.02B(1). In addition, the regulations provide that "A dentist shall seek appropriate education, training, and experience when developing competence in a new service or technique. COMAR 10.44.32.02B(7).
Therefore, the use of Botox, dermal fillers and similar drugs by a dentist must fall within the definition of dentistry, and the dentist must be competent in its administration.

Massachusetts
A Dentist licensed under MGL Chapter 112, Section 45 who holds ADA Board Certification in Oral and Maxillofacial Surgery may administer botulinum toxin and dermal fillers in the course of treatment for oral or maxillofacial disease, disfigurement, or disfunction. Additionally, it is the Board's policy that dentists licensed under M.G.L. Chapter 112, Section 45 who do not hold ADA Board Certification in Oral and Maxillofacial Surgery may use botulinum toxins and/or dermal fillers with patients so long as it is part of the delivery of the patient's comprehensive dental treatment plan; is limited to the practice of dentistry; and the dentist has successfully completed training of a minimum of eight (8) hours in administration of botulinum toxins and/or eight (8) hours in administration of dermal fillers that includes instruction in the anatomy of head and neck, neurophysiology, patient selection, pharmacological effects and contraindications, management of complications, informed consent, and hands-on training on the administration of such agents. The training must be accredited by the American Dental Association's Continuing Education Recognition Program (CERP), the Academy of General Dentistry's Program Approval for Continuing Education (PACE) or other nationally-recognized and accredited entity approved by the Board. Please note that full compliance with the provisions of 234 CMR 5.15 is required. This

includes but is not limited to:
 obtaining the patient's medical and dental history;
 conducting a clinical exam; and
 obtaining specific informed consent before botulinum toxins and/or dermal fillers are administered.

Michigan
No information available

Minnesota
No information available

Mississippi
In **Mississippi**, we do not have any rules/requirements, *per se*, regarding dermal fillers and Botox; however, the Board determined in 2007 that only currently licensed oral and maxillofacial surgeons could perform "extraoral cosmetic procedures" with the appropriate training, etc. That determinations, as well as others, regarding Botox and dermal fillers insofar as who can utilize them, can be found on the Board's FAQ page for Scope of Practice, a link to which is as follows: **http://www.dentalboard.ms.gov/msbde/msbde.nsf/webpages/FAQ_scope?OpenDocument**

- **May Dentox/Botox could be utilized by licensed Mississippi dentists in the treatment of TMD?**

  *No. At its 05/08/2009 meeting, the Board determined that it does not have sufficient information to deem Dentox/Botox as an appropriate treatment modality for TMD. At its 10/16/2015 meeting, the Board considered another request as to whether Botox and Dermal Fillers may be utilized by all licensed Mississippi dentists for dental esthetics, facial pain, and the treatment of TMD/TMJ. Once again, the Board reaffirmed its 10/19/2007 determination regarding the use of Botox and Dermal Fillers. In other words, the Board's position remains the same, i.e., this is **NOT** permitted.*

Missouri
Called and spoke with the board, they stated that it is not allowed in the state of Missouri, that it was not in their scope of practice.

Montana
No information available

Nebraska
The Board's opinion is that it is appropriate for a dentist to use dermal fillers for cosmetic/esthetic purposes and it is the practitioner's responsibility to be competent in the use of dermal fillers.

Nevada
(November 2015 Board Meeting Minutes): Anyone holding a general dental license that possessed the skills and training may administer injectables and that any dental hygienists that possessed the skills and training may also do so, but it would have to be under the direct supervision of a Nevada licensed dentist.

New Hampshire
The Board has determined that a dentist can perform dermal fillers and botox procedures within the scope of practice of dentistry Pursuant to RSA 317-A:20 (d)

New Jersey

13:30-8.4A **Administration Of Injectable Pharmacologics**

a) For purposes of this section, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

"Injectable pharmacologic" means any medication classified as a neurotoxin, adjuvant or therapeutic agent including, but not limited to, hyaluronic acid (such as Restylane®), fillers (such as collagen), Botulinum Toxin Type A (such as Botox®) or similar products that have been approved by the Federal Food and Drug Administration.

"Peri-oral area" means the gums, cheeks, jaws, lips and oral cavity and associated tissues.

b) No dentist shall administer an injectable pharmacologic unless the minimum standards of training and procedure set forth in this section are satisfied.

c) A dentist may administer an injectable pharmacologic for the cosmetic or functional enhancement of peri-oral tissue only in a dental treatment setting.

d) A dentist may administer an injectable pharmacologic only after having completed a Board-approved post-doctoral course that is sufficient to prepare a dentist to satisfactorily administer injectable pharmacologics safely and effectively, as provided in (f) below. The course shall be offered at an accredited dental school, in a hospital-based program or in a college or university clinical setting.

e) Notwithstanding (d) above, a dentist who holds a specialty permit in oral and maxillofacial surgery issued by the Board pursuant to N.J.A.C. 13:30-6.1 shall not be required to complete the Board-approved course set forth in (f) below prior to administering injectable pharmacologics.

f) In order to obtain Board approval for a course on injectable pharmacologics, a course provider shall submit a course outline, including course content and objectives and the curriculum vitae of the instructor(s), for Board review and approval. The course outline shall indicate whether the training is visual, hands-on or lecture. An approved course shall be at least 21 hours in length and shall include instruction in the following:

1) Anatomy of head and neck;
2) Neurophysiology, including facial tissues, parasympathetic, sympathetic and peripheral nervous systems relative to peri-oral tissue, and facial architecture;
3) Patient selection, including indications and contraindications;
4) Pharmacological effects and contraindications, including potential drug interactions;
5) Management of complications; and
6) Informed consent.

g) The course administrator shall issue a certificate of completion to a dentist who successfully completes the approved course.

h) A dentist who desires to administer injectable pharmacologics shall submit to the Board, within 30 days of completing the course, a certified true copy of the certificate of course completion provided to the dentist by the course administrator.

i) Prior to administering, dispensing or prescribing injectable pharmacologics to a patient, the dentist shall conduct an appropriate physical examination within the scope of dental practice, obtain a complete medical history, including the patient's previous medications, allergies and sensitivities and comprehensively assess the dental needs of the patient. The patient history shall be maintained in the patient's record for a period of not less than seven years. Specific notations on the use of injectable pharmacologics, including the type of agent, dosage, duration and any untoward reactions, shall be recorded in the patient record.

j) A dentist shall not delegate the administration of an injectable pharmacologic, except to a licensed health care professional who is authorized pursuant to the laws and/or rules in this State governing the professional's health care practice to provide injections under the direction of a dentist.

k) The use of injectable pharmacologics without first having met the minimum standards for training and the procedures contained in this section shall constitute a deviation from the acceptable standards of practice required of a licensee and may subject a dentist to the penalties set forth in N.J.S.A. 45:1-21 et seq.

l) A dentist shall not advertise, offer or otherwise represent the provision of treatment or

services related to injectable pharmacologics unless the dentist has completed the Board-approved course outlined in (f) above.
m) Nothing in this section shall be construed to authorize a dentist to treat diseases, disorders or conditions that are outside the scope of the practice of dentistry, as defined in N.J.S.A. 45:6-19.

New Mexico
16.5.14.8 Administration Of Botulinum Neurotoxin (Botox) And Dermal Fillers: The board does not issue permits for the administration of botox or dermal fillers. The board does not regulate dental materials of any type; however, due to the rising utilization of these materials by dentists, the board sets forth the following requirements.
A. Before administering botulinum neurotoxin or dermal fillers, in connection with the practice of dentistry as defined in Section 61-5A-4, a dentist must receive satisfactory training at a dental institution accredited by the commission on dental accreditation (CODA) or successfully completed a board approved continuing education course of instruction that includes a minimum of the following:
(1) patient assessment and consultation for botulinum neurotoxin and dermal fillers;
(2) indications and contraindications for these techniques;
(3) safety and risk issues for botulinum neurotoxin/dermal fillers injectable therapy;
(4) proper preparation and delivery techniques for desired outcomes;
(5) enhancing and finishing esthetic dentistry cases with dermal fillers;
(6) botulinum neurotoxin treatment of temporomandibular dysfunction;
(7) knowledge of adverse reactions and management and treatment of possible complications;
(8) patient evaluation of best esthetic and therapeutic outcomes;
(9) integrating botulinum neurotoxin and dermal filler therapy into dental therapeutic and esthetic treatment plans; and
(10) 16 hours total, including eight hours minimum live patient hands-on training including diagnosis, treatment planning and proper dosing and delivery of botox and dermal fillers;
B. Botulinum neurotoxin and dermal fillers shall only be administered in dental offices using universal precautions as required by the federal centers for disease control. All dental auxiliaries are prohibited from administering either botulinum neurotoxin or dermal fillers.
D. Continuing education courses shall be approved by the academy of general dentistry (AGD) program approval for continuing education (PACE), American dental association (ADA) continuing education recognition program (CERP) or other dental or medical entities accepted by the board.
All dental auxiliaries are prohibited from administering either botulinum neurotoxin or dermal fillers.
D. Continuing education courses shall be approved by the academy of general dentistry (AGD) program approval for continuing education (PACE), American dental association (ADA) continuing education recognition program (CERP) or other dental or medical entities accepted by the board.

New York
Use of botox and dermal fillers is allowed provided it is used as a part of treatment for dental reconstructive treatment, otherwise is not permitted by dentists

North Carolina
The injection of botox and/or dermal fillers does not constitute the practice of dentistry. N.C.G.S 90-29 specifically lists what activities constitute the practice of dentistry.

North Dakota (accepts courses taken from the AAFE and the FACE)
20-02-01-11. Permit for the use of dermal fillers and botulinum toxin for dental use.
1. The rules in this chapter are adopted for the purpose of defining standards for the administration of dermal fillers and botulinum toxin by a dentist if the use is limited to the practice of dentistry as defined in North Dakota Century Code 43-28-01(7). Notwithstanding a dentist who specializes in oral and maxillofacial surgery, the board may issue a permit to a

dentist who applies on forms prescribed by the board and pays the fee as required by section 20-05-01-01(1) to administer botulinum toxin or dermal fillers for the purpose of functional, therapeutic, and aesthetic dental treatment purposes under the following conditions:
a. The dentist provides evidence that demonstrates:
(1) The applicant has completed a course and received satisfactory training in a residency or other educational program accredited by the commission on dental accreditation of the American dental association; or
(2) The applicant has successfully completed a board-approved continuing education course of instruction within the previous three months of application which includes neurophysiology, including facial tissues, parasympathetic, sympathetic, and peripheral nervous systems relative to the peri-oral tissue, and facial architecture, and:
(a) Patient assessment and consultation for botox and dermal fillers;
(b) Indications and contraindications for techniques;
(c) Proper preparation and delivery techniques for desired outcomes;
(d) Enhancing and finishing esthetic dentistry cases with dermal fillers;
(e) Botulinum neurotoxin treatment of temporomandibular joint syndrome and bruxism;
(f) Knowledge of adverse reactions and management and treatment of possible complications;
(g) Patient evaluation for best esthetic and therapeutic outcomes;
(h) Integrating botulinum neurotoxin and dermal filler therapy into dental therapeutic and esthetic treatment plans; and
(i) Live patient hands-on training, including diagnosis, treatment planning, and proper dosing and delivery of botox and dermal fillers.

Ohio

POLICY REGARDING THE USE OF RESTALYN, BOTOX, AND OTHER DERMA FILLERS BY LICENSED DENTISTS

Preamble: The purpose of this policy is to clarify the Ohio State Dental Board's (Board) position regarding the use of Botox, and Restalyn and other Derma-Fillers, by licensed dentists in the state of Ohio.

The Dental Practice Act gives the Board discretion to make determinations as to what is included in the practice of dentistry, what is and is not within the scope of practice for dentists, and what acts or omissions qualify as not meeting the accepted standards of care for the profession.

Over the past few years the Board has considered the question of whether the use of Botox, Restalyn and/or other dermal fillers was within the scope of practice of dentistry. The Board has revisited this issue. The Board determined that the use of these materials and agents can be considered within the scope of dentistry. However, these treatments are limited to use only in the oral and maxillofacial areas. There are further limitations based on the specific education and training received by the dentist providing these services. This insures an adequate diagnosis will be made and an ability to recognize and treat complications.

The education and training required is to be equal to that provided by ADA accredited programs within the dental schools and residency programs. This is the basis for determining the scope of practice for dentists. Therefore, as an example, a periodontist cannot provide lip augmentation services as that is not within the scope of practice for periodontists; an orthodontist cannot administer Botox, as that is not within the scope of practice for orthodontists.

It is important to keep in mind that this policy deals with an important, ever evolving area of practice. Please direct all questions regarding this subject to the Board office

Oklahoma
Resolution and declaratory ruling R-2012-3 Clarifications of previous rulings concerning the use of Botox and Medcial Micropigmentation in a Dental Office.
It is the belief of the Dental Board that he use of all botulism toxins and dermafillers can have a beneficial medical use in the practice of dentistry. These procedures if used in a dental office can only be performed by a licensed dentist.
All injections must be maintained in the patient records required to be kept for 3years. A dnetla hygienist, holding a valid local anesthesia permit, may only provide intra-oral block and infiltration injection, for the purpose of providing local anesthesia under the direct supervision of a dentist.
No dental hygienist may administer any type of extra-oral injection including but not limited to anesthetics, botulism toxins or derma fillers.

Pennsylvania
Who can administer Botox in Pennsylvania? Board of Dentistry does not currently have any policies regarding use of Botox and dermal fillers by dentists, though a policy has been proposed and is under consideration.

Rhode Island
The Administrator advised that this subject had been reviewed and studied by the Sub-Committee for Rules & Regulations in the past and it was determined that by virtue of the definition of dentistry in the Dental Practice Act and the Rules & Regulations it is within the scope of practice for dentists to administer Botox and dermal fillers. However, the Committee was of the opinion it is best to keep it broad and not to include specific language or guideline to address this practice. It was further advised that dentists offering such services would have to answer to their medical malpractice carriers.

South Carolina
There are currently no regulations regarding use of Botox or Dermal fillers by dentists.

South Dakota
There are currently no regulations regarding use of Botox or Dermal fillers by a licensed dentist.

Tennessee
Rule 0460-02-.06
The Tennessee Board of Dentistry determines that the dental practice of Oral and Maxillofacial Surgery includes the following procedures which the Board finds are included in the curricula of dental schools accredited by the American Dental Association, Commission on Dental Accreditation, post-graduate training programs or continuing education courses:
1. Rhinoplasty;
2. Blepharoplasty;
3. Rytidectomy;
4. Submental liposuction;
5. Laser resurfacing;
6. Browlift, either open or endoscopic technique;
7. Platysmal muscle plication;
8. Dermabrasion;
9. Otoplasty;
10. Lip augmentation; and
11. Botox injections or future FDA approved neurotoxins.

Texas
Dental Practice Act does not specifically address facial cosmetic surgery or treatment but it does define the scope of dentistry as being limited to “human teeth, oral cavity, alveolar process, gums, jaws, or directly related and adjacent masticatory structures.

"**[1]** This scope is broadened for dentists with an ADA-recognized specialty of oral and maxillofacial surgery to include “the diagnosis of and the surgical and adjunctive treatment of diseases, injuries, and defects involving the functional and aesthetic aspects of the hard and soft tissues of the oral and maxillofacial region.
”**[2]** Based on the language in the statute, the Board has determined that the use of facial cosmetic procedures outside the stomatognathic system
[3] is not within the scope of practice for a dentist who does not have the specialty of oral and maxillofacial surgery. The products and pro procedures included within the heading of “facial cosmesis
”**[4]** can only be used for the diagnosis and treatment of functional issues of the stomatognathic system as part of a comprehensive treatment plan. Their use for isolated cosmetic purposes is permitted only for those dentists who have the specialty of oral and maxillofacial surgery.

Utah
Made a call to the board spoke with Lisa who stated that nothing has been put into place. But that at the last board meeting it was stated that Botox can be used as part of dental treatment.

Vermont
No information available.

Virginia
In order for an oral and maxillofacial surgeon to perform aesthetic or cosmetic procedures, he shall be certified by the board pursuant to § 54.1-2709.1 of the Code. Such certification shall only entitle the licensee to perform procedures above the clavicle or within the head and neck region of the body.

B. Based on the applicant's education, training, and experience, certification may be granted to perform the following procedures for cosmetic treatment:

1. Rhinoplasty and other treatment of the nose;

2. Blepharoplasty and other treatment of the eyelid;

3. Rhytidectomy and other treatment of facial skin wrinkles and sagging;

4. Submental liposuction and other procedures to remove fat;

5. Laser resurfacing or dermabrasion and other procedures to remove facial skin irregularities;

6. Browlift (either open or endoscopic technique) and other procedures to remove furrows and sagging skin on the upper eyelid or forehead;

7. Platysmal muscle plication and other procedures to correct the angle between the chin and neck;

8. Otoplasty and other procedures to change the appearance of the ear; and

9. Application of injectable medication or material for the purpose of treating extra-oral cosmetic conditions.

Washington

The Dental Quality Assurance Commission has issued an interpretive statement about Dentist Scope of Practice – Use of Botulinum Toxin Injections/Dermal Fillers (PDF). The interpretive statement was approved by the commission on July 26, 2013, and filed by the Office of the Code Reviser on August 20, 2013, as WSR 13-17-090.

The use of botulinum toxin injections or dermal fillers in the soft tissues throughout the face can be within the scope of practice of a dentist licensed under chapter 18.32.020 RCW when:

Used to treat functional or esthetic dental conditions and their direct esthetic consequences; and

The treating dentist has appropriate, verifiable training and experience.

The use of botulinum toxin injections or dermal fillers outside the treatment of dental-related conditions for purely cosmetic purposes isn't within the scope of practice of dentists not specialty trained as an oral and maxillofacial surgeon.

Following on the next page is the interpretive Statement:

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

PO Box 47890 .Olympia, Washington 98504-7890

NOTICE OF ADOPTION OF AN INTERPRETIVE STATEMENT OR POLICY STATEMENT

Title of Interpretive or Policy Statement: Dentist Scope of Practice – Use of Botulinum Toxin Injections / Dermal Fillers (IS-1)

Issuing Entity: Dental Quality Assurance Commission

Subject Matter: Use of Botulinum Toxin Injections / Dermal Fillers by Dentists

Effective Date: July 26, 2013

Contact Person:

Jennifer Santiago, Program Manager
Health Systems Quality Assurance
Department of Health
PO Box 47852
Olympia, WA 98504-7852
360.236.4893

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON

FILED

DATE: August 20, 2013

Department of Health

Health Systems Quality Assurance
Interpretive Statement

Title:	Dentist Scope of Practice – Use of Botulinum Toxin Injections / Dermal Fillers	**Number:** IS-1
Reference:	RCW 18.32.020	
Contact:	Jennifer Santiago, Program Manager	
Effective Date:	July 26, 2013	
Supersedes:		
Approved by:	Paul W. Bryan, D.M.D., Chair Dental Quality Assurance Commission	

The use of botulinum toxin injections or dermal fillers in the soft tissues throughout the face can be within the scope of practice of a dentist licensed under chapter 18.32 RCW when:

- Used to treat functional or esthetic dental conditions and their direct esthetic consequences, and
- The treating dentist has appropriate, verifiable training and experience.

The use of botulinum toxin injections or dermal fillers outside the treatment of dental related conditions for purely cosmetic purposes is not within the scope of practice of dentists not specialty trained as an oral and maxillofacial surgeon.

Background and Analysis

Definitions

Botulinum Toxin: An injected drug prepared from botulin used to temporarily paralyze muscle.

Dermal Filler: An injectable gel made from naturally-occurring substances, including collagen and hyaluronic acid, usually used to add volume to aging tissue.

Dentist: A dentist licensed in the state of Washington under chapter 18.32 RCW who does not have the requisite training to represent himself or herself as an oral/maxillofacial surgeon.

Description of Issue

Are botulinum toxin injections or dermal filler treatments within the scope of practice for dentistry?

Analysis

RCW 18.32.020 defines dentistry:

"A person practices dentistry, within the meaning of this chapter, who (I) represents himself or herself as being able to diagnose, treat, remove stains and concretions from teeth, operate or prescribe for any disease, pain, injury, deficiency, deformity, or physical condition of the human teeth, alveolar process, gums, or jaw, or (2) offers or undertakes by any means or methods to diagnose, treat, remove stains or concretions from teeth, operate or prescribe for any disease, pain, injury, deficiency, deformity, or physical condition of the same, or take impressions of the teeth or jaw, or (3) owns, maintains, or operates an office for the practice of dentistry, or (4) engages in any of the practices included in the curricula of recognized and approved dental schools or colleges, or (5) professes to the public by any method to farnish, supply, construct, reproduce, or repair any prosthetic denture, bridge, appliance, or other structure to be worn in the human mouth...

The practice of dentistry includes the performance of any dental or oral and maxillofacial surgery. "Oral and maxillofacial surgery" means the specialty of dentistry that includes the diagnosis and surgical and adjunctive treatment of diseases, injuries, and defects of the hard and soft tissues of the oral and maxillofacial region. "

RCW 18.32.020 defines the practice of dentistry as treatment on teeth, the alveolar process, gums or the jaw (oral and maxillofacial surgery excepted).

The definition of "dentistry" defines "oral and maxillofacial surgery" as a specialty of dentistry. Dentists in Washington State without approved training required to designate themselves as oral and maxillofacial surgeons may still practice some procedures associated with that specialty and within the facial regions of that specialty as long as they don't misrepresent themselves as an oral and maxillofacial surgeon and it is a procedure the dentist has training to perform. Practice in this specialty allows for *"...diagnosis and surgical and adjunctive treatment of diseases, injuries, and defects of the hard and soft tissues of the oral and maxillofacial region.* "

RCW 18.32.020 (4) also allows for practices included in the curricula of "recognized and approved dental schools or colleges."

Dental training recognizes the functional aspects and resulting esthetic ramifications of dental conditions and dental treatment. Dentists are trained in evaluation of the peri-oral soft tissue, the muscles of facial expression and the muscles of mastication. Dentists are also trained in treatment of functional conditions associated with these same soft tissues including but not limited to bruxism, tension headaches, temporomandibular joint problems, myofasical pain conditions, limited inter-dental papilla volume, hyperactive masseters, deficient and irregular lip and smile lines, maxillary gingival excess (gummy smile), maxillary gingival deficiency, and angular chelitis. The use of botulinum toxin injections or dermal fillers for conditions like these is already treatment that is recognized and acceptable. What typically isn't taught in dental schools, outside of oral and maxillofacial surgery training, is the use of botulinum toxin injections or dermal fillers for strictly the esthetic correction of fine lines and furrowing that results in the skin from the muscles of facial expression.

It is relevant to note that treatment of functional problems with botulinum toxin injections requires a practitioner to know and understand the functional AND esthetic consequences or effects of therapeutic botulinum toxin injections within the muscles of mastication and of expression covering the entire face.

Given the standard training and experience of dentists the use of botulinum toxin injections or dermal fillers in the soft tissues throughout the face can be within the scope of practice of a dentist when:

- Used to treat functional or esthetic dental conditions and their direct esthetic consequences, and
- The treating dentist has appropriate, verifiable training and experience.

The use of botulinum toxin injections or dermal fillers outside the treatment of dental related conditions for purely cosmetic purposes is not within the scope of practice of dentists not specialty trained as an oral and maxillofacial surgeon.

West Virginia

Doesn't have any particular laws or rules addressing this subject, but does have a position statement at the link provided:
http://wvdentalboard.org/policy%20on%20use%20of%20dermal%20fillers%20and%20botox.pdf
West Virginia Board of Dental Examiners Policy Regarding the Use of Botox and Other Dermal Fillers *The Dental Practice Act does not prohibit the use of Botox and other dermal fillers by a dentist licensed in the State of West Virginia. Dentists are limited to using these materials in the oral and maxillofacial area. Dentists are further limited based on the specific education and training received for providing these services.*

Wisconsin

At the January 4, 2012 meeting of the Dentistry Examining Board the following policy position was adopted: The use of dermal fillers and botox by a licensed dentist in the state of Wisconsin is allowable for functional, therapeutic, and aesthetic treatment purposes in accordance with the practice of dentistry as defined in s. 447.01 of the Wisconsin Statutes. It is expected that dentists will obtain appropriate training to be able to perform such services competently. Such training shall be provided by organizations or institutions recognized to provide continuing education courses in accordance with s. 447.056 of the Wisconsin Statutes.

Wyoming

The board does not have any rules or laws that address these issues.

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

Oregon Board of Dentistry Committee Meeting Dates

All Committee meetings will take place at the Oregon Board of Dentistry Offices located at 1500 SW 1st Ave., Suite 770, Portland Oregon.

Oregon Board of Dentistry
Rules Oversight Committee Meeting
Wednesday, July 13, 2016
6:30 p.m.

Oregon Board of Dentistry
Anesthesia Committee Meeting
Tuesday, July 26, 2016
6:30 p.m.

Please mark your calendar for these dates. Agendas will be sent at a later date.

If you have any questions, please contact Executive Director, Stephen Prisby at 971-673-3200 or Stephen.Prisby@state.or.us

Oregon Board of Dentistry
Committee and Liaison Assignments
May 2016 - April 2017

STANDING COMMITTEES

Communications

Purpose: To enhance communications to all constituencies
Committee:

Alton Harvey, Sr., Chair
Yadira Martinez, R.D.H., E.P.P.
Todd Beck, D.M.D.
Barry Taylor, D.M.D., ODA Rep.
Gail Aamodt, R.D.H., M.S., ODHA Rep.
Linda Kihs, CDA, EFDA, OMSA, MADAA, ODAA Rep.

Subcommittees:

- Newsletter – Amy B. Fine, D.M.D., Editor

Dental Hygiene

Purpose: To review issues related to Dental Hygiene
Committee:

Yadira Martinez, R.D.H., E.P.P., Chair
Jose Javier, D.D.S.
Alicia Riedman, R.D.H., E.P.P.
David J. Dowsett, D.M.D., ODA Rep.
Wilber Ramirez-Rodriguez, R.D.H., ODHA Rep.
Mary Harrison, CDA, EFDA, EFODA, FADAA, ODAA Rep.

Enforcement and Discipline

Purpose: To improve the discipline process
Committee:

James Morris, Chair
Alicia Riedman, R.D.H., E.P.P.
Todd Beck, D.M.D.
Julie Ann Smith, D.D.S., M.D., M.C.R.
Jason Bajuscak, D.M.D., ODA Rep.
Jill Mason, R.D.H., ODHA Rep.
Mary Harrison, CDA, EFDA, EFODA, FADAA, ODAA Rep.

Subcommittees:

Evaluators

- Todd Beck, D.M.D., Senior Evaluator
- Gary Underhill, D.M.D., Evaluator

Licensing, Standards and Competency

Purpose: To improve licensing programs and assure competency of licensees and applicants
Committee:

Amy B. Fine, D.M.D., Chair
Gary Underhill, D.M.D.
Yadira Martinez, R.D.H., E.P.P.
Todd Beck, D.M.D.
Daren L. Goin, D.M.D., ODA Rep.
Susan Kramer, R.D.H., ODHA Rep.
Mary Harrison, CDA, EFDA, EFODA, FADAA, ODAA Rep.

Rules Oversight

Purpose: To review and refine OBD rules
Committee:

Brandon Schwindt, D.M.D., Chair
Amy Fine, D.M.D.
Alicia Riedman, R.D.H., E.P.P.
Jose Javier, D.D.S.
Bruce Burton, D.M.D., ODA Rep.
Lynn Ironside, R.D.H., ODHA Rep.
Bonnie Marshall, CDA, EFDA, EFODA, MADAA, ODAA Rep.

LIAISONS

American Assoc. of Dental Administrators (AADA) — Stephen Prisby, Executive Director
American Assoc. of Dental Boards (AADB)

- Administrator Liaison – Stephen Prisby, Executive Director
- Board Attorneys' Roundtable – Lori Lindley, SAAG - Board Counsel
- Dental Liaison – Todd Beck, D.M.D.
- Hygiene Liaison – Yadira Martinez, R.D.H., E.P.P.

American Board of Dental Examiners (ADEX)

- House of Representatives – Amy Fine, D.M.D.
- Dental Exam Committee – Amy Fine, D.M.D.

Commission on Dental Competency Steering Committee (CDCA)

- Amy Fine, D.M.D.
- Yadira Martinez, R.D.H., E.P.P.

Oregon Dental Association – Julie Ann Smith, D.D.S., M.D., M.C.R.
Oregon Dental Hygienists' Association Yadira Martinez, R.D.H.,E.P.P.
Oregon Dental Assistants Association – Julie Ann Smith, D.D.S., M.D., M.C.R.
Western Regional Exam Board (WREB)

- Dental Exam Review Committee – Amy Fine, D.M.D.
- Hygiene Exam Review Committee – Yadira Martinez, R.D.H., E.P.P.

OTHER

Administrative Workgroup

Purpose: To update Board and agency policies and guidelines. Consult with Executive Director on administrative issues. Conduct evaluation of Executive Director.

Committee:

Julie Ann Smith, D.D.S., M.D., M.C.R., Chair
James Morris
Yadira Martinez, R.D.H., E.P.P.

Subcommittee:

Budget/Legislative – *(President, Vice President, Immediate Past President)*

- Julie Ann Smith, D.D.S, M.D., M.C.R.
- Todd Beck, D.M.D.
- Alton Harvey, Sr.

Anesthesia

Purpose: To review and make recommendations on the Board's rules regulating the administration of sedation in dental offices.

Committee:

Julie Ann Smith, D.D.S., M.D., M.C.R., Chair
Brandon Schwindt, D.M.D.
Rodney Nichols, D.M.D.
Daniel Rawley, D.D.S.
Mark Mutschler, D.D.S.
Jay Wylam, D.M.D.
Normund Auzins, D.M.D.
Eric Downey, D.D.S.
Ryan Allred, D.M.D.
Michael Doherty, D.D.S.

*Not Selected by the OBD

EXECUTIVE DIRECTOR'S REPORT

EXECUTIVE DIRECTOR'S REPORT
June 17, 2016

Board Member & Staff Updates

Governor Kate Brown appointed Jose Javier, DDS of Portland to succeed Jonna Hongo, DMD who served two terms on the Board. I attended Dr. Javier's senate confirmation hearing on May 23rd. Dr. Javier's term began on June 1st and expires April 1, 2020. Dr. Javier attended new board member orientation at the OBD on June 7th with staff and Lori Lindley participating.

On May 2nd I appointed Teresa Haynes to serve as the OBD's Acting Office Manager and Ingrid Nye as the Acting Examination and Licensing Manager. They both are working out of class, typically that is for a period of one year, and at that time we will assess their fit and desire to continue on in those positions. Our Office Specialist position was posted on the state's employment website and the OBD website from May 9 – May 22. Interviews will be conducted the week of June 13 and we should hire someone by the end of the month.

OBD Budget Status Report

Attached is the latest budget report for the 2015 - 2017 Biennium. This report, which is from July 1, 2015 through April 30, 2016, shows revenue of $1,600,715.16 and expenditures of $1,066,009.18. If Board members have questions on this budget report format, please feel free to ask me. **Attachment #1**

2017-19 Budget Planning & Management Classification Project

The process continues with our Current Service Level (and all agencies) being evaluated by DAS CFO's Office. I am formulating additional budget request beyond current service level to anticipate additional costs upgrades in technology, impact on OBD if the OMB becomes semi-independent, increase in compensation for Board members' per diem and possible additional staff resources needed to implement strategic plan initiatives.

On June 1st DAS Acting COO George Naughton and Madeline Zike DAS HR held a brief meeting to update Agency Directors on the status of the Oregon Management Project which is on hold, most likely for another three years. **Attachment #2**

Customer Service Survey

Attached are the legislatively mandated survey results from July 1, 2015 – June 1, 2016, and comments received. The results of the survey show that the OBD continues to receive positive ratings from the majority of those that submit a survey. **Attachment #3**

Board and Staff Speaking Engagements

Teresa Haynes and I made a License Application Presentation to the graduating Dental Students at OHSU in Portland on Thursday, April 28, 2016.

Teresa Haynes and I made a License Application Presentation to the graduating Dental Hygiene Students at Portland Community College in Portland on Friday, April 29, 2016.

Teresa Haynes and Ingrid Nye made a License Application Presentation to the graduating Dental Hygiene Students at Lane Community College in Eugene on Monday, May 2, 2016.

Dr. Paul Kleinstub, Dental Director/Chief Investigator made a Board Updates/Enforcement Presentation to the Permanente Dental Associates Meeting in Portland on Saturday, May 14, 2016.

I made a Board Updates Presentation to the Lane County Dental Society in Eugene on Thursday, June 2, 2016.

Dr. Daniel Blickenstaff, Investigator made a Board Updates/Career Orientation Presentation to the second year Dental Hygiene students at Portland Community College in Portland on Friday, June 3, 2016.

Teresa Haynes and Ingrid Nye planned to make a License Application Presentation to the graduating Dental Hygiene Students at Pacific University in Forest Grove on Thursday, June 16, 2016.

AADA/AADB Annual Meetings Oct 16-19, 2016

The Board needs to authorize my attendance at the American Association of Dental Administrators and the American Association of Dental Boards Annual meetings scheduled October 16 -19 in Denver, Co. Senior Assistant Attorney General, Lori Lindley, will be attending the Board Attorneys' Roundtable Meeting that is held in conjunction with the AADB Meeting. Dr. Todd Beck and Ms. Yadira Martinez who are the dental and dental hygiene liaisons will be authorized by me to attend the AADB Meeting. **ACTION REQUESTED**

2017 OBD Calendar

Attached are the board approved meeting dates for 2017. The Board adopted these dates at the April 22nd Board meeting. **Attachment #4**

Strategic Planning Session

The Board held a very successful and productive strategic planning session April 22-23, 2016. The draft document is being finalized with staff input and then will go back to the Board for final approval before being shared with our Licensees, stakeholders and the public.

Newsletter

The last newsletter was published in December. I anticipate the next edition going out later in the year, which will incorporate the Board's Strategic Plan along with other important news and updates relevant to our Licensees. Articles from our new President Dr. Julie Ann Smith, outgoing board member Dr. Jonna Hongo and new board member biography of Dr. Jose Javier already have space reserved in the next newsletter.

Appn Year 2017

BOARD OF DENTISTRY
Fund 3400 BOARD OF DENTISTRY
For the Month of APRIL 2016

REVENUES

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
0975	OTHER REVENUE	23,917.48	1,103.87	25,021.35	55,001.00	29,979.65
0505	FINES AND FORFEITS	66,000.00	5,000.00	71,000.00	75,000.00	4,000.00
0205	OTHER BUSINESS LICENSES	1,440,080.00	45,546.00	1,485,626.00	3,141,259.00	1,655,633.00
0410	CHARGES FOR SERVICES	11,844.00	66.50	11,910.50	17,200.00	5,289.50
0605	INTEREST AND INVESTMENTS	3,500.71	656.60	4,157.31	8,000.00	3,842.69
0210	OTHER NONBUSINESS LICENSES AND FEES	2,250.00	750.00	3,000.00	16,000.00	13,000.00
		1,547,592.19	**53,122.97**	**1,600,715.16**	**3,312,460.00**	**1,711,744.84**

TRANSFER OUT

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	20,920.00	53,685.00	74,605.00	216,000.00	141,395.00
		20,920.00	**53,685.00**	**74,605.00**	**216,000.00**	**141,395.00**

PERSONAL SERVICES

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	48,529.55	6,067.58	54,597.13	175,030.00	120,432.87
3180	SHIFT DIFFERENTIAL	30.38	19.50	49.88	0.00	-49.88
3170	OVERTIME PAYMENTS	1,671.20	865.46	2,536.66	3,771.00	1,234.34
3160	TEMPORARY APPOINTMENTS	2,746.89	2,754.24	5,501.13	3,920.00	-1,581.13
3110	CLASS/UNCLASS SALARY & PER DIEM	340,046.67	44,009.50	384,056.17	1,142,595.00	758,538.83
3221	PENSION BOND CONTRIBUTION	17,551.79	2,146.25	19,698.04	67,003.00	47,304.96
3230	SOCIAL SECURITY TAX	26,322.28	3,608.33	29,930.61	90,716.00	60,785.39
3250	WORKERS' COMPENSATION ASSESSMENT	169.46	23.04	192.50	552.00	359.50
3270	FLEXIBLE BENEFITS	79,515.26	8,851.73	88,366.99	240,768.00	152,401.01
3260	MASS TRANSIT	1,956.61	248.05	2,204.66	6,881.00	4,676.34
3210	ERB ASSESSMENT	90.24	9.60	99.84	352.00	252.16
3190	ALL OTHER DIFFERENTIAL	0.00	0.00	0.00	35,483.00	35,483.00
		518,630.33	**68,603.28**	**587,233.61**	**1,767,071.00**	**1,179,837.39**

SERVICES and SUPPLIES

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
4175	OFFICE EXPENSES	34,796.88	1,032.74	35,829.62	84,561.00	48,731.38
4575	AGENCY PROGRAM RELATED SVCS & SUPP	36,429.69	3,250.56	39,680.25	165,516.01	125,835.76
4400	DUES AND SUBSCRIPTIONS	5,802.95	20.00	5,822.95	1,043.96	-4,778.99
4715	IT EXPENDABLE PROPERTY	2,110.32	0.00	2,110.32	5,421.00	3,310.68

Attachment #1

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
4100	INSTATE TRAVEL	10,366.95	1,552.57	11,919.52	49,208.00	37,288.48
4125	OUT-OF-STATE TRAVEL	0.00	0.00	0.00	0.00	0.00
4250	DATA PROCESSING	2,697.17	228.96	2,926.13	6,412.00	3,485.87
4275	PUBLICITY & PUBLICATIONS	3,699.90	1,521.70	5,221.60	13,800.00	8,578.40
4150	EMPLOYEE TRAINING	14,650.42	2,678.86	17,329.28	68,577.04	51,247.76
4425	FACILITIES RENT & TAXES	58,007.92	6,466.25	64,474.17	154,455.00	89,980.83
4200	TELECOMM/TECH SVC AND SUPPLIES	6,722.23	717.50	7,439.73	23,155.99	15,716.26
4315	IT PROFESSIONAL SERVICES	8,400.00	0.00	8,400.00	52,460.00	44,060.00
4300	PROFESSIONAL SERVICES	83,893.36	19,897.93	103,791.29	125,917.20	22,125.91
4650	OTHER SERVICES AND SUPPLIES	46,247.51	2,815.31	49,062.82	71,185.81	22,122.99
4325	ATTORNEY GENERAL LEGAL FEES	26,384.00	0.00	26,384.00	224,149.00	197,765.00
4225	STATE GOVERNMENT SERVICE CHARGES	19,210.21	49.68	19,259.89	39,124.99	19,865.10
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	0.00	0.00	0.00	655.00	655.00
4700	EXPENDABLE PROPERTY $250-$5000	0.00	0.00	0.00	5,421.00	5,421.00
4475	FACILITIES MAINTENANCE	0.00	0.00	0.00	542.00	542.00
		359,419.51	**40,232.06**	**399,651.57**	**1,091,605.00**	**691,953.43**

SPECIAL PAYMENTS

Budget Obj	Budget Obj Title	Prior Month	Current Month	Bien to Date	Financial Plan	Unobliq
6443	DIST TO OREGON HEALTH AUTHORITY	56,023.00	23,101.00	79,124.00	185,128.00	106,004.00
		56,023.00	**23,101.00**	**79,124.00**	**185,128.00**	**106,004.00**

		3400		
		Monthly Activity	Biennium Activity	Financial Plan
REVENUES	REVENUE	53,122.97	1,600,715.16	3,312,460.00
	Total	53,122.97	1,600,715.16	3,312,460.00
EXPENDITURES	PERSONAL SERVICES	68,603.28	587,233.61	1,767,071.00
	SERVICES AND SUPPLIES	40,232.06	399,651.57	1,091,605.00
	SPECIAL PAYMENTS	23,101	79,124	185,128.00
	Total	131,936.34	1,066,009.18	3,043,804.00
TRANSFER OUT	TRANSFER OUT	53,685	74,605	216,000.00
	Total	53,685	74,605	216,000.00

Attachment #1

The Oregon Management Project

Building the team to lead innovation across state government and to tackle complex problems.

The Problem:

State government's relationship with managers is broken and our philosophy as an employer is woefully outdated. To deliver the improved operations and outcomes Oregonians, the Governor and the Legislature envision, the state must develop, retain and attract leaders with the necessary skills and abilities. To that end, we need to bring our employment system for managers into the modern day.

The Solution:

This project will outline options for greater flexibility in total compensation, improved training and accountability programs that focus on outcomes, as well as better ways to recruit and support the right people, in the right job for the right amount of time.

The Work:

In 2013, Oregon's Enterprise Leadership Team this organized a project team to begin improving the current system by developing a series of recommended legislative and administrative actions over the next few years. The package will define Oregon's management philosophy, our system of classification and compensation, and our recruitment, retention and training practices.

As a primary step, we've engaged professionals who have helped other states successfully update their classification systems, and initiated a comprehensive market comparison to develop a clear and useable classification system and a transparent, competitive and responsible compensation structure.

The Outcomes:

- Oregon has a management team with the skills and abilities to engage diverse stakeholders to solve the complex challenges facing the state.
- Managers have the right tools and training.
- Greater flexibility to hold managers accountable to outcomes.
- Compensation is tied to outcomes and pegged to the market.
- Oregon attracts the best and brightest leaders possible to state service.
- Stronger managers will help foster engaged and empowered employees.
- Oregon's leadership is diverse and reflects the population.

Attachment #2

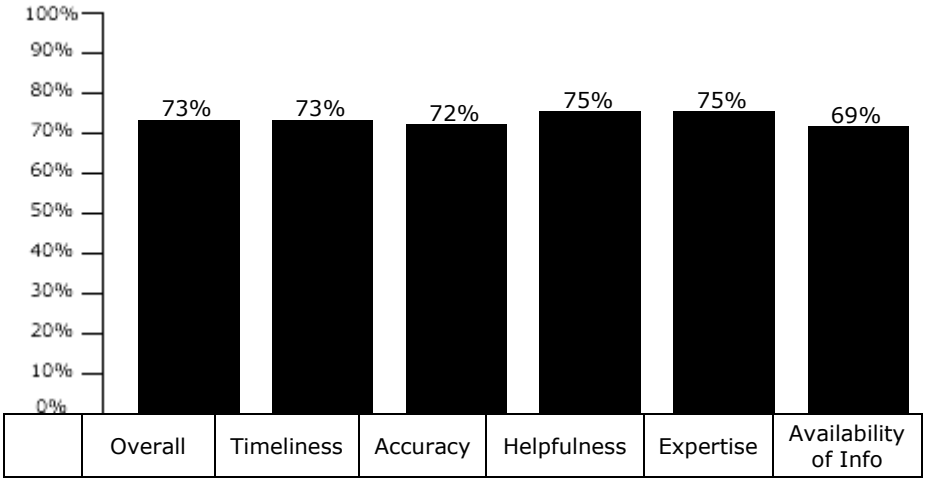
Survey Reports

OBD

Showing Data for: OBD | Time Period: All Surveys | Change View

Number of Responses: 82

Percent Rating Service Good or Excellent



Rating Totals By Question

Question	Don't Know	Poor	Fair	Good	Excellent
Q1	7	10	10	19	36
Q2	7	12	9	17	37
Q3	11	10	8	17	36
Q4	11	12	6	17	36
Q5	8	15	10	13	36
Q6	7	13	7	20	35

Question #1: TIMELINESS: How would you rate the timeliness of services provided by the Oregon Board of Dentistry?
Question #2: ACCURACY: How do you rate the ability of the Oregon Board of Dentistry to provide services correctly the first time?
Question #3: HELPFULNESS: How do you rate the helpfulness of the Oregon Board of Dentistry employees?
Question #4: EXPERTISE: How do you rate the knowledge and expertise of the Oregon Board of Dentistry employees?
Question #5: AVAILABILITY OF INFORMATION: How do you rate the availability of information at the Oregon Board of Dentistry?
Question #6: OVERALL SERVICE: How do you rate the overall quality of service provided by the Oregon Board of Dentistry?

Comments Received

Posted	Comment
5/25/2016 6:23:16 PM	I have learned through personal experience that the Board's administrative staff is not trustworthy.
5/11/2016 8:10:15 AM	You are not asking the right question. How difficult is it to navigate/access patient information from the sites to be able to take this into account as a provider needs to write a prescription?
5/9/2016 5:21:48 PM	Takes too long to get thru cases, I do not have an answer on how to make things go faster, howev er.
5/3/2016 7:56:29 AM	The ODB allows customers to submit questions online, rather than call their office, which should be great. However, typically their email response is please call the office. How is this helpful?
4/15/2016 1:47:20 PM	Extremely disappointed.
3/30/2016 7:28:54 AM	Thank you for all your hard work.
3/15/2016 8:01:48 AM	I realize paying an exorbitant amount of money to fund more and more regulation, pay salaries of bureaucrats is.... The fees continue to climb....
3/15/2016 8:01:35 AM	I realize paying an exorbitant amount of money to fund more and more regulation, pay salaries of bureaucrats is.... The fees continue to climb....
2/23/2016 4:31:18 PM	Ms. Theresa Haynes does an excellent job of communicating with the renewel process.
2/11/2016 11:33:07 AM	Very prompt response to my email. Thank you!
2/11/2016 11:32:55 AM	Very prompt response to my email. Thank you!
1/11/2016 9:05:02 PM	After 3 attempts to discuss the questions that I have to transfer my dental hygiene license, I have had no success in contacting the professional that has the knowledge to help me.
1/10/2016 4:22:23 PM	I seem to get into the 15% random audit a lot
1/10/2016 4:22:17 PM	I seem to get into the 15% random audit a lot
12/22/2015 7:52:45 PM	I cannot open the newsletter. Also, I feel it was important see which professionals had violated the rules. I cannot possibly look up every individual, so it is not helpful or informative any more.
12/22/2015 6:18:02 PM	The mission statement of this agency has been to protect the public. Making it a challenge to find the names of licensees that have been disciplined protects the licensee, not the public.
12/22/2015 1:55:25 PM	Other than license renewals, I have never had any dealings with the Board.
12/22/2015 1:14:42 PM	If the audits are random and only 15% than why am I being audited for 2 consecutive renewals? Maybe they are alphabetically. You should change this to be more fair.
11/11/2015 9:03:10 PM	I appreciate all your help making this move easier Thank you Wendy
10/21/2015 7:09:40 AM	She just had to look l me up to see where my license renewal was due.
10/21/2015 7:09:34 AM	She just had to look l me up to see where my license renewal was due.
10/9/2015 11:53:53 AM	It took 3 phone calls to get the retirement form I needed. Ms Haynes quickly sent me an email form, the previous office help apparently couldn't get the request taken care of at all
9/10/2015 7:03:31 PM	Teresa was very prompt about sending my receipt for my license. Thank you, Barb
9/9/2015 7:47:23 PM	The board is not staffed sufficiently for investigators. Some cases take a year to resolve just due to sheer case load. The data provided is not a clear data visual representation. It would be great i
9/9/2015 4:00:35 PM	I would appreciate knowing what the mandatory five dollar workforce survey fee covers. A survey, in my experience, should be a voluntary experience to receive the best results.
9/9/2015 3:59:04 PM	why is a notary involved? that step will inhibit many providers from signing up. I don't have to have a notary for basically anything else these days.
9/9/2015 2:35:55 PM	I would like to see a response given when a provider gets their CE courses audited. A Pass for all courses accepted or a Fail if they aren't-some type of follow up for all the info we send in.
9/9/2015 12:12:54 PM	I have tried to use the Prescription Drug Monitoring website a few times and find it Very Difficult to Access patient information. Can you make more User Friendly?

9/1/2015 8:16:34 AM	I have called several times for licensing information. Each call, I received a warm, friendly correct answer instantly. Refreshing that this caliber of service does exist somewhere in the world.
8/7/2015 8:21:03 AM	You efficiently let us know of the meeting for rule changes, but what ARE the rule changes you are considering? Please email us of the summary of the issues with links of information on each issue.
8/5/2015 9:07:36 PM	Keep up the good work!
8/5/2015 5:22:46 PM	I am retired and won't be renewing my license. Coralie
8/4/2015 5:28:59 PM	End Tidal CO2 monitoring is unnecessary for enteral moderate sedation due to the fact that patients do not enter into significant respiratory depression.
8/4/2015 11:57:17 AM	it is ridiculous you are charging hygienist a manditory 5.00 to take a survey. When I told the dentist I work for that, he laughed. That is extorsion!!
8/4/2015 9:46:22 AM	Keep up the great work!
8/4/2015 7:22:27 AM	It would be nice if the Board of Dentistry would actually hire an Exceutive Director that had a clue about dentistry!
8/4/2015 7:14:06 AM	Happy with obd services.
7/24/2015 2:57:17 PM	Teresa gave excellent service and helped me immediately. She went over an above the expectation of service. She is knowledgeable, efficient and helpful. She helped me navigate the Web site.

January						
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April						
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June						
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December						
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31						

Holidays

Jan 1	New Year's Day
Jan 2	New Year's Day (Observed)
Jan 16	Martin Luther King Day
Feb 20	Presidents' Day
April 16	Easter Sunday
May 29	Memorial Day
Jul 4	Independence Day
Sep 4	Labor Day
Sep 21-22	Rosh Hashanah
Sep 30	Yom Kippur
Nov 10	Veterans Day (Observed)
Nov 11	Veterans Day
Nov 23	Thanksgiving Day
Nov 24	OBD Staff Holiday
Dec 13-20	Chanukah
Dec 25	Christmas Day

Important OBD Dates

○	Evaluator's Meeting
□	Board Meeting
TBD	CDCA Annual Conference
TBD	ODC Conference
TBD	AADA & AADB Mid Year Meeting
TBD	Strategic Planning Session
TBD	ADEX House Meeting
TBD	AADA & AADB Annual Meeting

Other Significant Events

TBD	ODA House of Delegates
TBD	Mission of Mercy

UNFINISHED BUSINESS & RULES

OREGON BOARD OF DENTISTRY - DENTAL ASSISTING NATIONAL BOARD, INC.

AGREEMENT FOR THE PROVISION OF TESTING AND CERTIFICATE SERVICES

This Agreement is made by and between the Dental Assisting National Board, Inc. (DANB), hereafter called "DANB," an Illinois not-for-profit corporation that develops and administers testing programs from its offices at 444 N. Michigan Ave., Suite 900, Chicago, Illinois 60611 and the Oregon Board of Dentistry, hereafter called the "State," with offices at 1500 SW 1st Ave., Ste. # 770, Portland, OR 97201.

In consideration of the mutual promises and covenants between the parties contained in this Agreement, the sufficiency of which is hereby agreed to by the parties, and intending to be legally bound hereby, the parties agree as follows:

1. Description of the Services. DANB shall provide the Services for the State as described in this Section 1:

   a. Exam/Items

      i. The Oregon Basic (ORB) exam, containing between 100 and 125 multiple-choice items; and

      ii. The Oregon Expanded Duties – General (ORXG), containing between 90 and 100 multiple-choice items; and

      iii. The Oregon Expanded Duties – Orthodontic (ORXO), containing between 100-125 multiple-choice items; and

      iv. The Oregon Clinical Radiologic Proficiency (ORCL) exam, are the subject of this Agreement.

   b. Exam Development, Administration and Scoring

      (1) DANB's Expanded Functions Dental Exam (EFDA) exam committee, led by DANB's psychometric team, will review the current exams, draft new items and recommend new exam versions based on the state's exam blueprint at least every five to seven years (or more often if the State requests changes due to updates to state requirements), for the ORB, ORXG and ORXO exams. DANB recommends that there be at least 5 total items to test each sub-content area of the exam blueprint to provide meaningful data to candidates about performance in each area if they fail the exam. Each time the exam is updated, the EFDA exam committee will also conduct a standard setting study and recommend a pass point to the State.

      (2) To develop the exam, the State will provide the approved exam blueprint(s) as requested by DANB or when updates are required based on changes to the state dental practice act.

(3) Upon development of new versions of the ORB, ORXG and/or ORXO exams, DANB psychometric staff will meet with representatives appointed by the State by webinar for the State to provide review and approval of the new exam versions, exam items and exam pass points.

(4) A final review of the ORB, ORXG and/or ORXO exams will be conducted by DANB's copyeditor prior to publication. DANB will maintain the existing item pool and related statistics on its computerized item banking system.

(5) DANB will recruit and train experts to evaluate the ORCL full mouth series – to be evaluated based on the State-specific requirements.

c. Issuance of State-Specific Certificates

DANB currently, and will continue to, issues the certificates for 1-3. With a tentative start date of July 1, 2016, DANB will begin also issuing the certificates for 4-11. (The start date is flexible depending on when the State is ready for DANB to start. The start date will be no later than Jan. 1, 2017).

(1) Oregon Certification for Radiologic Proficiency (ORRad)

(2) Oregon Expanded Functions – General Dental Assisting (EFDA)

(3) Oregon Expanded Functions – Orthodontic Assisting (EFODA)

(4) Oregon Expanded Functions – Orthodontic Assisting by credential (EFODA)

(5) Oregon Expanded Functions – General Dental Assisting by credential (EFDA)

(6) Oregon Certification for Radiologic Proficiency by credential (ORRad)

(7) Oregon Expanded Functions – General Dental Assisting with Restorative Functions add-on (EFDA-RF)

(8) Oregon Expanded Functions – Preventive Dental Assistant (EFPDA)

(9) Oregon Anesthesia Assistant (AnA)

(10) Oregon Anesthesia Assistant with IV Therapy (AnA-IV)

(11) Future certificates that the State approves and that DANB approves as well

d. Exam and Certification Application Packets

(1) DANB will develop and print exam and certificate application packets. The State will provide final approval. DANB will update the exam and certificate application packets annually and will provide them to candidates through www.danb.org and by paper copy upon request.

(2) All DANB policies related to processing exam and certificate applications, managing candidate contact, and administering the exams will apply to the Oregon state-specific exams (listed in section 1.a.) and to the state-specific certificates issued by DANB on behalf of the State (listed in section 1.c.) Such DANB policies and procedures will be included in the exam and certification application packets and will be available to the State with its annual exam and certificate application packets review.

(3) DANB will establish, and may from time to time change, application processing fees and other related fees (including but not limited to exam cancellation and rescheduling fees) to be paid by candidates, outside of the specific exam fee. The specific Oregon state-specific exam and certificate fees are noted in Section 2 of this Agreement.

(4) The State will establish eligibility requirements that must be met to take the exams and earn the certificates listed in this Agreement.

(5) DANB will review and process exam and certificate applications, ensuring that each candidate has met the State-established eligibility requirements and paid the current application fees. DANB will also process and assess fees associated with requests from exam candidates to cancel their exam, extend the window within which the exam appointment can be made, etc. These fees will be equal to the fees that DANB charges its DANB national exam candidates for the same services.

d. Candidate Communication

(1) At the discretion or direction of the State, all inquiries regarding candidate eligibility and requirements will be directed to DANB. DANB will respond to candidate inquiries regarding test sites, exam administration and scoring. DANB's toll-free number 1-800-367-3262 and e-mail address danbmail@danb.org will be available for this program.

e. Exam Administration

(1) DANB will, through its contractual relationship with a computerized testing vendor, support the proctored administration of the exams in 1.a. (ORB, ORXG and ORXO exams) through a computer test delivery network employing security measures that meet or exceed industry standards. All candidates must present valid identification at the test center as required by DANB, in order to be authorized to test.

(2) DANB will notify candidates when their applications have been processed and they are approved to take the exam(s). Notifications will include a toll-free registration telephone number and a web site through which candidates may seek a testing appointment date. Candidates will be provided with a 60-day period during which time their testing must occur.

(3) DANB and its computerized testing vendor will make appropriate arrangements for reasonable testing accommodations that may be necessary to comply with the Americans with Disabilities Act.

(4) All improper behavior by a candidate relating in any way to the Oregon exams, whether occurring before, during or after an exam appointment will be reported by testing vendor personnel to DANB. Such incidents will be handled at the sole discretion of DANB pursuant to DANB's Discipline Policy and Procedures, and the State will be notified of any sanctions that may be imposed.

f. ORB, ORXG and ORXO Exam Results Reporting

(1) Candidates will receive a printed preliminary exam results on-site at the computerized testing center.

(2) DANB will send official exam results and certificates to each candidate.

(3) DANB will provide the State with monthly lists of passing and failing Oregon exam candidates, along with an annual cumulative listing, and a list of candidates who earned certificates listed in 1.c.

(4) Candidates may request duplicate exam results for five (5) years from the date the exam was administered and a duplicate certificate for the duration of this agreement.

g. Retention

(1) DANB will maintain computerized records of candidates' performance on the exams indefinitely.

2. Fees paid to DANB by the exam/certificate candidates

a. Each exam candidate will pay a per-application exam fee according to the following schedule:

Term Period	ORCL Exam Fee	ORB Exam Fee	ORXG Exam Fee	ORB & ORXG Administered Together Exam Fee	ORXO Exam Fee	ORB & ORXO Administered Together Exam Fee
Jan. 1, 2016 – Dec. 31, 2018	$200	$250	$225	$300	$225	$300
Jan. 1, 2019 – Dec. 31, 2021	$225	$275	$250	$350	$250	$350

Note: Exam Fees include a $75 nonrefundable application processing fee

b. Each certificate candidate will pay a per-application certificate fee according to the following schedule:

Term Period	ORRad	ORXG	ORXO	ORRad by Credential	ORXG by Credential	ORXO by Credential
July 1, 2016 – Dec. 31, 2021	$50	$50	$50	**$150** Application fee $75 Certification fee $75	**$150** Application fee $100 Certification fee $50	**$150** Application fee $100 Certification fee $50

Term Period	EFDA-RF	EF-Ped	AnA	AnA-IV
July 1, 2016 – Dec. 31, 2021	$50	$50	**$75** Application fee $25 Certification fee $50	**$75** Application fee $25 Certification fee $50

3. Fees paid to the State by DANB. DANB agrees to pay the State a fee of $12 for every certificate listed in 1.c. issued by DANB to the candidate through 2018. Beginning Jan. 1, 2019, this fee will increase to $15.

4. Ownership Rights.

   a. The State hereby expressly agrees that all rights to and interests in any items written for the Oregon exams (listed in 1.a.) and any and all parts thereof and any materials produced by DANB prior to or under this Agreement, including but not limited to copyrights, are and will remain the sole property of DANB. The State hereby expressly agrees that all research data, manuscripts, marketing lists, data bases, diagrams, charts, tables, and other similar lists and materials obtained or developed by DANB prior to or as part of the Services are and will remain the sole property of DANB, and that any such materials in the possession of the State will be surrendered to DANB by the State immediately upon DANB's.

   b. DANB intellectual property will not be used by the State for any purpose other than those expressly allowed by the terms of this Agreement. Any use of DANB trademarks shall conform with DANB's Trademark Usage Guidelines, attached to this Agreement as Appendix A.

5. Confidentiality. The State hereby understands and agrees that the content of the Oregon exams (listed in 1.a.) is proprietary and strictly confidential information. The State understands and agrees that it will not release or disclose, directly or indirectly, in writing or orally, any question or any part of any question from the Oregon exams (listed in 1.a.) to any person or entity. The State further understands and agrees that the unauthorized receipt, retention, possession, copying or disclosure of any Oregon exam materials (listed in 1.a.), including but not limited to the content of any exam question, before, during, or after the administration of an Oregon exam (listed in 1.a.) may result in legal action.

6. Notices and Other Communications. Any notice which any party hereto gives to the other party hereunder shall be in writing and shall be deemed given when delivered in person to a representative of the party, or upon receipt after deposited in the United States certified or registered mail, return receipt requested or upon receipt if sent by recognized, national, overnight express mail, addressed to the party, at the address of such party set forth below, or at such other address as the party to whom notice is to be given has specified by notice hereunder to the party seeking to give such notice:

If to the State:	Stephen Prisby Executive Director Oregon Board of Dentistry 1500 SW 1st Ave., Ste. # 770 Portland, OR 97201
If to DANB:	Cynthia C. Durley, MEd, MBA Executive Director Dental Assisting National Board, Inc. 444 N. Michigan Avenue, Suite 900 Chicago, IL 60611

7. Representations and Warranties. The State represents and warrants that all exam items and other materials provided by the State to the DANB under this Agreement are original, or that appropriate permission to use such materials has been obtained, and that DANB's use of such materials in the delivery of the Oregon exams (listed in 1.a.) will not infringe any copyright or other proprietary right of any person. The responsibility for assuring that no infringement shall occur in connection with materials provided by the State rests solely and exclusively with the State.

8. Term and Termination.

   a. The term of this Agreement shall commence upon signature by duly authorized representatives of both DANB and the State and shall continue through December 31, 2018 unless terminated earlier upon written notice by either party as described below.
   b. Either party may terminate this agreement upon twelve (12) months written notice to the other party.

The dates and fees in this Agreement are contingent upon the execution of this Agreement by duly authorized representatives of both DANB and the State by June 1, 2016.

DENTAL ASSISTING NATIONAL BOARD, INC.

By: Cynthia C. Durley, MEd, MBA
Name

Title: Executive Director

Cynthia C Durley
Signature

5/17/16
Date

OREGON DENTAL BOARD

By: Stephen Prisby
Name

Title: Executive Director

Stephen Prisby
Signature

5/19/16

818-035-0040

Expanded Functions of Dental Hygienists

(1) Upon completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association or other course of instruction approved by the Board, a dental hygienist who completes a Board approved application shall be issued an endorsement to administer local anesthetic agents and local anesthetic reversal agents under the general supervision of a licensed dentist. Local anesthetic reversal agents shall not be used on children less than 6 years of age or weighing less than 33 pounds.

(2) Upon completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association or other course of instruction approved by the Board, a dental hygienist may administer nitrous oxide under the indirect supervision of a licensed dentist in accordance with the Board's rules regarding anesthesia.

(3) Upon completion of a course of instruction approved by the Oregon Health Authority, Public Health Division, a dental hygienist may purchase Epinephrine and administer Epinephrine in an emergency.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: DE 5-1984, f. & ef. 5-17-84; DE 3-1986, f. & ef. 3-31-86; DE 2-1992, f. & cert. ef. 6-24-92; OBD 3-1998, f. & cert. ef. 7-13-98; OBD 7-1999, f. 6-25-99, cert. ef. 7-1-99; OBD 8-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 2-2007, f. 4-26-07, cert. ef. 5-1-07; OBD 3-2007, f. & cert. ef. 11-30-07; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

CORRESPONDENCE

ADEA | THE VOICE OF DENTAL EDUCATION

AMERICAN DENTAL EDUCATION ASSOCIATION

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The mission of ADEA is to lead institutions and individuals in the dental education community to address contemporary issues influencing education, research and the delivery of oral health care for the overall health and safety of the public.

655 K Street, NW
Suite 800
Washington, DC 20001
Phone: 202.289.7201
Fax: 202.289.7204
adea.org

April 21, 2016

RECEIVED
MAY 0 9 2016
Oregon Board of Dentistry

Dr. Alton Harvey Sr.
President
Oregon Board of Dentistry
1500 SW 1st Avenue
Suite 770
Portland, OR 97201

Dear Dr. Harvey:

The American Dental Education Association (ADEA) represents all 66 U.S. dental schools and, subsequently, the deans of these schools. The ADEA Council of Deans (ADEA Council) met at the 2016 ADEA Annual Session & Exhibition in Denver and voted to send this communication to all U.S. state dental boards regarding the issue of portability of licenses and the use of human subjects in clinical licensure examinations.

The ADEA Council is aware that the American Dental Association (ADA) and the ADEA principal officers recently sent a letter to many state dental boards encouraging greater portability of licensure throughout the United States. Given the mobility of this society, the ADEA Council supports this general principle, as dentists now move more frequently and unexpectedly from state to state, often for reasons beyond their control. This is especially true for dentists within their first 10 years of practice, military dentists and dentists with partners in other highly mobile professions. Given the fact that some states and jurisdictions now recognize licenses from other states independent of the type of licensure exam taken initially, the ADEA Council respectfully requests that your board develop reciprocal licensure policies and agreements so that dentists who possess a valid, unrestricted license in any state or jurisdiction in the United States would be eligible for dental licensure and able to practice in your state.

Also, the ADEA Council wishes to reiterate its position in opposition to the use of human subject, patient-based components of clinical licensure examinations. The ADEA House of Delegates in March 2014 unanimously passed a resolution, ADEA 5H-2014, which "recommends the elimination of the human subject/patient-based components of clinical licensure examinations and the adoption of an alternative and validated process for the clinical assessment of candidates for licensure." At the 2016 ADEA Annual Session & Exhibition in March 2016, the ADEA Council reaffirmed its position on licensure and its support of Resolution 5H-2014.

Some dental schools have made individual decisions to participate in the Clinical Integrated Format (CIF), also known as the Buffalo Model (CIF-Buffalo), largely to assist their students in navigating the only examination track that currently exists for licensure in certain states. The ADEA Council wishes to state that the decision by dental schools to participate in the CIF-Buffalo version of ADEX examination offered by the Commission on Dental Competency Assessment (CDCA) should not be interpreted as an endorsement of that specific examination format, which still involves participation of human subjects.

In light of the aforementioned, we respectfully ask that you carefully consider the positions of the ADEA Council, as detailed above. These positions were formulated after many hours of thoughtful and careful deliberation and we believe they have the ability to profoundly affect oral health professionals in this country and their capacity to deliver the best care possible to this nation's population.

We welcome the opportunity to discuss these matters in greater detail.

Sincerely,

Marsha A. Pyle, D.D.S., M.Ed.
Chair, ADEA Council of Deans

R. Lamont MacNeil, D.D.S., M.Dent.Sc.
Board Director, ADEA Council of Deans

cc: ADEA Board of Directors
ADEA Council of Deans

Andrew L. Cole
LeClairRyan
180 Admiral Cochrane Drive, Suite 520
Annapolis, Maryland 21401

Chad Buckendahl, Ph.D.
ACS Ventures, LLC
11035 Lavender Hill Drive #160-433
Las Vegas, Nevada 89135

May 17, 2016

Dr. Stanwood Kanna
President
American Board of Dental Examiners, Inc.
P.O. Box 50718
Mesa, Arizona 85208

Dear Dr. Kanna,

We write at your request to address and respond to certain assertions made in a recent joint communication issued by the American Dental Association (ADA) and the American Dental Education Association (ADEA) (the "ADA/ADEA Letter"). In their letter, the ADA and ADEA make certain assertions regarding the comparability of clinical licensure examinations in dentistry offered by different agencies. Premised on this assertion, the ADA and ADEA recommend that state boards of dentistry relax their due diligence in evaluating testing options so as to foster portability of licenses across state lines and avoid antitrust concerns. We are concerned not only by the unsupported claims regarding comparability of licensure examinations and the possibility of antitrust concerns, but also by a clear conflict of interest that is not disclosed in the ADA/ADEA Letter.

We understand that the ADA has publicly declared that it is developing its own dental clinical licensure examination. It is unclear why the ADA would seek to become a participant in the dental licensure testing arena, an arena in which it purports to find no fault with *any* of the several existing clinical licensure examinations, unless its motivation is to capture some or all of the revenue stream from these examinations. The ADA's status as a potential future examination provider presents a clear conflict of interest and taints its recommendation that all states should accept all examinations. What is particularly insidious is that this recommendation is presented as though coming from a neutral observer.

In addition to this undisclosed conflict of interest, and the faulty reasoning behind the ADA's purported comparative analysis of examinations (discussed more fully below), the ADA has recently acknowledged that it has not, contrary to representations in the ADA/ADEA Letter, conducted the "careful analysis" of the various clinical licensure examinations suggested in the letter.

In a May letter to the ADEX, Dr. Jeffers, writing on behalf of the ADA Licensure Task Force,[1] acknowledges that the ADA has not in fact conducted any meaningful comparative evaluation or analysis of the various clinical licensure examinations.[2] In his letter Dr. Jeffers requests that the ADEX turn over its technical information so that the ADA may conduct the very analysis it previously claimed to have conducted. It is not clear why, in the first instance, the ADA feels it is responsible for undertaking a comparative analysis of clinical licensure examinations, but it is clear that the ADA has not, to date, actually performed any meaningful analysis.

Notwithstanding the fact that the ADA and ADEA have not, to date, conducted any meaningful comparative analysis of dental licensure examinations, the ADA/ADEA Letter purports to set forth information demonstrating the comparability of these tests. To assist you in understanding the technical components of test development and validation, and to explain why the technical aspects of the ADA/ADEA Letter are essentially meaningless, we highlight specific technical issues in the ADA/ADEA Letter and address them by providing a brief description of the key elements that stakeholders should consider when evaluating the comparability of clinical licensure examinations in dentistry. These key elements are based on a validation framework for licensure testing programs that prioritizes sources of evidence that are most important to supporting the interpretation and use of scores (Kane, 2006; Buckendahl & Plake, 2006). For licensure testing programs at risk for legal challenge, these key elements focus on 1) domain specification, 2) fairness for candidates, 3) reliability of scores and decisions, and 4) passing scores that reflect entry-level practice (see Buckendahl & Hunt, 2005).

Because some technical information for licensure testing programs is often proprietary and not publicly available, it is difficult for an external agency unfamiliar with program specifics to comment on the development and validation. Notwithstanding these difficulties, and the ADA's acknowledgement that it lacks sufficient information from which to make comparative determinations, the ADA/ADEA Letter suggests that this has occurred. Specifically, the ADA/ADEA Letter asserts that "The ADA has conducted a careful analysis of the examinations administered by each of the clinical testing agencies. . . .and has come to the conclusion that these examinations. . . .[are] conceptually comparable." The authors then continue to assert a number of characteristics of these examinations that are purported to be comparable to the point of interchangeable with respect to the resultant decisions about candidates' minimum competency.

Upon closer inspection of each of these bullet points, there are a number of problems with the authors' approach. Many of the statements are generic to the point of applying to virtually any credible licensure examination program (e.g., guidance from the *Test Standards*, documenting activities in a technical report, conducting a practice analysis, taking steps to

---

[1] Dr. Jeffers is also one of the signatories to the February 26, 2016 letter to state dental boards.
[2] As an aside, it is also not clear to us that the ADA possesses the requisite expertise necessary to conduct such an evaluation even if were free from conflicts of interest, and had sufficient information with which to do so.

reduce bias, conducting empirical analysis). It is not possible to evaluate the comparability of the substance of the examinations at such a cursory level. Fortune and Cromack (1995) provide a useful description of the characteristics of a clinical licensure examination program that could be considered in an independent evaluation. Further, some of the assertions are inaccurate.

Specifically, the authors indicate that each agency "makes a determination of candidate minimum competency in periodontics on a patient-based exam for scaling and root planning; and utilizes simulation to determine minimum competency in prosthodontics (crown preparation) and endodontics." Although the ADEX exams administered by CDCA and CITA, and the exams administered by SRTA provide a periodontal scaling examination as an option for States that require it, this is not a required component of the examination as determined by the programs' practice analysis. CRDTS and WREB do require a patient-based periodontal scaling examination. Similarly, ADEX, SRTA, and CRDTS examinations include a clinical skills performance prosthodontics examination, WREB's examinations do not. In addition, CRDTS does not include a diagnosis and treatment planning exam. The inclusion or exclusion of domains is a function of the practice analysis process and results; not merely a function of sampling error, as suggested by the authors. This mere topic level similarity is an insufficient basis from which to conclude comparability.

Although each agency has a restorative component in its examination, the scoring and evaluation criteria, its application, and the resultant decisions may be very different. For example, the differential interpretation of the impact of remaining caries in a restorative preparation by agencies is an important one to highlight. If one agency's scoring criteria defines this as a domain critical error that would fail a candidate on that exam versus another agency's interpretation that this represents something that may be characteristic of a passing candidate, the decision by the agency as well as the risk management decisions by a State board of dentistry cannot be interpreted as trivial.

A comprehensive evaluation of the comparability of examinations would include at a minimum: technical manuals, administration manuals (candidate and examiner), scoring criteria, and reliability and decision consistency evidence. This evidence is promulgated as a professional expectation in the *Standards for Educational and Psychological Testing* (AERA, APA, & NCME, 2014). The review and conclusions suggested by the ADA/ADEA Letter's authors do not suggest that an in-depth analysis of the unique aspects of these programs were considered.

The authors' inclusion of the example of efforts to create a Uniform Bar Exam does not support the premise or conclusion of the letter, nor is it a comparable example. The ADA and ADEA do not seek the adoption of a 'uniform' licensure examination, rather the ADA and ADEA suggest that every state should accept *every* available examination. That would be analogous to suggesting that in the legal profession every state accept the bar exam developed by every other state. We are aware of no move in the legal profession, or any other profession, to adopt such a policy.

Notwithstanding that the fact that the ADA has conducted no meaningful evaluation of the comparability of dental licensure examinations, the ADA/ADEA Letter asserts that the purported comparability of examinations means that any state dental board that accepts fewer than all of the examinations acts in an "arbitrary" and "specious" manner and in restraint of trade (by restricting interstate mobility of licenses). By raising the spectre of antitrust liability, the ADA and ADEA seek to bully state dental boards into abdicating their obligation to evaluate the various licensure examinations and instead simply accept all licensure examinations as the 'least anticompetitive' option.

Each state dental board is tasked by its state with vetting dental licensure exams. It is the duty of each State board to determine which test or tests best differentiate between qualified and non-qualified applicants for licensure in order to protect the public from the practice of dentistry by unqualified individuals.

Licensure, by its very nature, is anti-competitive in the sense that it restricts entry into a particular market. That being said, the Supreme Court has long recognized that some anti-competitive restrictions are necessary for certain professions in order to protect the public. As the Supreme Court noted in its recent decision *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 135 S.Ct. 1101 (2015), "States . . . when acting in their respective realm need not adhere in all contexts to a model of unfettered competition. . . . [I]n some spheres, they impose restrictions on occupations . . . or otherwise limit competition to achieve public objectives. . . . If every duly enacted state law or policy were required to conform to the mandates of the Sherman Act, thus promoting competition at the expense of other values a State may deem fundamental, federal antitrust law would impose an impermissible burden on the States' power to regulate." *Id.* at 1104 (quoting *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 133 (1978).

While State dental boards should certainly be mindful of antitrust concerns while carrying out their functions and duties, it is misplaced for the ADA/ADEA Letter to raise such concerns in the context of designating licensure examinations. Unlike the regulation of teeth whitening presented in *North Carolina State Board of Dental Examiners*, which involved extra-legislative action by the North Carolina State Board of Dental Examiners, virtually every state designates its approved licensure examination by statute, or by a legislative rule. This sort of deliberate state action is specifically protected from antitrust liability. As noted in *North Carolina State Board of Dental Examiners*, "State legislation . . . will satisfy [the] standard [for *Parker*[3] immunity] and *ipso facto* are exempt from the operation of the antitrust laws because they are an undoubted exercise of state sovereign authority." *Id.* at 1110.

It is worth pointing out that the ADA stated in its *Amicus* brief in *North Carolina State Board of Dental Examiners* that it "support[ed] the determination by state legislatures across this country that the health professions should be regulated by knowledgeable health care professionals who have practical experience in the profession that they are regulating." The ADA also stated that it believed "the public is best served when state regulatory boards duly

[3] The phrase *Parker* immunity refers to the Supreme Court's 1943 decision in *Parker v. Brown*, 317 U.S. 341 (1943) in which it held that States are immune from antitrust law when acting in their sovereign capacity.

constituted in accordance with state law are free to make decisions on public health issues based on clinical experience without fear of second-guessing under the federal antitrust laws." Now, contrary to its prior position, it appears the ADA, rather than supporting the independence of State dental boards,' suggests that the states should essentially abdicate their responsibility to protect the public from the unqualified practice of dentistry to the ADA, and simply follow the lead of the ADA in accepting all licensure examinations.

Please feel free to contact us with questions.

Sincerely,

Andrew L. Cole
Attorney at Law
LeClairRyan

Chad W. Buckendahl, Ph.D.
Partner
ACS Ventures, LLC

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Disclosures of Conflict

Dr. Buckendahl has provided varying levels of consultation for the following organizations that are involved in dental licensure testing: American Dental Association, American Board of Dental Examiners, Commission on Dental Competency Assessments (formerly North East Regional Board of Dental Examiners), Council of Interstate Testing Agencies, CSW Computer Simulations, Kentucky Board of Dentistry, National Dental Examining Board of Canada, North Carolina Board of Dental Examiners, and Southern Regional Testing Agency.

ADA American Dental Association®
America's leading advocate for oral health

ADEA THE VOICE OF DENTAL EDUCATION

February 26, 2016

Dr. Zebulon Vance Morgan IV
President
South Carolina Board of Dentistry
P.O. Box 11329
Columbia, SC 29211-1329

Dear Doctor Morgan:

We are writing to express the high level of concern that the American Dental Association (ADA), its Licensure Task Force and Council on Dental Education and Licensure, and the American Dental Education Association (ADEA) have with regard to the status of licensure for dentists in the United States. While licensure portability is an important matter to dental professionals, particularly to those pursuing initial licensure or attempting to relocate to another state, it is clear that the dental boards of a number of states, including your own, continue to engage in conduct that restricts, rather than enhances, that portability.

As you know, there are five clinical test administration agencies for dentistry: the Commission on Dental Competency Assessments (CDCA, formerly NERB); Central Regional Dental Testing Service, Inc. (CRDTS); Council of Interstate Testing Agencies, Inc. (CITA); the Southern Regional Testing Agency, Inc. (SRTA); and the Western Regional Examining Board (WREB). The ADA has conducted a careful analysis of the examinations administered by each of the clinical testing agencies (CDCA and CITA administer the American Board of Dental Examiners (ADEX) dental exam, while CRDTS, SRTA, and WREB administer their own exams) and has come to the conclusion that these examinations adhere to a common set of core design and content requirements that renders them conceptually comparable. In particular, each agency:

- utilizes the *Standards for Educational and Psychological Testing* as the guidelines for evaluating the validity of their exams;
- produces a publically available technical report that documents and summarizes available validity and reliability evidence concerning the examinations;
- utilizes conjunctive scoring, requiring candidates to pass each of a series of tests in order to pass the full examination;
- conducts a practice analysis on a regular basis to ensure that test content reflects normal, everyday tasks performed in general dental practice;
- reduces examiner bias and enhances fairness by ensuring that examiners do not know the identity of the candidate whose performance they are evaluating;

- requires three examiners to evaluate performance on each exam and sub-exam;
- requires examiners to participate in calibration exercises to align examiner perspectives and provide a common frame of reference;
- conducts prospective and retrospective evaluations of examiner consistency and reliability;
- makes a determination of candidate minimal competency in restorative dentistry on a patient-based exam for a Class III composite resin preparation and restoration and either a Class II amalgam or composite resin preparation and restoration;
- makes a determination of candidate minimal competency in periodontics on a patient-based exam for scaling and root planning; and
- utilizes simulation to determine minimal competency in prosthodontics (crown preparation) and endodontics.

Given the aforementioned commonality in design and content requirements, any apparent differences in the performance of these clinical examinations can be called into question and potentially interpreted as simply reflecting sampling error. In light of this, accepting the results from certain clinical examinations and not others appears specious. It has been a longstanding policy of the ADA that it represents unnecessary and meaningless duplication to require a candidate seeking licensure in different states to demonstrate his or her theoretical knowledge and clinical skill on separate examinations for each jurisdiction, especially when it is clear that the core requirements, administration, and outcomes are virtually indistinguishable between each examination.

It is our understanding that your state affirmatively elects not to accept the examination results from all of these test administration agencies. The decision of your board, as well as the boards of a number of other states, to accept the test results of only a select number of clinical test administration agencies appears highly arbitrary. Moreover, those decisions have an arguably anticompetitive effect in restricting the mobility of dentists wishing to move from one state to another. As you know, the whole concept of licensure is currently under attack because of its inherent effect on competition; it is therefore incumbent on the dental profession to ensure that any such restraints are not susceptible to a claim that they are unreasonable in nature. Indeed, the House of Delegates of the American Bar Association recently passed a resolution urging bar admission authorities in various states to adopt a Universal Bar Examination in order to facilitate mobility for new lawyers. This concept of mobility among professionals is obviously gaining additional momentum.

In light of these circumstances, we respectfully request that your Board pursue the necessary steps to accept successful completion of all of the clinical test administration agency examinations for dental licensure in your state. Recognizing that the dental board's primary mission is protecting the public in your state, we believe that the board has the authority and autonomy to pursue this change. It will increase portability of dental professionals and access to quality dental care for patients.

We would be pleased to meet with you or your board to further discuss this matter.

Sincerely,

Carol Gomez Summerhays, D.D.S., M.A.G.D.
President
American Dental Association

Huw F. Thomas, B.D.S., M.S., Ph.D.
Dean, Tufts University School of Dental Medicine
Chair of the ADEA Board of Directors

Gary L. Roberts, D.D.S.
President-elect

Cecile A. Feldman, D.M.D., M.B.A.
Dean, Rutgers School of Dental Medicine
Chair-elect of the ADEA Board of Directors

Gary E. Jeffers, D.M.D., M.S.
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Associate Dean for Education
University of Iowa College of Dentistry
Immediate Past Chair of the ADEA Board of Directors

Daniel J. Gesek, Jr., D.M.D.
Chair
Council on Dental Education and Licensure

KMH:eg

cc: Ms. Kate K. Cox, administrator, South Carolina Board of Dentistry
Dr. John J. Sanders, dean, Medical University of South Carolina James B. Edwards College of Dental Medicine
Dr. Christopher T. Griffin, president, South Carolina Dental Association
Mr. Phil Latham, executive director, South Carolina Dental Association
Dr. Julian Hal Fair, III, ADA Trustee, Sixteenth District
Dr. Kathleen O'Loughlin, executive director and chief operating officer (ADA)
Dr. Richard W. Valachovic, president and chief executive officer (ADEA)

ADEX
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May 17, 2016

Oregon Board of Dentistry
1500 SW 1st Ave. Suite 770
Portland, OR 97201

Dear Members of the Oregon Board of Dentistry:

It has come to our attention that the ADA and ADEA have written to dental boards for several states and territories expressing a high level of concern over licensure portability. In the letters we have seen, the ADA and ADEA suggest that the ADA has "conducted a careful analysis of the examinations" offered by the various testing agencies (including those that offer the ADEX examination) and determined that the examinations are "conceptually comparable." The ADA and ADEA suggest that any state dental board that accepts fewer than all of the available clinical licensure examinations is acting arbitrarily and speciously and in an anticompetitive manner.

As a preliminary matter, the ADEX is not aware of any evaluation of its examination by the ADA. In fact, on May 10, 2016, Dr. Jeffers of the ADA Licensure Task Force wrote to the ADEX to request "the information necessary to understand the ADEX and the validity evidence that exists to support test usage and interpretation." Clearly the ADA had not conducted a "careful analysis" of the ADEX examination prior to its February letter.

We at ADEX are also perplexed by the ADA and ADEA stance on the best manner of increasing licensure portability. While licensure portability is more a matter of state practices regarding licensure by credential rather than an issue involving clinical licensure examinations, the ADA and ADEA letter does not even mention licensure by credential. Instead, the ADA and ADEA focus their letter on what we refer to as "test portability," i.e. the number of jurisdictions which accept a particular clinical licensure examination.

It is certainly true that test portability would be increased if every state dental board were to shirk its duty to evaluate the quality and validity of the various examinations and simply accept every available licensure examination. We at ADEX, however, believe a better way to improve test portability is to develop a better examination in an effort to obtain universal acceptance. That is what the ADEX has set out to do, and, as noted in Dr. Jeffers May 10, 2016 letter, the ADEX examination is now accepted in 45 jurisdictions. The ADEX is at a loss to understand the "high level of concern" regarding test portability voiced by the ADA and ADEA given the widespread acceptance of the ADEX examination.

What the ADA does not mention in its letter is that it has previously stated its intent to enter the clinical licensure testing arena. While it may be in the ADA's interest to pave the way for acceptance of its clinical licensure examination by urging dental boards to begin accepting all available examinations, it is likely not in the public interest to have dental boards stop paying careful attention to the qualities of dental licensure examinations.

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ADEXOFFICE@aol.com
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We have asked our psychometrician Dr. Chad Buckendahl to review and respond to the technical assertions regarding test comparability in the letter from the ADA and ADEA. We have also asked our lawyer Andrew Cole of LeClairRyan to review the antitrust issues. Their joint response to the ADEX is enclosed.

Sincerely yours,

Stanwood H. Kanna, President
American Board of Dental Examiners, Inc.

Enclosures

JCNDE JOINT COMMISSION ON NATIONAL DENTAL EXAMINATIONS

RECEIVED
MAY 17 2016
Oregon Board of Dentistry

May 4, 2016

Dr. Alton Harvey, Sr.
Board President/Chair
c/o Oregon Board of Dentistry
1500 SW 1st Ave., Suite 770
Portland, OR 97201

Dear Dr. Harvey:

The Joint Commission on National Dental Examinations ("Joint Commission") appreciates the opportunity to assist your dental board by providing information concerning the cognitive skills of dental and dental hygiene candidates seeking licensure in your jurisdiction. In our continuing efforts to improve the quality, accuracy, and clinical relevance of information we provide, the Joint Commission is pleased to provide additional details concerning our efforts to introduce the Integrated National Board Dental Examination (INBDE), and share details concerning how and when implementation will occur.

The INBDE is a next generation assessment that will integrate the biomedical, behavioral, and clinical sciences, to provide dental boards with a summative evaluation concerning whether dental licensure candidates possess the level of cognitive skills necessary to safely practice dentistry. **The Joint Commission anticipates the INBDE will be available for administration on August 1, 2020, with full replacement of the National Board Dental Examination (NBDE) scheduled to occur by August 1, 2022.** This letter serves as the official "four years' notice" the Joint Commission indicated it would provide to stakeholders and communities of interest, concerning these important events.

In anticipation of the release of the INBDE and the discontinuation of Parts I and II, the Joint Commission recommends your dental board undertake the following activities to learn about the INBDE and prepare to use it in licensure decision making:

- Review and monitor INBDE information on the Joint Commission's website (www.ada.org/JCNDE/INBDE).
- Attend the National Dental Examiners' Advisory Forum (NDEAF) annually.
- Review INBDE validity evidence and the results of field testing as these studies occur.
- Prepare to receive INBDE results on the first day of its availability.
- Consider whether any modifications to practice acts, rules, policies, or procedures will be required.
- Prepare to accept candidates who have successfully completed the National Boards. This could occur under either of the following sequences: 1) INBDE or 2) NBDE Parts I and II.
- Communicate information concerning the acceptability of the INBDE to future licensure candidates.

The Joint Commission recommends your dental board begin working with these considerations now, to ensure your board is prepared for the upcoming changes. Details concerning the INBDE implementation plan are enclosed. Dates appearing in the plan represent a best-case scenario and are subject to change. The Joint Commission's website contains additional background information concerning the INBDE, as well as information concerning communications and presentations on this topic to dental boards and communities of interest since 2010.

Thank you for your consideration and attention to this important matter. If you have any questions, please contact the Joint Commission (nbexams@ada.org) and we will be happy to assist.

Sincerely,

Luis J. Fujimoto DDS

Dr. Luis J. Fujimoto
Chair, Joint Commission on National Dental Examinations

Enclosure

211 East Chicago Avenue Chicago, Illinois 60611-2637
Main 800.232.1694 Fax 312.587.4105 ADA.org/JCNDE

National Board Dental Examinations Standard Setting Update

David M. Waldschmidt, Ph.D.
Secretary, JCNDE

March 15, 2016

Mission Statement of the JCNDE

"The JCNDE develops and conducts highly reliable, state of the art cognitive examinations that assist regulatory agencies in making valid decisions regarding licensure of oral health care professionals, develops and implements policy for the orderly, secure, and fair administration of its examinations, and is a leader and resource in assessment for the oral health care profession."

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Appointing Organizations and Current JCNDE Appointees

AADB (6)	**Luis J Fujimoto, DMD, JCNDE Chair** **Dale R Chamberlain, DDS** **Patricia Ann Parker, DMD** **David W Perkins, DMD** **William F Robinson, DDS** **Leonard P Weiss, DDS**
ADA (3)	**Cheryl Haley, DDS** **Lisa Heinrich-Null, DDS** **Rhett L Murray, DDS**
ADEA (3)	**Marc E Levitan, DDS, JCNDE Vice Chair** **Frank W Licari, DDS, MPH, MBA** **Nader Nadershahi, DDS, MBA, EdD**
ADHA (1)	**Melissa Gail Efurd, RDH, Ed.D**
ASDA (1)	**Greg P. Shank, BS**
Public (1)	**Issie L. Shelton-Jenkins, JD, LLM**
Liaisons & Observers	**Alvin W. Stevens, DMD (ADA Board Liaison)** **Jordan J Telin, BS (ASDA Observer)** Liaisons and observers do not participate in voting

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NBDE Purpose and Interpretation

- The purpose of the National Board Dental Examinations is to assist state boards in determining the qualifications of individuals seeking licensure to practice dentistry.
- The NBDE is used to determine whether the candidate possesses the minimally acceptable level of knowledge, cognitive skills, and ability that is necessary for the safe, entry-level general practice of dentistry:
  - Part I: Anatomic sciences, biochemistry-physiology, microbiology-pathology, and dental anatomy & occlusion.
  - Part II: Dental and clinical dental sciences.

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Standard Setting

- The National Board Examinations are criterion-referenced and not norm-referenced examinations.
- Subject matter experts identify standards (pass/fail points) following established procedures and criteria that reference specific skill level requirements, not by the process sometimes known as “grading on a curve.”
  - All candidates who demonstrate the necessary skill level through their examination performance will pass the examination (it is NOT the case that scoring is established to fail a certain percentage of examinees).
- The standard for each examination program is the same for all examination forms administered to candidates. This occurs through the use of equating procedures that control for subtle differences in difficulty in test items across examination forms.
- The standard for each examination is determined through a process called “standard setting”.

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Standard Setting: Overview and Purpose

- "Standard setting" refers to the structured process by which subject matter experts (SMEs) recommend a performance standard for an examination.
- The Joint Commission periodically conducts standard setting activities for the NBDE and NBDHE. The purpose of these activities is to establish a recommendation for the Joint Commission regarding the minimum score that a candidate should obtain in order to pass each examination.
- The Joint Commission conducts separate standard setting activities for the NBDE Part I, NBDE Part II and NBDHE.

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Standard Setting: Overview and Purpose

- The current performance standards for the NBDE Part I and NBDE Part II were set in 2007 and 2008, respectively.
- In late 2014, standard setting activities were conducted for purposes of updating the minimum passing scores for the NBDE Parts I and II, respectively.
- The NBDE Part I standard setting activities were held on October 27-28, 2014. The NBDE Part II standard setting activities were held on November 3-4, 2014. Both were conducted at the ADA offices in Chicago, IL.
- The 2014 standard setting activities for NBDE Parts I and II were facilitated by Dr. Gregory Cizek, a nationally recognized expert in standard setting who has authored several books on the subject (Cizek 2001, 2012; Cizek & Bunch, 2007).

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Standard Setting Panel Membership

- The NBDE Part I and Part II standard setting panels consisted of 10 and 12 members, respectively.
- The panels were composed of dental Subject Matter Experts (SMEs).
- The panels were selected to be broadly representative and aligned with the purpose of the examinations:
  - Practitioners
  - Dental school faculty
  - Joint Commission members
  - Members of state boards
  - Dental school deans and associate deans
  - Current and former NBDE Test Construction Committee members
  - Geographically representative
  - Gender balanced

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Bookmark Standard Setting Method

- An established standard setting method called the “Bookmark” method was used for the NBDE Part I and NBDE Part II standard setting activities.
- For the Bookmark method, panelists are asked to review a representative booklet of test items that have been sorted in ascending order of difficulty (i.e., easiest to hardest). The booklet of test items is called an “ordered item booklet” (OIB).
- After reviewing the OIB, each panelist places a “bookmark” on the page containing the last item he or she believes a “just qualified candidate” would have at least a two thirds (67%) chance of answering correctly.
- The panel’s recommended performance standard for the examination is derived from the median of the bookmarked pages, across panelists.

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The Just Qualified Candidate (JQC)

- The key referent in the bookmark procedure is the Just Qualified Candidate (JQC) – a hypothetical examinee whose knowledge, skills and abilities (KSAs) represent the lowest level that would still be considered acceptable to pass the examination.
- For the NBDE Part I, the JQC was defined as follows:

  "The JQC is a candidate, currently pursuing an approved training program in dentistry, who possesses the minimally acceptable level of knowledge, cognitive skills, and ability that is necessary to apply the biomedical, dental, and clinical dental sciences for the safe, entry-level general practice of dentistry."
- For the NBDE Part II, the JQC was defined as follows:

  "The JQC is a candidate, currently pursuing an approved training program in dentistry, who possesses the minimally acceptable level of knowledge, cognitive skills, and ability in the dental and clinical dental sciences – including the areas of professional ethics and patient management – that is necessary for the safe, entry-level general practice of dentistry."

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Standard Setting Process

- Prior to beginning the bookmark procedure, panelists engaged in small-group and whole-group discussions regarding the characteristics of the JQC. During these discussions, panelists described specific KSAs they believed the JQC would and would not possess.
- To ensure that panelists were familiar with the content and difficulty of the examination, panelists were administered a “mini form” of the test that was representative of the actual examination with respect to content, difficulty, and item formats. Upon completion, they were provided with an answer key so they could self-score their mini form.
- To ensure that the mechanics of the bookmark process were well understood by all, panelists also participated in a practice bookmarking round which was conducted using a “practice” OIB consisting of 12 test items.
- Staff were available throughout the activity to provide assistance and any necessary information and clarification concerning the NBDE program.

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Bookmark Standard Setting Method

- Three rounds of bookmarking were conducted. In each round, each panelist placed his or her bookmark on the page containing the last item he or she believed a “just qualified candidate” would have at least a two thirds (67%) chance of answering correctly.
- After each round, standard setting panelists were provided with the following information:
  - Information about how their bookmarked page compared to the bookmarked pages of other panelists (i.e., “normative information”).
  - Information about the prospective consequences of their bookmarked pages on the fail rate for the examination (i.e., “impact information”).
- After the second round, panelists were also provided with empirical information about the difficulty of the test items in the OIB.

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Bookmark Standard Setting Method

- After each round, panelists discussed their individual bookmark placements as a group and shared their thoughts and concerns.
- The panel's final recommended performance standard for each examination was based on the median of the bookmarked pages (across panelists) from the third bookmarking round.

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Panelist Feedback

- At five points during the standard setting activities, panelists were given an opportunity to provide feedback about the standard setting process.
- The feedback was collected through a series of evaluative questionnaires developed by Dr. Cizek.
- Participants' evaluations of all aspects of the process were uniformly strong and supportive.
- Each panelist indicated that they supported the final group-recommended performance standard.

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Panelist Feedback: NBDE Part I

- Panelist feedback from the final evaluative questionnaire: NBDE Part I

Survey Item Number and Statement	Mean Rating
1. The item difficulty information provided for generating the Round 3 ratings was helpful.	4.3
2. The instructions regarding how to use the item difficulty information were clear.	4.4
3. The discussion of the Round 2 Bookmark placements and instructions helped me understand what I needed to do to complete Round 3.	4.5
4. I am confident in my Round 3 Bookmark placement.	4.5
5. I had the opportunity to ask questions while working on my final recommendations.	5.0
6. The facilitators helped to answer questions while working on my final recommendations.	4.8
7. The timing and pace of the final round were appropriate.	4.7
8. Overall, the facilities and food service helped create a good working environment.	4.8
9. Overall, the materials were clear and helpful.	4.6

Key: Values are on a five-point scale, ranging from 1=Strongly Disagree to 5=Strongly Agree; NR = no response. All table entries are based on *n*=10 responses.

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Panelist Feedback: NBDE Part I

- Panelist feedback from the final evaluative questionnaire: NBDE Part I

Survey Item Number and Statement	Mean Rating
10. Overall, the training in the standard setting purpose and methods was clear.	4.5
11. Overall, I am confident that I was able to apply the standard setting method appropriately.	4.6
12. Overall, the standard setting procedures allowed me to use my experience and expertise to recommend cut score for the NBDE Part I.	4.7
13. Overall, the facilitators helped to ensure that everyone was able to contribute to the group discussions and that no one unfairly dominated the discussions.	4.5
14. Overall, I was able to understand and use the information provided (e.g., other panelists' ratings, item difficulty information).	4.5
15. Overall, I support the final group-recommended cut score as fairly representing the appropriate performance standard for the NBDE Part I.	4.6

Key: Values are on a five-point scale, ranging from 1=Strongly Disagree to 5=Strongly Agree; NR = no response. All table entries are based on *n*=10 responses.

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Panelist Feedback: NBDE Part II

- Panelist feedback from the final evaluative questionnaire: NBDE Part II

Survey Item Number and Statement	Mean Rating
1. The item difficulty information provided for generating the Round 3 ratings was helpful.	4.5
2. The instructions regarding how to use the item difficulty information were clear.	4.7
3. The discussion of the Round 2 Bookmark placements and instructions helped me understand what I needed to do to complete Round 3.	4.7
4. I am confident in my Round 3 Bookmark placement.	4.6
5. I had the opportunity to ask questions while working on my final recommendations.	4.9
6. The facilitators helped to answer questions while working on my final recommendations.	4.9
7. The timing and pace of the final round were appropriate.	4.5
8. Overall, the facilities and food service helped create a good working environment.	4.8
9. Overall, the materials were clear and helpful.	4.9

Key: Values are on a five-point scale, ranging from 1=Strongly Disagree to 5=Strongly Agree; NR = no response. All table entries are based on *n*=10 responses.

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Panelist Feedback: NBDE Part II

- Panelist feedback from the final evaluative questionnaire: NBDE Part II

Survey Item Number and Statement	Mean Rating
10. Overall, the training in the standard setting purpose and methods was clear.	4.8
11. Overall, I am confident that I was able to apply the standard setting method appropriately.	4.8
12. Overall, the standard setting procedures allowed me to use my experience and expertise to recommend cut score for the NBDE Part II.	4.8
13. Overall, the facilitators helped to ensure that everyone was able to contribute to the group discussions and that no one unfairly dominated the discussions.	4.9
14. Overall, I was able to understand and use the information provided (e.g., other panelists' ratings, item difficulty information).	4.8
15. Overall, I support the final group-recommended cut score as fairly representing the appropriate performance standard for the NBDE Part II.	4.9

Key: Values are on a five-point scale, ranging from 1=Strongly Disagree to 5=Strongly Agree; NR = no response. All table entries are based on *n*=12 responses.

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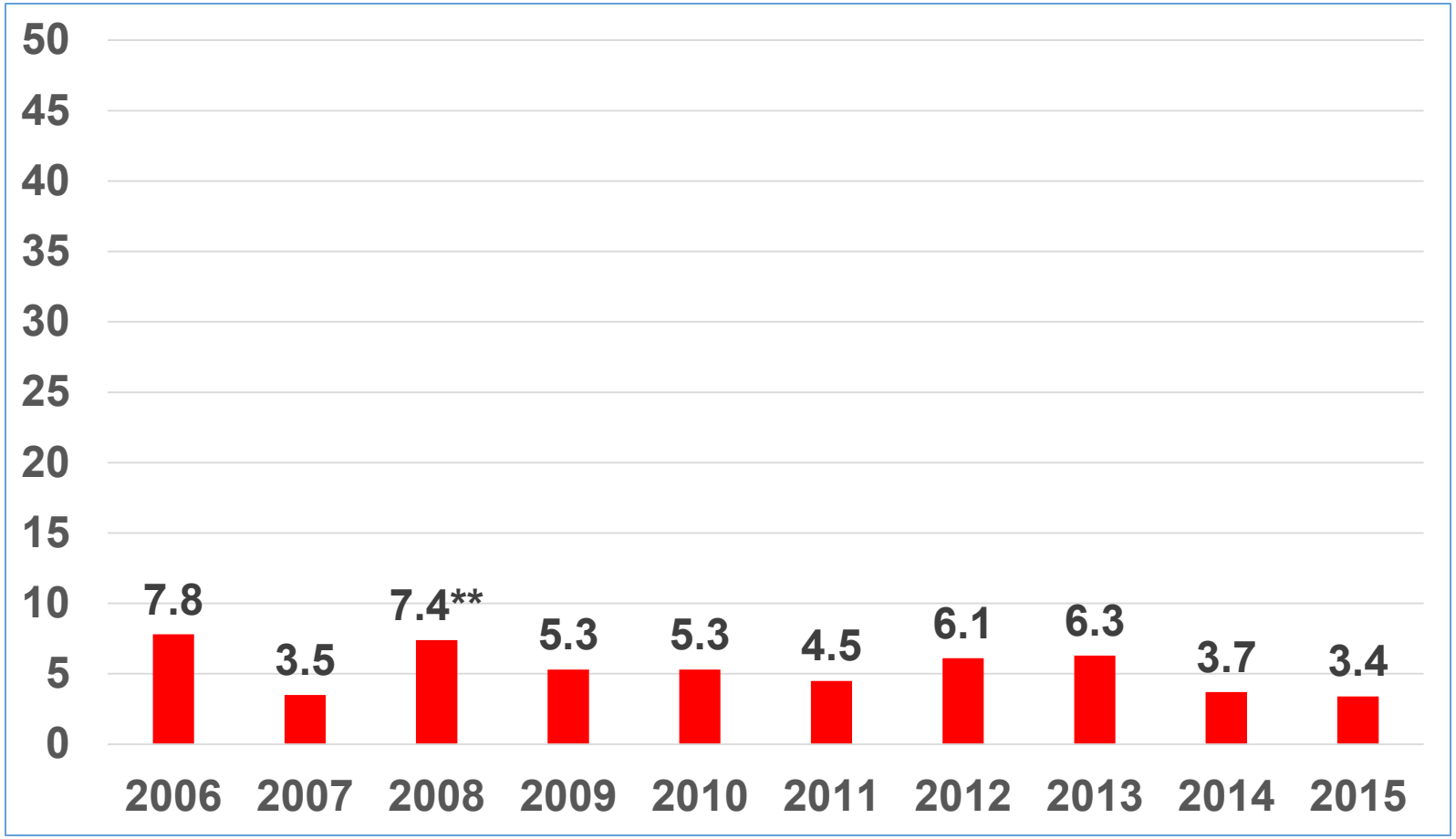
NBDE Part I Failure Rates (%)



** A new standard was introduced this year, based on updated standard setting activities.

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Standard Setting Results: NBDE Part I

- The 2014 NBDE Part I standard setting panel provided a recommendation to the Joint Commission concerning the minimum passing score for the NBDE Part I. The recommendation represented an **increase** in the performance standard for the NBDE Part I.

- In 2013, the current operational performance standard resulted in a failure rate of 6.3% for first-time test-takers from accredited dental programs. **If the panel's recommendation is applied to the same population, the resulting failure rate is 10.1%.**

- The recommendation from the 2014 NBDE Part I standard setting panel was approved by the Joint Commission in 2015. **The new standard will be implemented no sooner than April 2016.**

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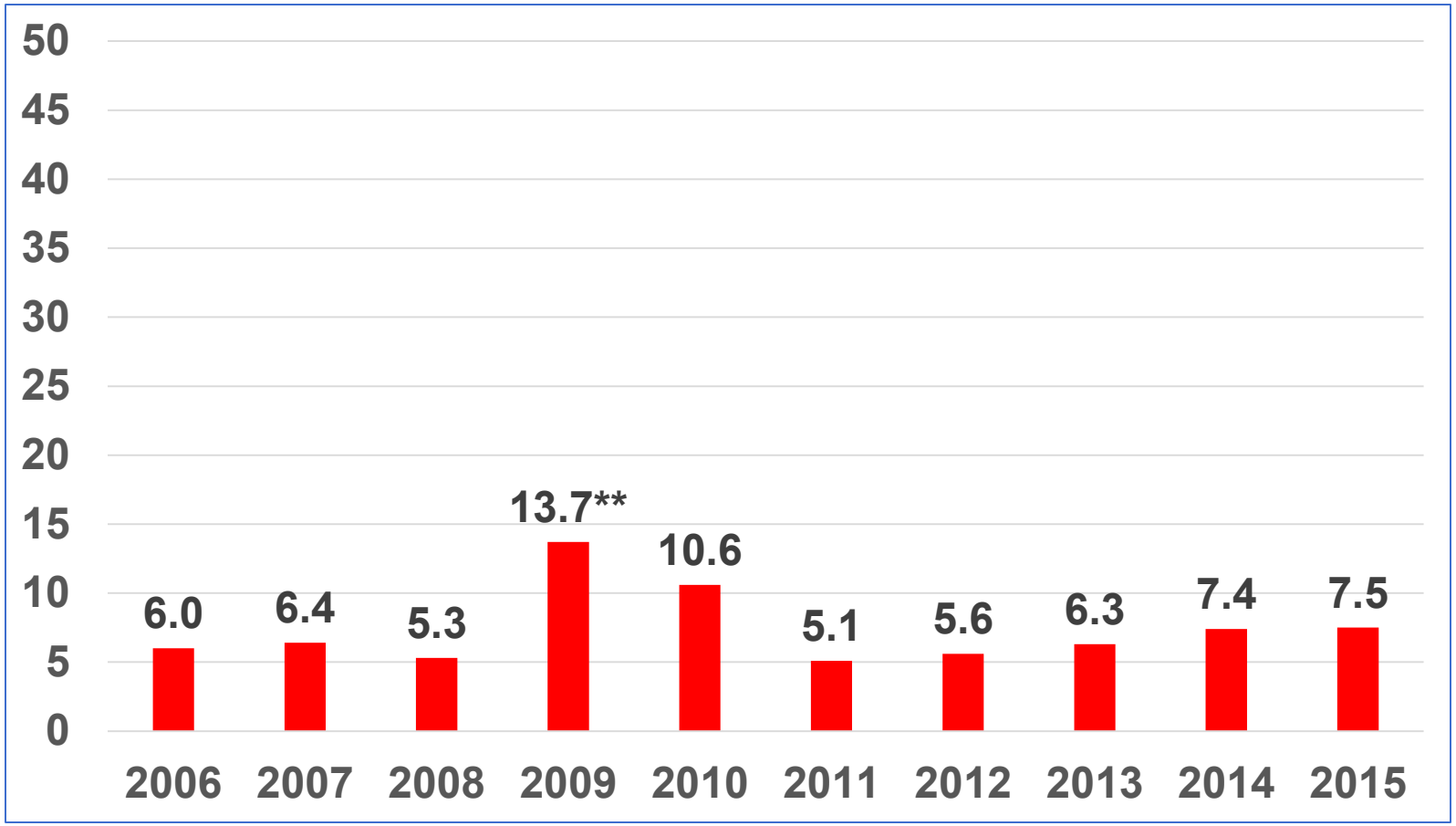
NBDE Part II Failure Rates (%)



** A new standard was introduced this year, based on updated standard setting activities.

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Standard Setting Results: NBDE Part II

- The 2014 NBDE Part II standard setting panel provided a recommendation for the Joint Commission concerning the minimum passing score for the NBDE Part II. The recommendation represented an **increase** in the performance standard for the NBDE Part II.

- **In 2013, the current operational performance standard resulted in a failure rate of 6.3% for first-time test-takers from accredited dental programs. If the panel's recommendation is applied to the same population, the resulting failure rate is 8.6%.**

- The recommendation from the 2014 NBDE Part II standard setting panel was approved by the Joint Commission in 2015**. The new standard will be implemented no sooner than April 2016.**

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Standard Setting

Q & A

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Thank you

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OTHER ISSUES

WREB presentation to the Oregon Board of Dentistry: Local Anesthesia (LA), Dental Hygiene (DH) and Restorative (RE) examinations

Kelly Reich, RDH - Co Director of Dental Hygiene Exam Development and Administration

Sharon Osborn Popp, Ph.D. – Testing Specialist/Psychometrician

WREB

From: Alynn Vienot [mailto:vienota@nhcoregon.org]
Sent: Tuesday, May 10, 2016 5:13 PM
To: Teresa Haynes <Teresa.Haynes@state.or.us>
Subject: Dental screening results letter language

Dear Teresa,

I am writing to find out if the language outlined in the Oral Health Screening Policy can be modified to meet our population's specific needs. We work with Head Start programs, and would like to use language that is a little different, but maintains the messages within the Oral Health 5creening Policy language (https://www.oregon.gov/dentistry/pages/screen_pol.aspx). Please find attached the screening results letter we'd like to use.

We have written the form, keeping in mind the reading level of our parent population, and also our desire to use active language to emphasize the importance of going to the dentist (both regular visits and especially for kids identified with treatment needs). We work with Head Start staff and coordinators that directly follow up with the families after the screenings to help them access care.

Please let me know if the language in the form is acceptable or if we need to use make our language identical to that found in the Oral Health Screening Policy.

Thank you.

Alynn Vienot, EPDH, MPH
Neighborhood Health Center
Dental Program Manager
Office: (503) 941-3027 Cell: (503) 567-2550

My email has changed to:
vienota@nhcoregon.org

Teresa Haynes

From: Teresa Haynes
Sent: Wednesday, May 11, 2016 6:28 AM
To: Stephen Prisby
Subject: FW: Dental screening results letter language
Attachments: HS Results Letter, NHC form- 05 10 2016 version.docx

Following is current Board's Policy:

Oral Health Screening Policy

2003 House Bill 3157, which was passed by the Legislature and signed into law by the Governor, allowed the Oregon Board of Dentistry (OBD) to develop written training and screening protocols so dental hygienists and dental assistants could independently perform Oral Health Screenings in Oregon.

The OBD on January 23, 2004 determined that no additional training was necessary for Oregon Dental Hygienists or Oregon Dental Assistants.

The OBD adopted specific language that must be on any Oral Health Screening Form that would be given to individuals or parents or guardians of minors who would be screened.

The following is the language and would need to be on any Oral Health Screening Form that would be used by any Oregon Dental Hygienist or Dental Assistant in compliance with Oregon Law.

This language was revised on March 1, 2006.

This is an oral health screening for _____.
A screening is just a quick look and does not take the place of a thorough examination by a dentist. Serious oral health problems may be missed in a screening. The person doing the screening may or may not have any dental training. [*Dental Hygienists or Dental Assistants may omit the previous sentence.*]

- **No visible signs of oral problems. See your dentist at least yearly.**
- **Visible signs of oral problems were found. A visit to a dentist is recommended to prevent serious or more costly problems.**
- **Visible signs or symptoms of serious dental needs were found. An immediate visit to a dentist is recommended.**

The Board encourages others who may do Oral Health Screenings to use this language on their screening forms.

If you have questions regarding this Oral Health Screening Policy, please feel free to contact the OBD at (971) 673-3200.

Take her request to the June 2016 Board meeting, or do we state that under the current Policy she must use the verbiage above?

T

YOUR CHILD'S RESULTS

D3 Head Start Program

Dental Screening/Fluoride Varnish

(Please share this information with your child's dentist)

Name of Child: _____
(First) (Middle Initial) (Last)

Date: _____

Your child's teeth were checked at school. Your child's results are marked below. This screening does not take the place of a visit to the dentist. Serious oral health problems may be missed in a screening.

RESULTS & REFERRALS

☐ 0 **No Obvious Problems**
No obvious problems were detected in your child's mouth. Take your child to the dentist for regular dental checkups.

☐ 1 **Early Dental Care Needed**
Cavities or possible small cavities were seen in your child's teeth. Arrange for your child to see a dentist for a complete examination as soon as possible before the cavities get bigger.

☐ 2 **Urgent Dental Care Needed**
Possible large cavities were seen in your child's teeth. Arrange for your child to see a dentist **as soon as possible**.

☐ **EMERGENCY REFERRAL TO DENTIST**
for pain, abscess, swelling or bleeding. Your child needs to see a dentist within 24 hours.

☐ **No Fluoride**
Your child did NOT receive fluoride varnish at school

AFTER GETTING FLUORIDE VARNISH

- Do not brush or floss your child's teeth until tomorrow
- Feed your child a soft food diet for the remainder of today and avoid hard foods like pretzels, candy and apples.

TIPS FOR HEALTHY SMILES

BABY TEETH ARE IMPORTANT!

- **Floss** your child's teeth and **brush** 2x daily
- **Limit sugary snacks and drinks.** Instead of cookies, give your child healthy snacks like fresh fruit, vegetables and cheese.
- **Regular dental exams** are important for every child even if they have never had a cavity. If your child already has dental fillings, they have a higher risk of developing more cavities.

From: Len BAROZZINI [mailto:len.barozzini@multco.us]
Sent: Friday, May 20, 2016 11:23 AM
To: Stephen Prisby
Cc: Amy Fine (afine@lcdv.org)
Subject: EFDA rules committee~

Hi Dr. Prisby:

My name is Len Barozzini, and I am the dental director for Multnomah County. Hope you are doing well. Recently I had a discussion with Dr. Amy Fine regarding the roles/duties of an Expanded Function Dental Assistant.

I would respectfully ask that the board consider requiring that an EFDA be required to be sealant trained/certified in order to receive their EFDA certificate. Reason being, myself, and many other community health clinics are emphasizing the need for sealants, which as you know are a very important metric for the state, and more importantly, an evidence-based practice for children. As we are finding it somewhat difficult to hire EFDA's who have their sealant certification, and courses are not offered as frequently as needed in the area, it would be a benefit to have EFDA's be ready to place sealants upon graduation.

Any consideration is deeply appreciated.

Regards,

Len

--
****

Len Barozzini, DDS
Dental Director

Multnomah County Health Department
426 SW Stark Street, 9th Floor
Portland, OR 97204
503.988.6737

DIVISION 42

DENTAL ASSISTING

818-042-0010
Definitions

(1) "Dental Assistant" means a person who, under the supervision of a dentist, renders assistance to a dentist, dental hygienist, dental technician or another dental assistant or renders assistance under the supervision of a dental hygienist providing dental hygiene services.

(2) "Expanded Function Dental Assistant" means a dental assistant certified by the Board to perform expanded function duties.

(3) "Expanded Function Orthodontic Assistant" means a dental assistant certified by the Board to perform expanded orthodontic function duties.

(4) "Direct Supervision" means supervision requiring that a dentist diagnose the condition to be treated, that a dentist authorize the procedure to be performed, and that a dentist remain in the dental treatment room while the procedures are performed.

(5) "Indirect Supervision" means supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.

(6) "General Supervision" means supervision requiring that a dentist authorize the procedures, but not requiring that a dentist be present when the authorized procedures are performed. The authorized procedures may also be performed at a place other than the usual place of practice of the dentist.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04

818-042-0020
Dentist and Dental Hygienist Responsibility

(1) A dentist is responsible for assuring that a dental assistant has been properly trained, has demonstrated proficiency, and is supervised in all the duties the assistant performs in the dental office. Unless otherwise specified, dental assistants shall work under indirect supervision in the dental office.

(2) A dental hygienist who works under general supervision may supervise a dental assistant in the dental office if the dental assistant is rendering assistance to the dental hygienist in providing dental hygiene services and the dentist is not in the office to provide indirect supervision. A dental hygienist with an Expanded Practice Permit may hire and supervise a dental assistant who will render assistance to the dental hygienist in providing dental hygiene services.

(3) The supervising dentist or dental hygienist is responsible for assuring that all required licenses, permits or certificates are current and posted in a conspicuous place.

(4) Dental assistants who are in compliance with written training and screening protocols adopted by the Board may perform oral health screenings under general supervision.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 2-2012, f. 6-14-12, cert. ef. 7-1-12

818-042-0030
Infection Control

The supervising dentist shall be responsible for assuring that dental assistants are trained in infection control, bloodborne pathogens and universal precautions, exposure control, personal protective equipment, infectious waste disposal, Hepatitis B and C and post exposure follow-up.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.140
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00

818-042-0040
Prohibited Acts

No licensee may authorize any dental assistant to perform the following acts:

(1) Diagnose or plan treatment.

(2) Cut hard or soft tissue.

(3) Any Expanded Function duty (818-042-0070 and 818-042-0090) or Expanded Orthodontic Function duty (818-042-0100) without holding the appropriate certification.

(4) Correct or attempt to correct the malposition or malocclusion of teeth except as provided by OAR 818-042-0100.

(5) Adjust or attempt to adjust any orthodontic wire, fixed or removable appliance or other structure while it is in the patient's mouth.

(6) Administer any drug except fluoride, topical anesthetic, desensitizing agents, over the counter medications per package instructions or drugs administered pursuant to OAR 818-026-0030(6), OAR 818-026-0050(5)(a) OAR 818-026-0060(11), 818-026-0065(11), 818-026-0070(11) and as provided in 818-042-0070 and 818-042-0115.

(7) Prescribe any drug.

(8) Place periodontal packs.

(9) Start nitrous oxide.

(10) Remove stains or deposits except as provided in OAR 818-042-0070.

(11) Use ultrasonic equipment intra-orally except as provided in OAR 818-042-0100.

(12) Use a high-speed handpiece or any device that is operated by a high-speed handpiece intra-orally.

(13) Use lasers, except laser-curing lights.

(14) Use air abrasion or air polishing.

(15) Remove teeth or parts of tooth structure.

(16) Cement or bond any fixed prosthetic or orthodontic appliance including bands, brackets, retainers, tooth moving devices, or orthopedic appliances except as provided in 818-042-0100.

(17) Condense and carve permanent restorative material except as provided in OAR 818-042-0095.

(18) Place any type of cord subgingivally except as provided in OAR 818-042-0090

(19) Take jaw registrations or oral impressions for supplying artificial teeth as substitutes for natural teeth, except diagnostic or opposing models or for the fabrication of temporary or provisional restorations or appliances.

(20) Apply denture relines except as provided in OAR 818-042-0090(2).

(21) Expose radiographs without holding a current Certificate of Radiologic Proficiency issued by the Board (818-042-0050 and 818-042-0060) except while taking a course of instruction approved by the Oregon Health Authority, Oregon Public Health Division, Office of Environmental Public Health, Radiation Protection Services, or the Oregon Board of Dentistry.

(22) Use the behavior management techniques known as Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient.

(23) Perform periodontal probing.

(24) Place or remove healing caps or healing abutments, except under direct supervision.

(25) Place implant impression copings, except under direct supervision.

(26) Any act in violation of Board statute or rules.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2000(Temp), f. 5-22-00, cert. ef. 5-22-00 thru 11-18-00; OBD 1-2001, f. & cert. ef. 1-08-01; OBD 15-2001; f. 12-7-01, cert. ef. 1-1-02; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 3-2007, f. & cert. ef. 11-30-07; OBD 1-2010, f. 6-22-10, cert. ef. 7-1-10; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 2-2012, f. 6-14-12, cert. ef. 7-1-12; OBD 6-2014, f.7-2-2014, cert. ef. 8-1-2014; OBD 6-2015, f. 7-9-05, cert. ef. 10-1-15

818-042-0050
Taking of X-Rays — Exposing of Radiographs

(1) A dentist may authorize the following persons to place films, adjust equipment preparatory to exposing films, and expose the films under general supervision:

(a) A dental assistant certified by the Board in radiologic proficiency; or

(b) A radiologic technologist licensed by the Oregon Board of Medical Imaging and certified by the Oregon Board of Dentistry (OBD) who has completed ten (10) clock hours in a Board approved dental radiology course and submitted a satisfactory full mouth series of radiographs to the OBD.

(2) A dentist or dental hygienist may authorize a dental assistant who has completed a course of instruction approved by the Oregon Board of Dentistry, and who has passed the written Dental Radiation Health and Safety Examination administered by the Dental Assisting National Board, or comparable exam administered by any other testing entity authorized by the Board, or other comparable requirements approved by the Oregon Board of Dentistry to place films, adjust equipment preparatory to exposing films, and expose the films under the indirect supervision of a dentist, dental hygienist, or dental assistant who holds an Oregon Radiologic Proficiency Certificate. The dental assistant must successfully complete the clinical examination within six months of the dentist authorizing the assistant to take radiographs.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 6-2014, f. 7-2-2014, cert. ef. 8-1-2014; OBD 6-2015, f. 7-9-15, cert. ef. 10-01-15

818-042-0060
Certification — Radiologic Proficiency

(1) The Board may certify a dental assistant in radiologic proficiency by credential in accordance with OAR 818-042-0120, or if the assistant:

(2) Submits an application on a form approved by the Board, pays the application fee and:

(a) Completes a course of instruction approved by the Oregon Board of Dentistry, in accordance with OAR 333-106-0055 or submits evidence the Oregon Health Authority, Center for Health Protection,

Radiation Protection Services recognizes that the equivalent training has been successfully completed;

(b) Passes the written Dental Radiation Health and Safety Examination administered by the Dental Assisting National Board, Inc. (DANB), or comparable exam administered by any other testing entity authorized by the Board, or other comparable requirements approved by the Oregon Board of Dentistry; and

(c) Passes a clinical examination approved by the Board and graded by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board, consisting of exposing, developing and mounting a full mouth series of radiographs or by exposing and mounting a digital full mouth series of radiographic images (14 to 18 periapical and 4 bitewing radiographic images) within one hour and under the supervision of a person permitted to take radiographs in Oregon. No portion of the clinical examination may be completed in advance; a maximum of three retakes is permitted (i.e., three individual radiographic exposures, not three full mouth series); only the applicant may determine the necessity of retakes. The radiographic images should be acquired on an adult patient with at least 24 fully erupted teeth. The full mouth series must be submitted for grading within six months after it is taken.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020, 679.025, 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 3-2007, f. & cert. ef. 11-30-07; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 3-2013, f. 10-24-13, cert. ef. 1-1-14; OBD 6-2014, f. 7-2-14, cert. ef. 8-1-2014

818-042-0070
Expanded Function Dental Assistants (EFDA)

The following duties are considered Expanded Function Duties and may be performed only after the dental assistant complies with the requirements of 818-042-0080:

(1) Polish the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains.

(2) Remove temporary crowns for final cementation and clean teeth for final cementation;

(3) Preliminarily fit crowns to check contacts or to adjust occlusion outside the mouth;

(4) Place temporary restorative material (i.e., zinc oxide eugenol based material) in teeth providing that the patient is checked by a dentist before and after the procedure is performed;

(5) Place and remove matrix retainers for alloy and composite restorations;

(6) Polish amalgam or composite surfaces with a slow speed handpiece;

(7) Remove excess supragingival cement from crowns, bridges, bands or brackets with hand instruments providing that the patient is checked by a dentist after the procedure is performed;

(8) Fabricate temporary crowns, and temporarily cement the temporary crown. The cemented crown must be examined and approved by the dentist prior to the patient being released;

(9) Under general supervision, when the dentist is not available and the patient is in discomfort, an EFDA may recement a temporary crown or recement a permanent crown with temporary cement for a patient of record providing that the patient is rescheduled for follow-up care by a licensed dentist as soon as is reasonably appropriate; and

(10) Perform all aspects of teeth whitening procedures.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 6-2015, f. 7-9-15, cert. ef. 10-01-15

818-042-0080
Certification — Expanded Function Dental Assistant (EFDA)

The Board may certify a dental assistant as an expanded function assistant:

(1) By credential in accordance with OAR 818-042-0120, or

(2) If the assistant submits a completed application, pays the fee and provides evidence of;

(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Basic or CDA examination, and the Expanded Function Dental Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by a licensed dentist that the applicant has successfully polished 12 amalgam or composite surfaces, removed supra-gingival excess cement from six (6) crowns or bridges with hand instruments; placed temporary

restorative material (i.e., zinc oxide eugenol based material) in six (6) teeth; preliminarily fitted six (6) crowns to check contacts or to adjust occlusion outside the mouth; removed six (6) temporary crowns for final cementation and cleaned teeth for final cementation; fabricated six (6) temporary crowns and temporarily cemented the crowns; polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis in six (6) patients; placed two matrix bands in each quadrant on teeth prepared for Class II restorations; and complete six (6) teeth whitening or bleach procedures.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 10-1999 (Temp), f. 12-2-99, cert. ef. 1-1-00 thru 6-28-00; OBD 8-2000, f. 6-22-00, cert. ef. 6-29-00; OBD 1-2004; f. 5-27-04, cert. ef. 6-1-04; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09

818-042-0090
Additional Functions of EFDAs

Upon successful completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association, or other course of instruction approved by the Board, a certified Expanded Function Dental Assistant may perform the following functions under the indirect supervision of a dentist or dental hygienist providing that the procedure is checked by the dentist or dental hygienist prior to the patient being dismissed:

(1) Apply pit and fissure sealants provided the patient is examined before the sealants are placed. The sealants must be placed within 45 days of the procedure being authorized by a dentist or dental hygienist.

(2) Apply temporary soft relines to complete dentures for the purpose of tissue conditioning.

(3) Place cord subgingivally.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 15-2001, f. 12-7-01, cert. ef. 1-1-02; OBD 1-2013, f. 5-15-13, cert. ef. 7-1-13; OBD 6-2014, f. 7-2-2014, cert. ef. 8-1-2014; OBD 6-2015, f. 7-9-15, cert. ef. 10-01-15

818-042-0095
Restorative Functions of Dental Assistants

(1) The Board shall issue a Restorative Functions Certificate (RFC) to a dental assistant who holds an Oregon EFDA Certificate, and has successfully completed:

(a) A Board approved curriculum from a program accredited by the Commission on Dental Accreditation of the American Dental Association or other course of instruction approved by the Board, and successfully passed the Western Regional Examining Board's Restorative Examination or other equivalent examinations approved by the Board within the last five years, or

(b) If successful passage of the Western Regional Examining Board's Restorative Examination or other equivalent examinations approved by the Board occurred over five years from the date of application, the applicant must submit verification from another state or jurisdiction where the applicant is legally authorized to perform restorative functions and certification from the supervising dentist of successful completion of at least 25 restorative procedures within the immediate five years from the date of application.

(2) A dental assistant may perform the placement and finishing of direct alloy or direct composite restorations, under the indirect supervision of a licensed dentist, after the supervising dentist has prepared the tooth (teeth) for restoration(s):

(a) These functions can only be performed after the patient has given informed consent for the procedure and informed consent for the placement of the restoration by a Restorative Functions dental assistant.

(b) Before the patient is released, the final restoration(s) shall be checked by a dentist and documented in the chart.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.010 & 679.250(7)
Hist.: OBD 3-2007, f. & cert. ef. 11-30-07; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 1-2013, f. 5-15-13, cert. ef. 7-1-13

818-042-0100
Expanded Functions – Orthodontic Assistant (EFODA)

(1) An EFODA may perform the following duties while under the indirect supervision of a licensed dentist:

(a) Remove orthodontic bands and brackets and attachments with removal of the bonding material and cement. An ultrasonic scaler, hand scaler or slow speed handpiece may be used. Use of a high speed handpiece is prohibited;

(b) Select or try for the fit of orthodontic bands;

(c) Recement loose orthodontic bands;

(d) Place and remove orthodontic separators;

(e) Prepare teeth for bonding or placement of orthodontic appliances and select, pre-position and cure orthodontic brackets, attachments and/or retainers after their position has been approved by the supervising licensed dentist;

(f) Fit and adjust headgear;

(g) Remove fixed orthodontic appliances;

(h) Remove and replace orthodontic wires. Place and ligate archwires. Place elastic ligatures or chains as directed;

(i) Cut arch wires; and

(j)Take impressions for study models or temporary oral devices such as, but not limited to, space maintainers, orthodontic retainers and occlusal guards.

(2) An EFODA may perform the following duties while under the general supervision of a licensed dentist:

(a) An expanded function orthodontic assistant may remove any portion of an orthodontic appliance causing a patient discomfort and in the process may replace ligatures and/or separators if the dentist is not available, providing that the patient is rescheduled for follow-up care by a licensed dentist as soon as is reasonably appropriate.

(b) An EFODA may recement orthodontic bands if the dentist is not available and the patient is in discomfort, providing that the patient is rescheduled for follow-up care by a licensed dentist as soon as is reasonably appropriate.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.025(2)(j) & 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2012, f. 6-14-12, cert. ef. 7-1-12

818-042-0110
Certification — Expanded Function Orthodontic Assistant

The Board may certify a dental assistant as an expanded function orthodontic assistant

(1) By credential in accordance with OAR 818-042-0120, or

(2) Completion of an application, payment of fee and satisfactory evidence of;

(a) Completion of a course of instruction in a program in dental assisting accredited by the American Dental Association Commission on Dental Accreditation; or

(b) Passage of the Basic, CDA or COA examination, and Expanded Function Orthodontic Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB)**,** or any other testing entity authorized by the Board; and certification by a licensed dentist that the applicant has successfully removed cement from bands using an ultrasonic or hand scaler, or a slow speed hand piece, on six (6) patients and recemented loose orthodontic bands, fit and adjust headgear, remove fixed orthodontic appliances and take impressions for four (4) patients.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 10-1999 (Temp). f. 12-2-99, cert. ef. 1-1-00 thru 6-28-00; OBD 8-2000, f. 6-22-00, cert. ef. 6-29-00; OBD 1-2013, f. 5-15-13, cert. ef. 7-1-13

818-042-0115
Expanded Functions – Certified Anesthesia Dental Assistant

(1) A dentist holding the appropriate anesthesia permit may verbally authorize a Certified Anesthesia Dental Assistant to:

(a) Administer medications into an existing intravenous (IV) line of a patient under sedation or anesthesia under direct visual supervision.

(b) Administer emergency medications to a patient in order to assist the licensee in an emergent situation under direct visual supervision.

(2) A dentist holding the appropriate anesthesia permit may verbally authorize a Certified Anesthesia Dental Assistant to dispense to a patient, oral medications that have been prepared by the dentist and given to the anesthesia dental assistant by the supervising dentist for oral administration to a patient under Indirect Supervision.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020(1), 679.025(1) & 679.250(7)
Hist.: OBD 1-2001, f. & cert. ef. 1-8-01; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

818-042-0116
Certification – Anesthesia Dental Assistant

The Board may certify a person as an Anesthesia Dental Assistant if the applicant submits a completed application, pays the certification fee and shows satisfactory evidence of:

(1) Successful completion of:

(a) The "Oral and Maxillofacial Surgery Anesthesia Assistants Program" or successor program, conducted by the American Association of Oral and Maxillofacial Surgeons; or

(b) The "Oral and Maxillofacial Surgery

Assistants Course" or successor course, conducted by the California Association of Oral and Maxillofacial Surgeons (CALAOMS), or a successor entity; or

(c) The "Certified Oral and Maxillofacial Surgery Assistant" examination, or successor examination, conducted by the Dental Assisting National Board or other Board approved examination; and

(2) Holding valid and current documentation showing successful completion of a Health Care Provider BLS/CPR course, or its equivalent.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.250(7)
Hist.: OBD 1-2001, f. & cert. ef. 1-8-01; OBD 2-2005, f. 1-31-05, cert. ef. 2-1-05; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

818-042-0117
Initiation of IV Line

Upon successful completion of a course in intravenous access or phlebotomy approved by the Board, a Certified Anesthesia Dental Assistant may initiate an intravenous (IV) infusion line for a patient being prepared for IV medications, sedation, or general anesthesia under the Indirect Supervision of a dentist holding the appropriate anesthesia permit.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020(1), 679.025(1) & 679.250(7)
Hist.: OBD 1-2001, f. & cert. ef. 1-8-01; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

818-042-0120
Certification by Credential

(1) Dental Assistants who wish to be certified by the Board in Radiologic Proficiency or as Expanded Function Dental Assistants, or as Expanded Function Orthodontic Dental Assistants shall:

(a) Be certified by another state in the functions for which application is made. The training and certification requirements of the state in which the dental assistant is certified must be substantially similar to Oregon's requirements; or

(b) Have worked for at least 1,000 hours in the past two years in a dental office where such employment involved to a significant extent the functions for which certification is sought; and

(c) Shall be evaluated by a licensed dentist, using a Board approved checklist, to assure that the assistant is competent in the expanded functions.

(2) Applicants applying for certification by credential in Radiologic Proficiency must obtain certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, of having successfully completed training equivalent to that required by OAR 333-106-0055 or approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 6-2014, f. 7-2-14, cert. ef. 8-1-2014

818-042-0130
Application for Certification by Credential

An applicant for certification by credential shall submit to the Board:

(1) An application form approved by the Board, with the appropriate fee;

(2) Proof of certification by another state and any other recognized certifications (such as CDA or COA certification) and a description of the examination and training required by the state in which the assistant is certified submitted from the state directly to the Board; or

(3) Certification that the assistant has been employed for at least 1,000 hours in the past two years as a dental assistant performing the functions for which certification is being sought.

(4) If applying for certification by credential as an EFDA or EFODA, certification by a licensed dentist that the applicant is competent to perform the functions for which certification is sought; and

(5) If applying for certification by credential in Radiologic Proficiency, certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, or the Oregon Board of Dentistry, that the applicant has met that agency's training requirements for x-ray machine operators, or other comparable requirements approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 6-2014, f. 7-2-2014, cert. ef. 8-1-2014

NYU Lutheran
NYU LANGONE
HEALTH SYSTEM
Department of Dental Medicine
Advanced Education in General Dentistry Program
150 55th Street
Brooklyn, New York 11220

RECEIVED
MAY 26 2016
Oregon Board
of Dentistry

May 24, 2016

Mr. Stephen Prisby
Executive Director
Oregon State Board of Dentistry
1500 SW 1st Avenue; Suite 770
Portland, OR 97201

Re: NYU Lutheran AEGD Program
Postdoctoral general dentistry resident eligibility for OR state dental license

Dear Mr. Prisby,

The Advanced Education in General Dentistry (AEGD) Program of NYU Lutheran is a postdoctoral, general dentistry residency program based in Brooklyn, New York. NYU Lutheran is the hospital/medical center sponsoring institution, and formally affiliated with community health centers and dental schools located throughout the United States. These community health centers and dental schools serve as clinical training sites for our AEGD residents. The NYU Lutheran AEGD program is one year in duration with an optional second year and accredited without reporting requirements by the Commission on Dental Accreditation of the American Dental Association. All of our affiliated community health centers and dental school training sites have been formally reviewed by CODA and approved for postdoctoral dental education and training.

According to the Oregon State Board of Dentistry OAR referenced and highlighted below, there exists the opportunity for an individual to acquire a license to practice dentistry without further examination. However, the OAR 818-021-0011; 1(b) as referenced below, seems to limit a candidate's opportunity to pursue this pathway as it appears that only general dentistry programs at CODA approved *dental schools* are recognized by the Oregon State Board of Dentistry.

818-021-0011

Application for License to Practice Dentistry Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

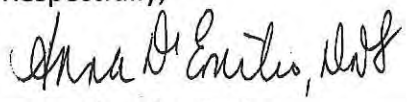
(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

On behalf of the NYU Lutheran AEGD program, I ask that the OR state board of dentistry consider accepting the qualifications of CODA accredited hospital/medical center-based postdoctoral general dentistry residency programs, and therefore allow graduates of the NYU Lutheran program to pursue the pathway that is available under OAR 818-021-0011; 1(b).

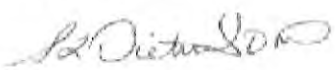
The AEGD program is prepared to provide to the Board additional information upon request. For this information, I can be contacted at Anna.D'Emilio@nyumc.org.

I appreciate the Board's review and consideration of this request.

Respectfully,



Anna D'Emilio, DDS
Vice President and Director, AEGD Program
NYU Lutheran



Susan L. Dietrich, DMD, MA
Vice President, Graduate Dental Education
NYU Lutheran

Stephen Prisby

Subject: FW: Credentials
Attachments: JB2.pdf; ATT00001.htm; jb_1.pdf; ATT00002.htm

From: Jessica Bruce <jessicab@hermistonkidsdentist.com>
Date: May 26, 2016, 9:57:58 AM MST
To: "Paul.Kleinstub@state.or.us" <Paul.Kleinstub@state.or.us>
Subject: Credentials

Good morning Paul,

I spoke with you on the phone about a month or so ago regarding my credentials with the Oregon Board of Dentistry. My application was denied due to working for a pediatric dentist in Washington. I had my place of employment contact you to follow up.

After speaking with my boss, Dr. Kyle House, I believe there is some misunderstanding about the process. He explained to me that after speaking with you, there was confusion on the OBD side as to why my credentials has not been approved yet and it would be discussed at the next board meeting. As Dr. House has not heard a reply, I am following up to get a status update for why my application has not been approved. I have attached a letter of request for review, like you expressed I should do.

I hope to hear from you soon.

Best regards,
Jessica

Jessica Bruce
53 Rio Senda St.,
Umatilla, OR 97882

Oregon Board of Dentistry
1600 SW 4th Ave., #770
Portland, OR 97201

Thursday, May 26, 2016

To whomever it may concern,

I am writing this in regards to the denial of my credentials for a Dental Assisting Certificate. My application has been denied twice; below is the following circumstances and process.

My previous employer for 1.5 years, Dentistry for Kids, Dr. James F. Collette, as a licensed dentist filled out the correct portion of my application. After realizing that all procedures on the checklist must be performed and the applicant must prove competency, he and myself arranged an appointment to sit down so I could perform these procedures in his presence. After our appointment he proceeded to fill out his form and sign acknowledging that I am competent in each procedure (refer to OBD law 818-042-0120 section B, C as well as OBD law 818-042-0130 section 3, 4, see attached form). This form, my application and a check with the appropriate fees totaling to $125, ($50 for application processing and $75 for radiographic proficiency) was sent to your office on March 23rd, 2016.

On April 3rd, 2016 a letter (see attached form) was written to inform me that my application was not able to be processed due to the fact Dr. Collette's form was not sent directly from him (this information is not indicated anywhere on the applications or website). This letter was received on April 7th, 2016 without the return of my original check. I made a call to the licensing manager on May 8th, 2016 to clarify what "directly from Dr. Collette" meant.

Dr. James Collette, once again, filled out and signed acknowledging that the applicant, myself, is competent in all procedures on the Verification of Hours forms and was sent directly from him. A new application was filled out by myself and sent overnight on April 11th, 2016.

On April 18th, 2016 at 8:10am, I made a call to the licensing manager in regards to her receiving the paperwork; I was informed it had not been received yet.

April 19th, 2016 at 9:31am, I called again to check the status. I was informed that my application was received and "sent back because payment was not sent with it and a payment is needed". I then explained that a new check was not sent with this application because my prior check had not been returned to me with the initial denial form. She then informed me that I had not needed to fill out a new application and your office was only waiting on Dr. Collette's form. I called my primary bank to check the status of my first check, they informed me that the funds for $125 was processed to the Oregon Board of Dentistry on March 29th, 2016, check #1027. After receiving this information, I called once more to inform the licensing manager that the money had already been processed. I also explained that I was not comfortable with the fact that my money had been taken, processed 3-4 weeks before my application was processed, and then told my 2nd application was sent back because payment had not gone with it.

April 20th, 2016 at 12:08pm, I called and Dr. Collette's paperwork had still not been received.

April 21st, 2016 at 1:32pm I called and spoke with the licensing manager; she informed me that the form was received but she had questions because I had previously been employed with a pediatric dentist. I asked if she can express what her concerns were; she told me that temporary crowns are not normally performed in pediatric offices and wanted to talk with the dentist. I explained I had performed the procedures in front of Dr. Collette and he has personally see to it that I am competent in each procedure. The licensing manager explained that I will not be approved for Oregon credentials through credentials because the procedures were not performed on patients. I was also told that each procedure needed to be a majority portion of my job and are required to be performed on patients; I asked where this information was written in the requirements. I was not provided with these written requirements.

After the previous conversation, I called again on the same day at 2:20pm to inform the licensing manager that I had routinely done these procedures in school and that is where I was educated (being as in Washington State, it is not a requirement to attend school to obtain an assistant certification). I was told the education was not applicable to the credentials I was applying for.

April 22nd, 2016 at 11:51am, I called and left a message with Stephan's and Paul's answering machine.

On Monday, April 25th, 2016, I received a phone call at 7:09am from Paul. I explained all the previous conversations and information. Paul asked if I had ever performed a permanent crown cementation on a patient before. I informed him that as a dental assistant, I am not allowed to perform any procedure that is to be considered a 'permanent' procedure on a patient. He explained the same stipulations the licensing manager had explained. As explained in previous days to the licensing manager, I explained to Paul that in the Oregon Board of Dentistry requirements, referring to OBD law 818-042-0120 section B, C as well as OBD law 818-042-0130 section 2, 3, (see attached form) it does *not* state procedures are *required* to be performed on patients as a majority portion of my job. The stipulations I am being told that are restricting my application from proceeding to certification are not stated anywhere in any document under the OBD requirements.

As the OBD law requirements state "...that the applicant has successfully polished 12 amalgam or composite surfaces, removed supra-gingival excess cement from six (6) crowns or bridges with hand instruments; placed temporary restorative material (i.e., zinc oxide eugenol based material) in six (6) teeth; preliminary fitted six (6) crowns to check contacts or to adjust occlusion outside the mouth; removed six (6) temporary crowns and temporarily cemented the crowns; polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis in six (6) patients; placed two matrix bands in each quadrant on teeth prepared for Class II restorations; and complete six (6) teeth whitening or bleach procedures" (refer to OBD law 818-042-0080 section B, attached copy) and "...certification that the assistant has been employed for at least 1000 hours in the past two years as a dental assistant performing the functions for which certification is being sought", "...if applying for certification by credential as an EFDA or EFODA, certification by a licensed dentist that the applicant is competent to perform the functions for which certification is sought" (refer to OBD law 818-042-0130 section 3, 4, attached copy).

The laws listed above do not state that the required procedures MUST be performed on patients or state they MUST be a majority portion of my job. They clearly state that a licensed dentist must acknowledge the applicant, myself, is competent to perform functions which are being sought. Dr. James F. Collette, a license and board certified dentist of Dentistry for Kids, has provided, twice, that he is completely aware I am competent and can perform all procedures being sought.

According to the OBD law requirements listed above and attached, I legally qualify for certification in Oregon. I request that my application for credentials through credentials be reviewed again as the reasoning for denial are unfounded in the Oregon Board of Dentistry requirements.

Sincerely,

Jessica Bruce

Jessica Bruce

The following duties are considered Expanded Function Duties and may be performed only after the dental assistant complies with the requirements of 818-042-0080:

(1) Polish the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains;

(2) Remove temporary crowns for final cementation and clean teeth for final cementation;

(3) Preliminarily fit crowns to check contacts or to adjust occlusion outside the mouth;

(4) Place temporary restorative material (i.e., zinc oxide eugenol based material) in teeth providing that the patient is checked by a dentist before and after the procedure is performed;

(5) Place and remove matrix retainers for alloy and composite restorations;

(6) Polish amalgam or composite surfaces with a slow speed handpiece;

(7) Remove excess supragingival cement from crowns, bridges, bands or brackets with hand instruments providing that the patient is checked by a dentist after the procedure is performed;

(8) Fabricate temporary crowns, and temporarily cement the temporary crown. The cemented crown must be examined and approved by the dentist prior to the patient being released;

(9) Under general supervision, when the dentist is not available and the patient is in discomfort, an EFDA may recement a temporary crown or recement a permanent crown with temporary cement for a patient of record providing that the patient is rescheduled for follow-up care by a licensed dentist as soon as is reasonably appropriate; and

(10) Perform all aspects of teeth whitening procedures.

Stat. Auth.: ORS 679 & 680
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09; OBD 3-2015, f. 9-8-15, cert. ef. 10-1-15

818-042-0080

Certification — Expanded Function Dental Assistant (EFDA)

The Board may certify a dental assistant as an expanded function assistant:

(1) By credential in accordance with OAR 818-042-0120, or

(2) If the assistant submits a completed application, pays the fee and provides evidence of;

(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Basic or CDA examination, and the Expanded Function Dental Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by a licensed dentist that the applicant has successfully polished 12 amalgam or composite surfaces, removed supra-gingival excess cement from six (6) crowns or bridges with hand instruments; placed temporary restorative material (i.e., zinc oxide eugenol based material) in six (6) teeth; preliminarily fitted six (6) crowns to check contacts or to adjust occlusion outside the mouth; removed six (6) temporary crowns for final cementation and cleaned teeth for final cementation; fabricated six (6) temporary crowns and temporarily cemented the crowns; polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis in six (6) patients; placed two matrix bands in each quadrant on teeth prepared for Class II restorations; and complete six (6) teeth whitening or bleach procedures.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.250(7)
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 10-1999(Temp), f. 12-2-99, cert. ef. 1-1-00 thru 6-28-00; OBD 8-2000, f. 6-22-00, cert. ef. 6-29-00; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 2-2009, f. 10-21-09, cert. ef. 11-1-09

818-042-0090

Additional Functions of EFDAs

Upon successful completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association, or other course of instruction approved by the Board, a certified Expanded Function Dental Assistant may perform the following functions under the indirect supervision of a dentist or dental hygienist providing that the procedure is checked by the dentist or dental hygienist prior to the patient being dismissed:

(c) The "Certified Oral and Maxillofacial Surgery Assistant" examination, or successor examination, conducted by the Dental Assisting National Board or other Board approved examination; and

(2) Holding valid and current documentation showing successful completion of a Health Care Provider BLS/CPR course, or its equivalent.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.250(7)
Hist.: OBD 1-2001, f. & cert. ef. 1-8-01; OBD 2-2005, f. 1-31-05, cert. ef. 2-1-05; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

818-042-0117

Initiation of IV Line

Upon successful completion of a course in intravenous access or phlebotomy approved by the Board, a Certified Anesthesia Dental Assistant may initiate an intravenous (IV) infusion line for a patient being prepared for IV medications, sedation, or general anesthesia under the Indirect Supervision of a dentist holding the appropriate anesthesia permit.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020(1), 679.025(1) & 679.250(7)
Hist.: OBD 1-2001, f. & cert. ef. 1-8-01; OBD 1-2006, f. 3-17-06, cert. ef. 4-1-06

818-042-0120

Certification by Credential

(1) Dental Assistants who wish to be certified by the Board in Radiologic Proficiency or as Expanded Function Dental Assistants, or as Expanded Function Orthodontic Dental Assistants shall:

(a) Be certified by another state in the functions for which application is made. The training and certification requirements of the state in which the dental assistant is certified must be substantially similar to Oregon's requirements; or

(b) Have worked for at least 1,000 hours in the past two years in a dental office where such employment involved to a significant extent the functions for which certification is sought; and

(c) Shall be evaluated by a licensed dentist, using a Board approved checklist, to assure that the assistant is competent in the expanded functions.

(2) Applicants applying for certification by credential in Radiologic Proficiency must obtain certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, of having successfully completed training equivalent to that required by OAR 333-106-0055 or approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.020, 679.025 & 679.250
Hist.: OBD 9-1999, f. 8-10-99, cert. ef. 1-1-00; OBD 2-2003, f. 7-14-03 cert. ef. 7-18-03; OBD 4-2004, f. 11-23-04 cert. ef. 12-1-04; OBD 3-2005, f. 10-26-05, cert. ef. 11-1-05; OBD 4-2011, f. & cert. ef. 11-15-11; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

818-042-0130

Application for Certification by Credential

An applicant for certification by credential shall submit to the Board:

(1) An application form approved by the Board, with the appropriate fee;

(2) Proof of certification by another state and any other recognized certifications (such as CDA or COA certification) and a description of the examination and training required by the state in which the assistant is certified submitted from the state directly to the Board; or

(3) Certification that the assistant has been employed for at least 1,000 hours in the past two years as a dental assistant performing the functions for which certification is being sought.

(4) If applying for certification by credential as an EFDA or EFODA, certification by a licensed dentist that the applicant is competent to perform the functions for which certification is sought; and

(5) If applying for certification by credential in Radiologic Proficiency, certification from the Oregon Health Authority, Center for Health Protection, Radiation Protection Services, or the Oregon Board of Dentistry, that the applicant has met that agency's training requirements for x-ray machine operators, or other comparable requirements approved by the Oregon Board of Dentistry.

Stat. Auth.: ORS 679

From: Michael Ryhn [mailto:mjryhn@gmail.com]
Sent: Sunday, June 05, 2016 11:26 AM
To: Stephen Prisby
Cc: Julie Ann Smith D.D.S., M.D.
Subject: Request for assistance for a military OMS Residency

Good morning -

Attached is a request for assistance for the OMS program at Tripler Army Medical Center located in Honolulu, HI. Currently, all of the major maxillofacial trauma goes to The Queen's Hospital and our residents are lacking in major trauma as well as reconstruction.

Please allow us the opportunity to improve the trauma exposure we currently receive through a Tyler Texas two month rotation with additional exposure with Dr Eric Dierks.

Sincerely,

MJ Ryhn

Stephen.Prisby@state.or.us

Julie Ann Smith, DDS, MD smitjuli@ohsu.edu

Stephen Prisby
Oregon Board of Dentistry
1500 SW 1st Ave
Suite #770
Portland, OR 97201

Dear Mr. Prisby:

I am an Army oral and maxillofacial surgeon and the Program Director for the advanced education training program in Oral and Maxillofacial Surgery at Tripler Army Hospital in Honolulu, Hawaii. Our four year residency program in OMS is well-rounded but lacks exposure to a high volume of major neck dissection surgery for oral cancer, and we lack the broad-scope experience in major craniomaxillofacial trauma, including airway trauma, that is available through the Head and Neck Surgical Associates at Legacy Emanuel and Portland Providence Hospitals there in Portland. The HNSA and its surgeons are well-known and they host a number of rotating residents from around the US and elsewhere. I feel this training would be important in the training of an Army OMS who would then be ready to deployment into a trauma unit in an area of active conflict.

In conjunction with the HNSA, I am planning a series of one-month rotations for our residents to obtain this valuable experience. As this surgical learning environment inherently involves patient contact, I need to explore with you our options for obtaining either a temporary Oregon dental license or recognition by the Oregon Board of Dentistry that our residents will be on official military assignment in Portland, as they are here in Hawaii, making a specific Oregon license unnecessary. Our residents all have unrestricted licensure to practice in a US state.

Our funding for the training of military residents in all disciples has undergone significant cutbacks over the past few years. Our Army residents would suffer a personal economic hardship should they be forced to purchase standard Oregon dental licensure and I am looking for alternatives. The Army MD general surgery and emergency medicine rotators to HNSA and Emanuel from Madigan Army Hospital in Ft. Lewis Washington have gotten Oregon medical permits for a very reasonable fee, I believe $185, and I wonder if a similar program might be available for our DDS/DMD residents.

The military is looking to privatize specialties in the military that are not prepared to deploy. This trauma experience is exactly what we need.

Thank you very much for your help in this matter. I can be reached at michael.j.ryhn.mil@mail.mil or mjryhn@gmail.com or on my cell phone at 910 916 0356.

Sincerely

Michael J Ryhn
Lieutenant Colonel, Dental Corps
Tripler OMS Residency Program Director

I am attaching this narrative to explain what the purpose of the suggested change would be. I am basically suggesting an additional pathway for licensure without further examination for candidates who have graduated from a non-US dental school under 818-021-0011.

The additional path would allow dentists who are currently licensed in the US and have appropriate experience and CE hours to obtain an active Oregon license.

Section (1)B(c) already exists as an additional requirement for the candidates mentioned in 818-021-011B(a),(b); Therefore mentioning it would be a repetitive statement , considering the fact that section(d),(e),(f) are being added to each section of 818-021-0011B(a),(b).

Thank you for your attention,

Laleh Hedayat

818-021-0011

Application for license to practice dentistry without further examination

1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:

A. Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; OR
B. Having graduated from a dental school located outside the United States or Canada.

a. Completion of a pre-doctoral dental education program of not less than two years at a dental school of at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association AND

- holding an active license to practice dentistry, without restrictions, in any state ; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is , or has been, the subject of any final pending disciplinary action; AND
- having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States Public Health Services or the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3500 hours in the five years immediately prior to application; AND
- Having conducted 40 hours of continuing education in accordance with the Boards continuing education requirements contained in these rules within the two years immediately preceding application.

b. Completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English Language ; AND

- holding an active license to practice dentistry, without restrictions, in any state ; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is , or has been, the subject of any final pending disciplinary action; AND
- having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States Public Health Services or the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3500 hours in the five years immediately prior to application; AND

- Having conducted 40 hours of continuing education in accordance with the Boards continuing education requirements contained in these rules within the two years immediately preceding application .

c. Having passed the dental clinical examination conducted by a regional testing agency or by a state dental licensing authority m

- holding an active license to practice dentistry, without restrictions, in any state ; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is , or has been, the subject of any final pending disciplinary action; AND
- having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States Public Health Services or the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3500 hours in the five years immediately prior to application; AND
- Having conducted 40 hours of continuing education in accordance with the Boards continuing education requirements contained in these rules within the two years immediately preceding application.

2) Applicants must pass the Board’s Jurisprudence Examination.

Current rule in Dental Practice Act

818-021-0011

Application for License to Practice Dentistry Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Having passed the dental clinical examination conducted by a regional testing agency or by a state dental licensing authority; and

(d) Holding an active license to practice dentistry, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

(e) Having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately prior to application; and

(f) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

(3) A dental license granted under this rule will be the same as the license held in another state; i.e., if the dentist holds a general dentistry license, the Oregon Board will issue a general (unlimited) dentistry license. If the dentist holds a license limited to the practice of a specialty, the Oregon Board will issue a license limited to the practice of that specialty. If the dentist holds more than one license, the Oregon Board will issue a dental license which is least restrictive.

Stat. Auth.: ORS 679
Stats. Implemented: ORS 679.060, 679.065, 679.070, 679.080 & 679.090

From: Teresa Haynes
Sent: Tuesday, May 10, 2016 8:11 AM
To: Sam Barry
Cc: Stephen Prisby
Subject: RE: sterilization of low speed handpiece motors

Hi Sam:

I have cc'd Stephen Prisby, the Board's Executive Director, so that he may include this information for the next Board meeting, which will be on June 17, 2016.

Sincerely,

Teresa

Teresa Haynes
Acting Office Manager
Oregon Board of Dentistry
1500 SW 1st Avenue, Suite 770
Portland, OR 97201
Telephone: 971-673-3200
FAX: 971-673-3202
www.oregon.gov/dentistry

Your opinion matters. Please complete our Customer Satisfaction Survey at http://obd.oregonsurveys.com

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Please consider the environment before printing this e-mail.

From: Sam Barry [mailto:sbbarry@oregontrail.net]
Sent: Tuesday, May 10, 2016 7:19 AM
To: Teresa Haynes <Teresa.Haynes@state.or.us>
Subject: sterilization of low speed handpiece motors

Teresa
On March 28th the CDC released the "Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care", which is available at this website: http://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care.pdf On page 14 it states that low speed handpiece motors should be heat sterilized between patients. Does the Oregon Board of Dentistry have an official position on this?
Thank you!
Sam

Summary of Infection Prevention Practices in Dental Settings

Basic Expectations for Safe Care

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Note to Readers

This document is a summary guide of basic infection prevention recommendations for all dental health care settings. These include traditional settings such as private dental practices, dental clinics, dental schools and educational programs (including dental assisting, dental hygiene, and laboratory) and nontraditional settings that often use portable dental equipment such as clinics held in schools for sealant and fluoride placement and in other sites for humanitarian dental missions.

While the information included in this document reflects existing evidence-based guidelines produced by the Centers for Disease Control and Prevention (CDC), it is not intended as a replacement for more extensive guidelines. This summary guide is based primarily upon elements of Standard Precautions and represents a summary of basic infection prevention expectations for safe care in dental settings as recommended in the *Guidelines for Infection Control in Dental Health-Care Settings—2003*. Readers are urged to use the Infection Prevention Checklist for Dental Settings (Appendix A), a companion to the summary; and to consult the full guidelines for additional background, rationale, and scientific evidence behind each recommendation.

Suggested Citation

Centers for Disease Control and Prevention. *Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health; March 2016.

Adapted from: *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*
http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

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Introduction

Transmission of infectious agents among patients and dental health care personnel (DHCP) in dental settings is rare. However, from 2003 to 2015, transmissions in dental settings, including patient-to-patient transmissions, have been documented.[1–4] In most cases, investigators failed to link a specific lapse of infection prevention and control with a particular transmission. However, reported breakdowns in basic infection prevention procedures included unsafe injection practices, failure to heat sterilize dental handpieces between patients, and failure to monitor (e.g., conduct spore testing) autoclaves.[2,3] These reports highlight the need for comprehensive training to improve understanding of underlying principles, recommended practices, their implementation, and the conditions that have to be met for disease transmission.

All dental settings, regardless of the level of care provided, must make infection prevention a priority and should be equipped to observe Standard Precautions and other infection prevention recommendations contained in CDC's *Guidelines for Infection Control in Dental Health-Care Settings—2003*.[5] The *Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care* summarizes current infection prevention recommendations and includes a checklist (Appendix A) that can be used to evaluate compliance.

The information presented here is based primarily upon the recommendations from the 2003 guideline and represents infection prevention expectations for safe care in dental settings. It is intended for use by anyone needing information about basic infection prevention measures in dental health care settings, but is not a replacement for the more extensive guidelines. Readers are urged to consult the full guidelines for additional background, rationale, and scientific evidence behind each recommendation. Additional topics and information relevant to dental infection prevention and control published by CDC since 2003 in this document can be found in Appendix B including

- Infection prevention program administrative measures.
- Infection prevention education and training.
- Respiratory hygiene and cough etiquette.
- Updated safe injection practices.
- Administrative measures for instrument processing.

For the purposes of this document, DHCP refers to all paid and unpaid personnel in the dental health care setting who might be occupationally exposed to infectious materials, including body substances and contaminated supplies, equipment, environmental surfaces, water, or air. This includes

- Dentists.
- Dental hygienists.
- Dental assistants.
- Dental laboratory technicians (in-office and commercial).
- Students and trainees.
- Contractual personnel.
- Other persons not directly involved in patient care but potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel).[5]

Objectives

By highlighting existing CDC recommendations, this summary guide

1. Provides basic infection prevention principles and recommendations for dental health care settings.
2. Reaffirms Standard Precautions as the foundation for preventing transmission of infectious agents during patient care in all dental health care settings.
3. Provides links to full guidelines and source documents that readers can reference for more detailed background and recommendations.

For additional references, background information, rationale, and evidence, readers should consult the references and resources listed in Appendix C. Detailed recommendations for dental health care settings can be found in the compendium document, *Recommendations from the Guidelines for Infection Control in Dental Health-Care Settings—2003*.

References

1. Redd JT, Baumbach J, Kohn W, et al. Patient-to-patient transmission of hepatitis B virus associated with oral surgery. *J Infect Dis.* 2007;195(9):1311–1314.
2. Radcliffe RA, Bixler D, Moorman A, et al. Hepatitis B virus transmissions associated with a portable dental clinic, West Virginia, 2009. *J Am Dent Assoc.* 2013;144(10):1110–1118.
3. Oklahoma State Department of Health. Dental Healthcare-Associated Transmission of Hepatitis C: Final Report of Public Health Investigation and Response, 2013. Available at: http://www.ok.gov/health2/documents/Dental%20Healthcare_Final%20Report_2_17_15.pdf.
4. Klevens RM, Moorman AC. Hepatitis C virus: an overview for dental health care providers. *J Am Dent Assoc.* 2013;144(12):1340–1347.
5. Centers for Disease Control and Prevention. Guidelines for infection control in dental health-care settings—2003. *MMWR Recomm Rep* 2003;52(RR-17):1–61. Available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf.

Fundamental Elements Needed to Prevent Transmission of Infectious Agents in Dental Settings

Administrative Measures

Infection prevention must be made a priority in any dental health care setting. At least one individual with training in infection prevention—the infection prevention coordinator—should be responsible for developing written infection prevention policies and procedures based on evidence-based guidelines, regulations, or standards. Policies and procedures should be tailored to the dental setting and reassessed on a regular basis (e.g., annually) or according to state or federal requirements. Development should take into consideration the types of services provided by DHCP and the patient population served, extending beyond the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard to address patient safety. The infection prevention coordinator should ensure that equipment and supplies (e.g., hand hygiene products, safer devices to reduce percutaneous injuries, and personal protective equipment) are available and should maintain communication with all staff members to address specific issues or concerns related to infection prevention. In addition, all dental settings should have policies and protocols for early detection and management of potentially infectious persons at initial points of patient encounter.

Key ADMINISTRATIVE RECOMMENDATIONS for Dental Settings

1. Develop and maintain infection prevention and occupational health programs.
2. Provide supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, safer devices to reduce percutaneous injuries, personal protective equipment).
3. Assign at least one individual trained in infection prevention responsibility for coordinating the program.
4. Develop and maintain written infection prevention policies and procedures appropriate for the services provided by the facility and based on evidence-based guidelines, regulations, or standards.
5. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter.

Infection Prevention Education and Training

Ongoing education and training of DHCP are critical for ensuring that infection prevention policies and procedures are understood and followed. Education on the basic principles and practices for preventing the spread of infections should be provided to all DHCP. Training should include both DHCP safety (e.g., OSHA bloodborne pathogens training) and patient safety (e.g., emphasizing job- or task-specific needs). Education and training should be provided during orientation to the setting, when new tasks or procedures are introduced and at a minimum, annually. Training records should be maintained according to state and federal requirements.

Key Recommendations for EDUCATION AND TRAINING in Dental Settings

1. Provide job- or task-specific infection prevention education and training to all DHCP.
   a. This includes those employed by outside agencies and available by contract or on a volunteer basis to the facility.
2. Provide training on principles of both DHCP safety and patient safety.
3. Provide training during orientation and at regular intervals (e.g., annually).
4. Maintain training records according to state and federal requirements.

Dental Health Care Personnel Safety

Infection prevention programs should also address occupational health needs, including vaccination of DHCP, management of exposures or infections in personnel requiring post-exposure prophylaxis or work restrictions, and compliance with OSHA bloodborne pathogens standard. Referral arrangements for medical services can be made with qualified health care professionals in an occupational health program of a hospital, with educational institutions, or with health care facilities that offer personnel health services.

Recommendations for prevention of infections in DHCP can be found in the following documents—*Guidelines for Infection Control in Dental Health-Care Settings—2003* (available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf), *Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)* (available at: http://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf), and OSHA Bloodborne Pathogens and Needlestick Prevention (available at: http://www.osha.gov/SLTC/bloodbornepathogens/index.html).

Key Recommendations for DENTAL HEALTH CARE PERSONNEL SAFETY

1. Current CDC recommendations for immunizations, evaluation, and follow-up are available. There is a written policy regarding immunizing DHCP, including a list of all required and recommended immunizations for DHCP (e.g., hepatitis B, MMR (measles, mumps, and rubella) varicella (chickenpox), Tdap (tetanus, diphtheria, pertussis).
2. All DHCP are screened for tuberculosis (TB) upon hire regardless of the risk classification of the setting.
3. Referral arrangements are in place to qualified health care professionals (e.g., occupational health program of a hospital, educational institutions, health care facilities that offer personnel health services) to ensure prompt and appropriate provision of preventive services, occupationally-related medical services, and postexposure management with medical follow-up.
4. Facility has well-defined policies concerning contact of personnel with patients when personnel have potentially transmissible conditions.

Program Evaluation

A successful infection prevention program depends on

- Developing standard operating procedures.
- Evaluating practices and providing feedback to DHCP.
- Routinely documenting adverse outcomes (e.g., occupational exposures to blood) and work-related illnesses in DHCP.
- Monitoring health care associated infections in patients.

Strategies and tools to evaluate the infection prevention program can include periodic observational assessments, checklists to document procedures, and routine review of occupational exposures to bloodborne pathogens. The Infection Prevention Checklist for Dental Settings found in Appendix A is one tool DHCP can use to evaluate their infection prevention program. Evaluation offers an opportunity to improve the effectiveness of both the infection-prevention program and dental practice protocols. If deficiencies or problems in the implementation of infection prevention procedures are identified—further evaluation and feedback, corrective action, and training (if applicable) is needed to eliminate the problems.

Key Recommendation for PROGRAM EVALUATION in Dental Settings

1. Establish routine evaluation of the infection prevention program, including evaluation of DHCP adherence to infection prevention practices.

Standard Precautions

Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. These practices are designed to both protect DHCP and prevent DHCP from spreading infections among patients. Standard Precautions include—

1. Hand hygiene.
2. Use of personal protective equipment (e.g., gloves, masks, eyewear).
3. Respiratory hygiene/cough etiquette.
4. Sharps safety (engineering and work practice controls).
5. Safe injection practices (i.e., aseptic technique for parenteral medications).
6. Sterile instruments and devices.
7. Clean and disinfected environmental surfaces.

Each element of Standard Precautions is described in the following sections. Education and training are critical elements of Standard Precautions, because they help DHCP make appropriate decisions and comply with recommended practices.

When Standard Precautions alone cannot prevent transmission, they are supplemented with Transmission-Based Precautions. This second tier of infection prevention is used when patients have diseases that can spread through contact, droplet or airborne routes (e.g., skin contact, sneezing, coughing) and are always used in addition to Standard Precautions. Dental settings are not typically designed to carry out all of the Transmission-Based Precautions (e.g., Airborne Precautions for patients with suspected tuberculosis, measles, or chickenpox) that are recommended for hospital and other ambulatory care settings. Patients, however, do not usually seek routine dental outpatient care when acutely ill with diseases requiring Transmission-Based Precautions. Nonetheless, DHCP should develop and carry out systems for early detection and management of

potentially infectious patients at initial points of entry to the dental setting. To the extent possible, this includes rescheduling non-urgent dental care until the patient is no longer infectious or referral to a dental setting with appropriate infection prevention precautions when urgent dental treatment is needed.

Hand Hygiene

Hand hygiene is the most important measure to prevent the spread of infections among patients and DHCP. Education and training programs should thoroughly address indications and techniques for hand hygiene practices before performing routine and oral surgical procedures.

For routine dental examinations and nonsurgical procedures, use water and plain soap (hand washing) or antimicrobial soap (hand antisepsis) specific for health care settings or use an alcohol-based hand rub. Although alcohol-based hand rubs are effective for hand hygiene in health care settings, soap and water should be used when hands are visibly soiled (e.g., dirt, blood, body fluids). For surgical procedures,[1] perform a surgical hand scrub before putting on sterile surgeon's gloves. For all types of hand hygiene products, follow the product manufacturer's label for instructions. Complete guidance on how and when hand hygiene should be performed, including recommendations regarding surgical hand antisepsis and artificial nails can be found in the *Guideline for Hand Hygiene in Health-Care Settings* (available at: http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf).

Key Recommendations for HAND HYGIENE in Dental Settings

1. Perform hand hygiene—
   - **a.** When hands are visibly soiled.
   - **b.** After barehanded touching of instruments, equipment, materials, and other objects likely to be contaminated by blood, saliva, or respiratory secretions.
   - **c.** Before and after treating each patient.
   - **d.** Before putting on gloves and again immediately after removing gloves.
2. Use soap and water when hands are visibly soiled (e.g., blood, body fluids); otherwise, an alcohol-based hand rub may be used.

Personal Protective Equipment

Personal protective equipment (PPE) refers to wearable equipment that is designed to protect DHCP from exposure to or contact with infectious agents. PPE that is appropriate for various types of patient interactions and effectively covers personal clothing and skin likely to be soiled with blood, saliva, or other potentially infectious materials (OPIM) should be available. These include gloves, face masks, protective eye wear, face shields, and protective clothing (e.g., reusable or disposable gown, jacket, laboratory coat). Examples of appropriate use of PPE for adherence to Standard Precautions include—

- Use of gloves in situations involving possible contact with blood or body fluids, mucous membranes, non-intact skin (e.g., exposed skin that is chapped, abraded, or with dermatitis) or OPIM.
- Use of protective clothing to protect skin and clothing during procedures or activities where

[1] Definition from 2003 CDC Dental Guidelines—Oral surgical procedures involve the incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or nonerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth, and suturing if needed).

contact with blood or body fluids is anticipated.

- Use of mouth, nose, and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.

DHCP should be trained to select and put on appropriate PPE and remove PPE so that the chance for skin or clothing contamination is reduced. Hand hygiene is always the final step after removing and disposing of PPE. Training should also stress preventing further spread of contamination while wearing PPE by:

- Keeping hands away from face.
- Limiting surfaces touched.
- Removing PPE when leaving work areas.
- Performing hand hygiene.

The application of Standard Precautions and guidance on appropriate selection and an example of putting on and removal of personal protective equipment is described in detail in the *2007 Guideline for Isolation Precautions* (available at: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf).

Key Recommendations for PERSONAL PROTECTIVE EQUIPMENT (PPE) in Dental Settings

1. Provide sufficient and appropriate PPE and ensure it is accessible to DHCP.
2. Educate all DHCP on proper selection and use of PPE.
3. Wear gloves whenever there is potential for contact with blood, body fluids, mucous membranes, non-intact skin or contaminated equipment.
   a. Do not wear the same pair of gloves for the care of more than one patient.
   b. Do not wash gloves. Gloves cannot be reused.
   c. Perform hand hygiene immediately after removing gloves.
4. Wear protective clothing that covers skin and personal clothing during procedures or activities where contact with blood, saliva, or OPIM is anticipated.
5. Wear mouth, nose, and eye protection during procedures that are likely to generate splashes or spattering of blood or other body fluids.
6. Remove PPE before leaving the work area.

Respiratory Hygiene/Cough Etiquette

Respiratory hygiene/cough etiquette infection prevention measures are designed to limit the transmission of respiratory pathogens spread by droplet or airborne routes. The strategies target primarily patients and individuals accompanying patients to the dental setting who might have undiagnosed transmissible respiratory infections, but also apply to anyone (including DHCP) with signs of illness including cough, congestion, runny nose, or increased production of respiratory secretions.

DHCP should be educated on preventing the spread of respiratory pathogens when in contact with symptomatic persons. Respiratory hygiene/cough etiquette measures were added to Standard Precautions in 2007. Additional information related to respiratory hygiene/cough etiquette can be found in the *2007 Guideline for Isolation Precautions* (available at: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf). Recommendations for preventing the spread of influenza are available at: http://www.cdc.gov/flu/professionals/infectioncontrol/.

Key Recommendations for RESPIRATORY HYGIENE/COUGH ETIQUETTE in Dental Settings

1. Implement measures to contain respiratory secretions in patients and accompanying individuals who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing throughout the visit.
   - **a.** Post signs at entrances with instructions to patients with symptoms of respiratory infection to—
     - **i.** Cover their mouths/noses when coughing or sneezing.
     - **ii.** Use and dispose of tissues.
     - **iii.** Perform hand hygiene after hands have been in contact with respiratory secretions.
   - **b.** Provide tissues and no-touch receptacles for disposal of tissues.
   - **c.** Provide resources for performing hand hygiene in or near waiting areas.
   - **d.** Offer masks to coughing patients and other symptomatic persons when they enter the dental setting.
   - **e.** Provide space and encourage persons with symptoms of respiratory infections to sit as far away from others as possible. If available, facilities may wish to place these patients in a separate area while waiting for care.
2. Educate DHCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens when examining and caring for patients with signs and symptoms of a respiratory infection.

Sharps Safety

Most percutaneous injuries (e.g., needlestick, cut with a sharp object) among DHCP involve burs, needles, and other sharp instruments. Implementation of the OSHA Bloodborne Pathogens Standard has helped to protect DHCP from blood exposure and sharps injuries. However, sharps injuries continue to occur and pose the risk of bloodborne pathogen transmission to DHCP and patients. Most exposures in dentistry are preventable; therefore, each dental practice should have policies and procedures available addressing sharps safety. DHCP should be aware of the risk of injury whenever sharps are exposed. When using or working around sharp devices, DHCP should take precautions while using sharps, during cleanup, and during disposal.

Engineering and work-practice controls are the primary methods to reduce exposures to blood and OPIM from sharp instruments and needles. Whenever possible, engineering controls should be used as the primary method to reduce exposures to bloodborne pathogens. Engineering controls remove or isolate a hazard in the workplace and are frequently technology-based (e.g., self-sheathing anesthetic needles, safety scalpels, and needleless IV ports). Employers should involve those DHCP who are directly responsible for patient care (e.g., dentists, hygienists, dental assistants) in identifying, evaluating and selecting devices with engineered safety features at least annually and as they become available. Other examples of engineering controls include sharps containers and needle recapping devices.

When engineering controls are not available or appropriate, work-practice controls should be used. Work-practice controls are behavior-based and are intended to reduce the risk of blood exposure by changing the way DHCP perform tasks, such as using

a one-handed scoop technique for recapping needles between uses and before disposal. Other work-practice controls include not bending or breaking needles before disposal, not passing a syringe with an unsheathed needle by hand, removing burs before disassembling the handpiece from the dental unit, and using instruments in place of fingers for tissue retraction or palpation during suturing and administration of anesthesia.

All used disposable syringes and needles, scalpel blades, and other sharp items should be placed in appropriate puncture-resistant containers located close to the area where they are used. Sharps containers should be disposed of according to state and local regulated medical waste rules.

For more information about sharps safety, see the *Guidelines for Infection Control in Dental Health-Care Settings—2003* (available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf), the CDC *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program* (available at: www.cdc.gov/sharpssafety/), and the CDC Sample Screening and Device Evaluation Forms for Dentistry (available at: www.cdc.gov/OralHealth/infectioncontrol/forms.htm).

Key Recommendations for SHARPS SAFETY in Dental Settings

1. Consider sharp items (e.g., needles, scalers, burs, lab knives, and wires) that are contaminated with patient blood and saliva as potentially infective and establish engineering controls and work practices to prevent injuries.
2. Do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body.
3. Use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g., between multiple injections and before removing from a non-disposable aspirating syringe).
4. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as possible to the area where the items are used.

Safe Injection Practices

Safe injection practices are intended to prevent transmission of infectious diseases between one patient and another, or between a patient and DHCP during preparation and administration of parenteral (e.g., intravenous or intramuscular injection) medications. Safe injection practices are a set of measures DHCP should follow to perform injections in the safest possible manner for the protection of patients. DHCP most frequently handle parenteral medications when administering local anesthesia, during which needles and cartridges containing local anesthetics are used for one patient only and the dental cartridge syringe is cleaned and heat sterilized between patients. Other safe practices described here primarily apply to use of parenteral medications combined with fluid infusion systems, such as for patients undergoing conscious sedation. Unsafe practices that have led to patient harm include 1) use of a single syringe—with or without the same needle—to administer medication to multiple patients, 2) reinsertion of a used syringe—with or without the same needle—into a medication vial or solution container (e.g., saline bag) to obtain additional medication for a single patient and then

using that vial or solution container for subsequent patients, and 3) preparation of medications in close proximity to contaminated supplies or equipment.

Safe injection practices were covered in the Special Considerations section (Aseptic Technique for Parenteral Medications) of the 2003 CDC dental guidelines. However, because of reports of transmission of infectious diseases by inappropriate handling of injectable medications, CDC now considers safe injection practices to be a formal element of Standard Precautions. Complete guidance on safe injection practices can be found in the *2007 Guideline for Isolation Precautions* (available at: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf). Additional materials, including a list of frequently asked questions from providers and a patient notification toolkit, are also available (http://www.cdc.gov/injectionsafety/). The *One & Only Campaign* is a public health effort to eliminate unsafe medical injections. The campaign is led by CDC and the Safe Injection Practices Coalition (SIPC). To learn more about safe injection practices and access training videos and resources, please visit http://www.oneandonlycampaign.org/.

Key Recommendations for SAFE INJECTION PRACTICES in Dental Settings

1. Prepare injections using aseptic technique[2] in a clean area.
2. Disinfect the rubber septum on a medication vial with alcohol before piercing.
3. Do not use needles or syringes* for more than one patient (this includes manufactured prefilled syringes and other devices such as insulin pens).
4. Medication containers (single and multidose vials, ampules, and bags) are entered with a new needle and new syringe, even when obtaining additional doses for the same patient.
5. Use single-dose vials for parenteral medications when possible.
6. Do not use single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution for more than one patient.
7. Do not combine the leftover contents of single-use vials for later use.
8. The following apply if multidose vials are used—
   - **a.** Dedicate multidose vials to a single patient whenever possible.
   - **b.** If multidose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., dental operatory) to prevent inadvertent contamination.
   - **c.** If a multidose vial enters the immediate patient treatment area, it should be dedicated for single-patient use and discarded immediately after use.
   - **d.** Date multidose vials when first opened and discard within 28 days, unless the manufacturer specifies a shorter or longer date for that opened vial.
9. Do not use fluid infusion or administration sets (e.g., IV bags, tubings, connections) for more than one patient.

[2] A technique that prevents or reduces the spread of microorganisms from one site to another, such as from patient to DHCP, from patient to operatory surfaces, or from one operatory surface to another.

* A Note about Administering Local Dental Anesthesia: When using a dental cartridge syringe to administer local anesthesia, do not use the needle or anesthetic cartridge for more than one patient. Ensure that the dental cartridge syringe is appropriately cleaned and heat sterilized before use on another patient.

Sterilization and Disinfection of Patient-Care Items and Devices

Instrument processing requires multiple steps using specialized equipment. Each dental practice should have policies and procedures in place for containing, transporting, and handling instruments and equipment that may be contaminated with blood or body fluids. Manufacturer's instructions for reprocessing reusable dental instruments and equipment should be readily available—ideally in or near the reprocessing area. Most single-use devices are labeled by the manufacturer for only a single use and do not have reprocessing instructions. Use single-use devices for one patient only and dispose of appropriately.

Cleaning, disinfection and sterilization of dental equipment should be assigned to DHCP with training in the required reprocessing steps to ensure reprocessing results in a device that can be safely used for patient care. Training should also include the appropriate use of PPE necessary for safe handling of contaminated equipment.

Patient-care items (e.g., dental instruments, devices, and equipment) are categorized as critical, semicritical, or noncritical, depending on the potential risk for infection associated with their intended use.

- Critical items, such as surgical instruments and periodontal scalers, are those used to penetrate soft tissue or bone. They have the greatest risk of transmitting infection and should always be sterilized using heat.
- Semicritical items (e.g., mouth mirrors, amalgam condensers, reusable dental impression trays) are those that come in contact with mucous membranes or non-intact skin (e.g., exposed skin that is chapped, abraded, or has dermatitis). These items have a lower risk of transmission. Because the majority of semicritical items in dentistry are heat-tolerant, they should also be sterilized using heat. If a semicritical item is heat-sensitive, DHCP should replace it with a heat-tolerant or disposable alternative. If none are available, it should, at a minimum, be processed using high-level disinfection.

  Note: Dental handpieces and associated attachments, including low-speed motors and reusable prophylaxis angles, should always be heat sterilized between patients and not high-level or surface disinfected. Although these devices are considered semicritical, studies have shown that their internal surfaces can become contaminated with patient materials during use. If these devices are not properly cleaned and heat sterilized, the next patient may be exposed to potentially infectious materials.

Digital radiography sensors are also considered semicritical and should be protected with a Food and Drug Administration (FDA)-cleared barrier to reduce contamination during use, followed by cleaning and heat-sterilization or high-level disinfection between patients. If the item cannot tolerate these procedures then, at a minimum, protect with an FDA-cleared barrier. In addition, clean and disinfect with an Environmental Protection Agency (EPA)-registered hospital disinfectant with intermediate-level (i.e., tuberculocidal claim) activity between patients. Because these items vary by manufacturer and their ability to be sterilized or high-level disinfected also vary, refer to manufacturer instructions for reprocessing.

- Noncritical patient-care items (e.g., radiograph head/cone, blood pressure cuff, facebow) are those that only contact intact skin. These items pose the least risk of transmission of infection. In the majority of cases, cleaning, or if visibly soiled, cleaning followed by disinfection with an EPA-registered hospital disinfectant is adequate. Protecting these surfaces with disposable barriers might be a preferred alternative.

Cleaning to remove debris and organic contamination from instruments should always occur before disinfection or sterilization. If blood, saliva, and other contamination are not removed, these materials can shield microorganisms and potentially compromise

the disinfection or sterilization process. Automated cleaning equipment (e.g., ultrasonic cleaner, washer-disinfector) should be used to remove debris to improve cleaning effectiveness and decrease worker exposure to blood. After cleaning, dried instruments should be inspected, wrapped, packaged, or placed into container systems before heat sterilization. Packages should be labeled to show the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date. This information can help in retrieving processed items in the event of an instrument processing/sterilization failure.

The ability of a sterilizer to reach conditions necessary to achieve sterilization should be monitored using a combination of biological, mechanical, and chemical indicators. Biological indicators, or spore tests, are the most accepted method for monitoring the sterilization process because they assess the sterilization process directly by killing known highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species). A spore test should be used at least weekly to monitor sterilizers. However, because spore tests are only performed periodically (e.g., once a week, once a day) and the results are usually not obtained immediately, mechanical and chemical monitoring should also be performed.

Mechanical and chemical indicators do not guarantee sterilization; however, they help detect procedural errors and equipment malfunctions. Mechanical monitoring involves checking the sterilizer gauges, computer displays, or printouts; and documenting the sterilization pressure, temperature, and exposure time in your sterilization records. Since these parameters can be observed during the sterilization cycle, this might be the first indication of a problem.

Chemical monitoring uses sensitive chemicals that change color when exposed to high temperatures or combinations of time and temperature. Examples include chemical indicator tapes, strips or tabs, and special markings on packaging materials. Chemical monitoring results are obtained immediately following the sterilization cycle and therefore can provide more timely information about the sterilization cycle than a spore test. A chemical indicator should be used inside every package to verify that the sterilizing agent (e.g., steam) has penetrated the package and reached the instruments inside. If the internal chemical indicator is not visible from the outside of the package, an external indicator should also be used. External indicators can be inspected immediately when removing packages from the sterilizer. If the appropriate color change did not occur, do not use the instruments. Chemical indicators also help to differentiate between processed and unprocessed items, eliminating the possibility of using instruments that have not been sterilized.

> **Note:** A single-parameter internal chemical indicator provides information regarding only one sterilization parameter (e.g., time or temperature). Multiparameter internal chemical indicators are designed to react to ≥ 2 parameters (e.g., time and temperature; or time, temperature, and the presence of steam) and can provide a more reliable indication that sterilization conditions have been met.

Sterilization monitoring (e.g., biological, mechanical, chemical monitoring) and equipment maintenance records are an important component of a dental infection prevention program. Maintaining accurate records ensures cycle parameters have been met and establishes accountability. In addition, if there is a problem with a sterilizer (e.g., unchanged chemical indicator, positive spore test), documentation helps to determine if an instrument recall is necessary.

Ideally, sterile instruments and supplies should be stored in covered or closed cabinets. Wrapped packages of sterilized instruments should be inspected before opening and use to ensure the packaging material has not been compromised (e.g., wet, torn, punctured) during storage. The contents of any compromised packs should be reprocessed (i.e., cleaned, packaged, and heat-sterilized again) before use on a patient.

Recommendations for the cleaning, disinfection, and sterilization of dental equipment can be found in the *Guidelines for Infection Control in Dental*

Health-Care Settings—2003 (available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf). Recommendations for the cleaning, disinfection, and sterilization of medical equipment are available in the *Guideline for Disinfection and Sterilization in Healthcare Facilities* (available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf). FDA regulations on reprocessing of single-use devices are available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.

Key Recommendations for STERILIZATION AND DISINFECTION OF PATIENT-CARE DEVICES for Dental Settings

1. Clean and reprocess (disinfect or sterilize) reusable dental equipment appropriately before use on another patient.
2. Clean and reprocess reusable dental equipment according to manufacturer instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.
   a. Have manufacturer instructions for reprocessing reusable dental instruments/equipment readily available, ideally in or near the reprocessing area.
3. Assign responsibilities for reprocessing of dental equipment to DHCP with appropriate training.
4. Wear appropriate PPE when handling and reprocessing contaminated patient equipment.
5. Use mechanical, chemical, and biological monitors according to manufacturer instructions to ensure the effectiveness of the sterilization process. Maintain sterilization records in accordance with state and local regulations.

Environmental Infection Prevention and Control

Policies and procedures for routine cleaning and disinfection of environmental surfaces should be included as part of the infection prevention plan. Cleaning removes large numbers of microorganisms from surfaces and should always precede disinfection. Disinfection is generally a less lethal process of microbial inactivation (compared with sterilization) that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Emphasis for cleaning and disinfection should be placed on surfaces that are most likely to become contaminated with pathogens, including clinical contact surfaces (e.g., frequently touched surfaces such as light handles, bracket trays, switches on dental units, computer equipment) in the patient-care area. When these surfaces are touched, microorganisms can be transferred to other surfaces, instruments or to the nose, mouth, or eyes of DHCP or patients. Although hand hygiene is the key to minimizing the spread of microorganisms, clinical contact surfaces should be barrier protected or cleaned and disinfected between patients. EPA-registered hospital disinfectants or detergents/disinfectants with label claims for use in health care settings should be used for disinfection. Disinfectant products should not be used as cleaners unless the label indicates the product is suitable for such use. DHCP should follow manufacturer recommendations for use of products selected for cleaning and disinfection (e.g., amount, dilution, contact time, safe use, and disposal). Facility policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials. Housekeeping surfaces, (e.g., floors, walls, sinks) carry less risk of disease transmission than clinical contact

surfaces and can be cleaned with soap and water or cleaned and disinfected if visibly contaminated with blood.

Additional guidance for the cleaning and disinfection of environmental surfaces—including for cleaning blood or body substance spills—is available in the *Guidelines for Environmental Infection Control in Health-Care Facilities* (available at: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf) and the *Guideline for Disinfection and Sterilization in Healthcare Facilities* (available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf).

Key Recommendations for ENVIRONMENTAL INFECTION PREVENTION AND CONTROL in Dental Settings

1. Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in dental health care settings.
   a. Use surface barriers to protect clinical contact surfaces, particularly those that are difficult to clean (e.g., switches on dental chairs, computer equipment) and change surface barriers between patients.
   b. Clean and disinfect clinical contact surfaces that are not barrier-protected with an EPA-registered hospital disinfectant after each patient. Use an intermediate-level disinfectant (i.e., tuberculocidal claim) if visibly contaminated with blood.
2. Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in health care settings.
3. Follow manufacturer instructions for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal).

Dental Unit Water Quality

Dental unit waterlines (i.e., plastic tubing that carries water to the high-speed handpiece, air/water syringe, and ultrasonic scaler) promote bacterial growth and development of biofilm due to the presence of long narrow-bore tubing, inconsistent flow rates, and the potential for retraction of oral fluids. Dental health care personnel and patients could be placed at risk of adverse health effects if water is not appropriately treated.

All dental units should use systems that treat water to meet drinking water standards (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria). Independent reservoirs—or water-bottle systems—alone are not sufficient. Commercial products and devices are available that can improve the quality of water used in dental treatment. Consult with the dental unit manufacturer for appropriate water maintenance methods and recommendations for monitoring dental water quality. During surgical procedures,[1] use only sterile solutions as a coolant/irrigant using an appropriate delivery device, such as a sterile bulb syringe, sterile tubing that bypasses dental unit waterlines, or sterile single-use devices.

Guidance on dental unit water quality can be found in the *Guidelines for Infection Control in Dental Health-Care Settings—2003* (available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf), and the CDC Boil-Water Advisories and the Dental Office Fact Sheet (available at: http://www.cdc.gov/oralhealth/infectioncontrol/faq/dentalunitwaterquality.htm).

Key Recommendations for DENTAL UNIT WATER QUALITY in Dental Settings

1. Use water that meets EPA regulatory standards for drinking water (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria) for routine dental treatment output water.
2. Consult with the dental unit manufacturer for appropriate methods and equipment to maintain the quality of dental water.
3. Follow recommendations for monitoring water quality provided by the manufacturer of the unit or waterline treatment product.
4. Use sterile saline or sterile water as a coolant/irrigant when performing surgical procedures.

Risk Assessment

Facilities are encouraged to use the Infection Prevention Checklist for Dental Settings (Appendix A)—a companion to the summary guide—to periodically assess practices in their facility and ensure they are meeting the minimum expectations for safe care. In the course of auditing practices, facilities may identify lapses in infection control. If such lapses are identified, efforts should be made to correct the practices, appropriately educate DHCP (if applicable), and determine why the correct practice was not being performed. In addition, consideration should also be made for determining the risk posed to patients by the deficient practices. Certain infection control lapses (e.g., reuse of syringes on more than one patient or to access a medication container that is used for subsequent patients, reuse of lancets) have resulted in bloodborne pathogen transmission and should be halted immediately. Identification of such lapses warrants immediate consultation with the state or local health department and appropriate notification and testing of potentially affected patients. Additional resources describing approaches to evaluation and management of infection control breaches identified in health care settings—including those involving lapses related to reprocessing of medical devices—can be found in CDC's Steps for Evaluating an Infection Control Breach (available at: http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html). In addition, for circumstances warranting patient notification, CDC has developed a Patient Notification Toolkit (available at: http://www. cdc.gov/injectionsafety/pntoolkit/index.html) to assist health care facilities with conducting a patient notification.

Conclusions

The information presented in this document represents basic infection prevention expectations for safe care in dental health care settings. This guidance is not all-encompassing. DHCP and others are encouraged to refer to the original source documents, which provide more detailed guidance and references for the information included in this guide. DHCP are also encouraged to visit the main CDC Web page (www.cdc.gov) for the most current infection prevention information about emerging pathogens and updated information about existing recommendations.

Source Documents

Dental Infection Prevention Guidelines

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

General Infection Prevention Guidelines

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Guideline for Hand Hygiene in Health-Care Settings, 2002
www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

Guideline for Infection Control in Healthcare Personnel, 1998
www.cdc.gov/hicpac/pdf/InfectControl98.pdf

Guidelines for Environmental Infection Control in Health-Care Facilities, 2003
www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005
www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization, 2011
www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006
www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf

Key Links for Additional Information

CDC Division of Oral Health
www.cdc.gov/oralhealth

CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines for Prevention of Healthcare Associated Infections
www.cdc.gov/hicpac/pubs.html

CDC Web site on Hand Hygiene
www.cdc.gov/handwashing

CDC Web site on Influenza
www.cdc.gov/flu

CDC Web site on Injection Safety
www.cdc.gov/injectionsafety

Appendix A

Infection Prevention Checklist for Dental Settings: Basic Expectations for Safe Care

The following is a companion to the *Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care*. The checklist should be used—

1. To ensure the dental health care setting has appropriate infection prevention policies and practices in place, including appropriate training and education of dental health care personnel (DHCP) on infection prevention practices, and adequate supplies to allow DHCP to provide safe care and a safe working environment.
2. To systematically assess personnel compliance with the expected infection prevention practices and to provide feedback to DHCP regarding performance. Assessment of compliance should be conducted by direct observation of DHCP during the performance of their duties.

DHCP using this checklist should identify all procedures performed in their setting and refer to appropriate sections of this checklist to conduct their evaluation. Certain sections may not apply (e.g., some settings may not perform surgical procedures or use medications in vials, such as for conscious sedation). If the answer to any of the applicable listed questions is no, efforts should be made to determine why the correct practice was not being performed, correct the practice, educate DHCP (if applicable), and reassess the practice to ensure compliance. Consideration should also be made to determine the risk posed to patients by the deficient practice. Certain infection prevention and control lapses (e.g., re-use of syringes on more than one patient, sterilization failures) can result in bloodborne pathogen transmission and measures to address the lapses should be taken immediately. Identification of such lapses may warrant immediate consultation with the state or local health department and appropriate notification and testing of potentially affected patients.

Section I lists administrative policies and dental setting practices that should be included in the site-specific written infection prevention and control program with supportive documentation. Section II describes personnel compliance with infection prevention and control practices that fulfill the expectations for dental health care settings. This checklist can serve as an evaluation tool to monitor DHCP compliance with the CDC's recommendations and provide an assurance of quality control.

Infection Prevention Checklist

Section I: Policies and Practices

I.1 Administrative Measures

Facility name:.....

Completed by:.....

Date:.....

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written infection prevention policies and procedures specific for the dental setting are available, current, and based on evidence-based guidelines (e.g., CDC/Healthcare Infection Control Practices Advisory Committee [HICPAC]), regulations, or standards **Note:** *Policies and procedures should be appropriate for the services provided by the dental setting and should extend beyond the Occupational Safety and Health Administration (OSHA) bloodborne pathogens training.*	❑ Yes ❑ No	
B. Infection prevention policies and procedures are reassessed at least annually or according to state or federal requirements, and updated if appropriate **Note:** *This may be performed during the required annual review of the dental setting's OSHA Exposure Control Plan.*	❑ Yes ❑ No	
C. At least one individual trained in infection prevention is assigned responsibility for coordinating the program	❑ Yes ❑ No	
D. Supplies necessary for adherence to Standard Precautions are readily available **Note:** *This includes, but is not limited to hand hygiene products, safer devices to reduce percutaneous injuries, and personal protective equipment (PPE).*	❑ Yes ❑ No	
E. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter **Note:** *System may include taking a travel and occupational history, as appropriate, and elements described under respiratory hygiene/cough etiquette.*	❑ Yes ❑ No	

I.2 Infection Prevention Education and Training

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. DHCP receive job or task-specific training on infection prevention policies and procedures and the OSHA bloodborne pathogens standard—		
a. upon hire	❑ Yes ❑ No	
b. annually	❑ Yes ❑ No	
c. when new tasks or procedures affect the employee's occupational exposure	❑ Yes ❑ No	
d. according to state or federal requirements	❑ Yes ❑ No	
Note: *This includes those employed by outside agencies and available by contract or on a volunteer basis to the dental setting.*		
B. Training records are maintained in accordance with state and federal requirements	❑ Yes ❑ No	

I.3 Dental Health Care Personnel Safety

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Facility has an exposure control plan that is tailored to the specific requirements of the facility (e.g., addresses potential hazards posed by specific services provided by the facility)	❑ Yes ❑ No	
Note: *A model template that includes a guide for creating an exposure control plan that meets the requirements of the OSHA Bloodborne Pathogens Standard is available at: https://www.osha.gov/Publications/osha3186.pdf.*		
B. DHCP for whom contact with blood or OPIM is anticipated are trained on the OSHA Bloodborne Pathogens Standard:		
a. upon hire	❑ Yes ❑ No	
b. at least annually	❑ Yes ❑ No	
C. Current CDC recommendations for immunizations, evaluation, and follow-up are available. There is a written policy regarding immunizing DHCP, including a list of all required and recommended immunizations for DHCP (e.g., hepatitis B, MMR (measles , mumps, rubella), varicella (chickenpox), Tdap (tetanus, diphtheria, pertussis)	❑ Yes ❑ No	

CONTINUED

I.3 Dental Health Care Personnel Safety

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
D. Hepatitis B vaccination is available at no cost to all employees who are at risk of occupational exposure to blood or other potentially infectious material (OPIM)	❑ Yes ❑ No	
E. Post-vaccination screening for protective levels of hepatitis B surface antibody is conducted 1-2 months after completion of the 3-dose vaccination series	❑ Yes ❑ No	
F. All DHCP are offered annual influenza vaccination **Note:** *Providing the vaccination at no cost is a strategy that may increase use of this preventive service.*	❑ Yes ❑ No	
G. All DHCP receive baseline tuberculosis (TB) screening upon hire regardless of the risk classification of the setting	❑ Yes ❑ No	
H. A log of needlesticks, sharps injuries, and other employee exposure events is maintained according to state or federal requirements	❑ Yes ❑ No	
I. Referral arrangements are in place to qualified health care professionals (e.g., occupational health program of a hospital, educational institutions, health care facilities that offer personnel health services) to ensure prompt and appropriate provision of preventive services, occupationally-related medical services, and postexposure management with medical follow-up	❑ Yes ❑ No	
J. Following an occupational exposure event, postexposure evaluation and follow-up, including prophylaxis as appropriate, are available at no cost to employee and are supervised by a qualified health care professional	❑ Yes ❑ No	
K. Facility has well-defined policies concerning contact of personnel with patients when personnel have potentially transmissible conditions. These policies include—		
a. work-exclusion policies that encourage reporting of illnesses and do not penalize staff with loss of wages, benefits, or job status	❑ Yes ❑ No	
b. education of personnel on the importance of prompt reporting of illness to supervisor	❑ Yes ❑ No	

I.4 Program Evaluation

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written policies and procedures for routine monitoring and evaluation of the infection prevention and control program are available	❑ Yes ❑ No	
B. Adherence with certain practices such as immunizations, hand hygiene, sterilization monitoring, and proper use of PPE is monitored and feedback is provided to DHCP	❑ Yes ❑ No	

I.5 Hand Hygiene

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Supplies necessary for adherence to hand hygiene for routine dental procedures (e.g., soap, water, paper towels, alcohol-based hand rub) are readily accessible to DHCP	❑ Yes ❑ No	
a. if surgical procedures are performed, appropriate supplies are available for surgical hand scrub technique (e.g., antimicrobial soap, alcohol-based hand scrub with persistent activity) **Note:** *Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.*	❑ Yes ❑ No	
B. DHCP are trained regarding appropriate indications for hand hygiene including handwashing, hand antisepsis, and surgical hand antisepsis **Note:** *Use soap and water when hands are visibly soiled (e.g., blood, body fluids). Alcohol-based hand rub may be used in all other situations.*	❑ Yes ❑ No	

I.6 Personal Protective Equipment (PPE)

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Sufficient and appropriate PPE is available (e.g., examination gloves, surgical face masks, protective clothing, protective eyewear/face shields, utility gloves, sterile surgeon's gloves for surgical procedures) and readily accessible to DHCP	❑ Yes ❑ No	
B. DHCP receive training on proper selection and use of PPE	❑ Yes ❑ No	

I.7 Respiratory Hygiene/Cough Etiquette

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Policies and procedures to contain respiratory secretions in people who have signs and symptoms of a respiratory infection, beginning at point of entry to the dental setting have been implemented. Measures include—		
a. posting signs at entrances (with instructions to patients with symptoms of respiratory infection to cover their mouths/noses when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after hands have been in contact with respiratory secretions)	❑ Yes ❑ No	
b. providing tissues and no-touch receptacles for disposal of tissues	❑ Yes ❑ No	
c. providing resources for patients to perform hand hygiene in or near waiting areas	❑ Yes ❑ No	
d. offering face masks to coughing patients and other symptomatic persons when they enter the setting	❑ Yes ❑ No	
e. providing space and encouraging persons with respiratory symptoms to sit as far away from others as possible—if possible, a separate waiting area is ideal	❑ Yes ❑ No	
B. DHCP receive training on the importance of containing respiratory secretions in people who have signs and symptoms of a respiratory infection	❑ Yes ❑ No	

I.8 Sharps Safety

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written policies, procedures, and guidelines for exposure prevention and postexposure management are available	❑ Yes ❑ No	
B. DHCP identify, evaluate, and select devices with engineered safety features (e.g., safer anesthetic syringes, blunt suture needle, safety scalpels, or needleless IV systems)—		
a. at least annually	❑ Yes ❑ No	
b. as they become available in the market	❑ Yes ❑ No	
Note: *If staff inquire about the availability of new safety devices or safer options and find none are available, DHCP can document these findings in their office exposure control plan.*		

I.9 Safe Injection Practices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written policies, procedures, and guidelines for safe injection practices (e.g., aseptic technique for parenteral medications) are available	❑ Yes ❑ No	
B. Injections are required to be prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment	❑ Yes ❑ No	

I.10 Sterilization and Disinfection of Patient-Care Items and Devices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written policies and procedures are available to ensure reusable patient care instruments and devices are cleaned and reprocessed appropriately before use on another patient	❑ Yes ❑ No	
B. Policies, procedures, and manufacturer reprocessing instructions for reusable instruments and dental devices are available, ideally in or near the reprocessing areas	❑ Yes ❑ No	
C. DHCP responsible for reprocessing reusable dental instruments and devices are appropriately trained—		
a. upon hire	❑ Yes ❑ No	
b. at least annually	❑ Yes ❑ No	
c. whenever new equipment or processes are introduced	❑ Yes ❑ No	
D. Training and equipment are available to ensure that DHCP wear appropriate PPE (e.g., examination or heavy duty utility gloves, protective clothing, masks, eye protection) to prevent exposure to infectious agents or chemicals **Note:** *The exact type of PPE depends on infectious or chemical agent and anticipated type of exposure.*	❑ Yes ❑ No	
E. Routine maintenance for sterilization equipment is—		
a. performed according to manufacturer instructions	❑ Yes ❑ No	
b. documented by written maintenance records	❑ Yes ❑ No	

CONTINUED

I.10 Sterilization and Disinfection of Patient-Care Items and Devices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
F. Policies and procedures are in place outlining dental setting response (e.g., recall of device, risk assessment) in the event of a reprocessing error/failure	❑ Yes ❑ No	

I.11 Environmental Infection Prevention and Control

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Written policies and procedures are available for routine cleaning and disinfection of environmental surfaces (i.e., clinical contact and housekeeping)	❑ Yes ❑ No	
B. DHCP performing environmental infection prevention procedures receive job-specific training about infection prevention and control management of clinical contact and housekeeping surfaces—		
a. upon hire	❑ Yes ❑ No	
b. when procedures/policies change	❑ Yes ❑ No	
c. at least annually	❑ Yes ❑ No	
C. Training and equipment are available to ensure that DHCP wear appropriate PPE (e.g., examination or heavy duty utility gloves, protective clothing, masks, and eye protection) to prevent exposure to infectious agents or chemicals	❑ Yes ❑ No	
D. Cleaning, disinfection, and use of surface barriers are periodically monitored and evaluated to ensure that they are consistently and correctly performed	❑ Yes ❑ No	
E. Procedures are in place for decontamination of spills of blood or other body fluids	❑ Yes ❑ No	

I.12 Dental Unit Water Quality

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Policies and procedures are in place for maintaining dental unit water quality that meets Environmental Protection Agency (EPA) regulatory standards for drinking water (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria) for routine dental treatment output water	❑ Yes ❑ No	
B: Policies and procedures are in place for using sterile water as a coolant/irrigant when performing surgical procedures **Note:** *Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.*	❑ Yes ❑ No	
C. Written policies and procedures are available outlining response to a community boil-water advisory	❑ Yes ❑ No	

Infection Prevention Checklist

Section II: Direct Observation of Personnel and Patient-Care Practices

Facility name: .....

Completed by: .....

Date: .....

II.1 Hand Hygiene is Performed Correctly

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. When hands are visibly soiled	❑ Yes ❑ No	
B. After barehanded touching of instruments, equipment, materials and other objects likely to be contaminated by blood, saliva, or respiratory secretions	❑ Yes ❑ No	
C. Before and after treating each patient	❑ Yes ❑ No	
D. Before putting on gloves	❑ Yes ❑ No	
E. Immediately after removing gloves	❑ Yes ❑ No	
F. Surgical hand scrub is performed before putting on sterile surgeon's gloves for all surgical procedures **Note:** *Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.*	❑ Yes ❑ No	

II.2 Personal Protective Equipment (PPE) is Used Correctly

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. PPE is removed before leaving the work area (e.g., dental patient care, instrument processing, or laboratory areas)	❑ Yes ❑ No	
B. Hand hygiene is performed immediately after removal of PPE	❑ Yes ❑ No	
C. Masks, Protective Eyewear, and Face Shields		
a. DHCP wear surgical masks during procedures that are likely to generate splashes or sprays of blood or other body fluids	❑ Yes ❑ No	
b. DHCP wear eye protection with solid side shields or a face shield during procedures that are likely to generate splashes or sprays of blood or other body fluids	❑ Yes ❑ No	
c. DHCP change masks between patients and during patient treatment if the mask becomes wet	❑ Yes ❑ No	

CONTINUED

II.2 Personal Protective Equipment (PPE) is Used Correctly

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
D. Gloves		
a. DHCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment	❑ Yes ❑ No	
b. DHCP change gloves between patients; do not wear the same pair of gloves for the care of more than one patient	❑ Yes ❑ No	
c. DHCP do not wash examination or sterile surgeon's gloves for the purpose of reuse	❑ Yes ❑ No	
d. DHCP wear puncture- and chemical-resistant utility gloves when cleaning instruments and performing housekeeping tasks involving contact with blood or OPIM	❑ Yes ❑ No	
e. DHCP wear sterile surgeon's gloves for all surgical procedures	❑ Yes ❑ No	
Note: *Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.*		
f. DHCP remove gloves that are torn, cut, or punctured and perform hand hygiene before putting on new gloves	❑ Yes ❑ No	
E. Protective Clothing		
a. DHCP wear protective clothing (e.g., reusable or disposable gown, laboratory coat, or uniform) that covers personal clothing and skin (e.g., forearms) likely to be soiled with blood, saliva, or OPIM	❑ Yes ❑ No	
b. DHCP change protective clothing if visibly soiled and immediately or as soon as possible if penetrated by blood or other potentially infectious fluids	❑ Yes ❑ No	

II.3 Respiratory Hygiene/Cough Etiquette

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Signs are posted at entrances (with instructions to patients with symptoms of respiratory infection to cover their mouths/noses when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after hands have been in contact with respiratory secretions)	❑ Yes ❑ No	

CONTINUED

II.3 Respiratory Hygiene/Cough Etiquette

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
B. Tissues and no-touch receptacles for disposal of tissues are provided	❑ Yes ❑ No	
C. Resources are provided for patients to perform hand hygiene in or near waiting areas	❑ Yes ❑ No	
D. Face masks are offered to coughing patients and other symptomatic persons when they enter the setting	❑ Yes ❑ No	
E. Persons with respiratory symptoms are encouraged to sit as far away from others as possible. If possible, a separate waiting area is ideal	❑ Yes ❑ No	

II.4 Sharps Safety

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Engineering controls (e.g., self-sheathing anesthetic needles, safety scalpels, needleless IV ports) are used to prevent injuries	❑ Yes ❑ No	
B. Work practice controls (e.g., one-handed scoop technique for recapping needles, removing burs before disconnecting handpieces) are used to prevent injuries	❑ Yes ❑ No	
C. DHCP do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body	❑ Yes ❑ No	
D. DHCP use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g., between multiple injections and before removing from a reusable aspirating syringe)	❑ Yes ❑ No	
E. All sharps are disposed of in a puncture-resistant sharps container located as close as possible to the area in which the items are used	❑ Yes ❑ No	
F. Sharps containers are disposed of in accordance with federal, state and local regulated medical waste rules and regulations	❑ Yes ❑ No	

II.5 Safe Injection Practices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Injections are prepared using an aseptic technique in a clean area free from contaminants or contact with blood, body fluids, or contaminated equipment	❑ Yes ❑ No	
B. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and other devices such as insulin pens) **Note:** *When using a dental cartridge syringe to administer local anesthesia, do not use the needle, syringe, or anesthetic cartridge for more than one patient. Ensure that the dental cartridge syringe is appropriately cleaned and heat sterilized before use on another patient.*	❑ Yes ❑ No	
C. The rubber septum on a medication vial is disinfected with alcohol before piercing	❑ Yes ❑ No	
D. Medication containers (single and multidose vials, ampules, and bags) are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient	❑ Yes ❑ No	
E. Single-dose (single-use) vials, ampules, and bags or bottles of intravenous solutions are used for only one patient	❑ Yes ❑ No	
F. Leftover contents of single-dose vials, ampules, and bags of intravenous solutions are not combined for later use	❑ Yes ❑ No	
G. Single-dose vials for parenteral medications are used when possible	❑ Yes ❑ No	

CONTINUED

II.5 Safe Injection Practices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
H. When using multidose medication vials		
a. multidose vials are dedicated to individual patients whenever possible	❑ Yes ❑ No	
b. multidose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., dental operatory) to prevent inadvertent contamination of the vial	❑ Yes ❑ No	
Note: *If a multidose vial enters the immediate patient treatment area it should be dedicated for single-patient use and discarded immediately after use.*		
c. multidose vials are dated when first opened and discarded within 28 days unless the manufacturer specifies a shorter or longer date for that opened vial	❑ Yes ❑ No	
Note: *This is different from the expiration date printed on the vial.*		
I. Fluid infusion and administration sets (i.e., IV bags, tubings, and connections) are used for one patient only and disposed of appropriately	❑ Yes ❑ No	

II.6 Sterilization and Disinfection of Patient-Care Items and Devices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Single-use devices are discarded after one use and not used for more than one patient	❑ Yes ❑ No	
B. Reusable critical and semicritical dental items and devices are cleaned and heat-sterilized according to manufacturer instructions between patient use **Note:** *If the manufacturer does not provide reprocessing instructions, the item or device may not be suitable for multi-patient use.*	❑ Yes ❑ No	
C. Items are thoroughly cleaned according to manufacturer instructions and visually inspected for residual contamination before sterilization	❑ Yes ❑ No	
D. Food and Drug Administration (FDA)-cleared automated cleaning equipment (e.g., ultrasonic cleaner, instrument washer, washer-disinfector) is used to remove debris to improve cleaning effectiveness and decrease worker exposure to blood	❑ Yes ❑ No	
E. Work-practice controls that minimize contact with sharp instruments (e.g., long-handled brush) are used and appropriate PPE is worn (e.g., puncture- and chemical-resistant utility gloves) if manual cleaning is necessary	❑ Yes ❑ No	
F. After cleaning and drying, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, hinged instruments are open, instruments are disassembled if indicated by the manufacturer)	❑ Yes ❑ No	
G. A chemical indicator is used inside each package. If the internal indicator is not visible from the outside, an exterior chemical indicator is also used on the package **Note:** *The chemical indicators may be integrated into the package design.*	❑ Yes ❑ No	
H. Sterile packs are labeled at a minimum with the sterilizer used, the cycle or load number, the date of sterilization, and if applicable an expiration date	❑ Yes ❑ No	

CONTINUED

II.6 Sterilization and Disinfection of Patient-Care Items and Devices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
I. FDA-cleared medical devices for sterilization are used according to manufacturer's instructions	❑ Yes ❑ No	
J. A biologic indicator (i.e., spore test) is used at least weekly and with every load containing implantable items	❑ Yes ❑ No	
K. Logs for each sterilizer cycle are current and include results from each load and comply with state and local regulations	❑ Yes ❑ No	
L. After sterilization, dental devices and instruments are stored so that sterility is not compromised	❑ Yes ❑ No	
M. Sterile packages are inspected for integrity and compromised packages are reprocessed before use	❑ Yes ❑ No	
N. Instrument packs are not used if mechanical (e.g., time, temperature, pressure) or chemical indicators indicate inadequate processing (e.g., color change for chemical indicators)	❑ Yes ❑ No	
O. The instrument processing area has a workflow pattern designed to ensure that devices and instruments clearly flow from high contamination areas to clean/sterile areas (i.e., there is clear separation of contaminated and clean workspaces)	❑ Yes ❑ No	
P. Reusable heat sensitive semicritical items that cannot be replaced by a heat stable or disposable alternative are high-level disinfected according to manufacturer's instructions	❑ Yes ❑ No	
Q. High-level disinfection products are used and maintained according to manufacturer instructions	❑ Yes ❑ No	
R. Dental handpieces (including the low-speed motor) and other devices not permanently attached to air and waterlines are cleaned and heat-sterilized according to manufacturer instructions	❑ Yes ❑ No	

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II.6 Sterilization and Disinfection of Patient-Care Items and Devices

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
S. If digital radiography is used in the dental setting—		
a. FDA-cleared barriers are used to cover the sensor and barriers are changed between patients	❑ Yes ❑ No	
b. after the surface barrier is removed, the sensor is ideally cleaned and heat sterilized or high-level disinfected according to the manufacturer's instructions. If the item cannot tolerate these procedures, then at a minimum, the sensor is cleaned and disinfected with an intermediate-level, EPA-registered hospital disinfectant	❑ Yes ❑ No	
Note: *Consult with manufacturers regarding compatibility of heat sterilization methods and disinfection products.*		

II.7 Environmental Infection Prevention and Control

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Clinical contact surfaces are either barrier-protected or cleaned and disinfected with an EPA-registered hospital disinfectant after each patient. An intermediate-level (i.e., tuberculocidal claim) disinfectant is used if visibly contaminated with blood	❑ Yes ❑ No	
B. Surface barriers are used to protect clinical contact surfaces that are difficult to clean (e.g., switches on dental chairs, computer equipment, connections to hoses) and are changed between patients	❑ Yes ❑ No	
C. Cleaners and disinfectants are used in accordance with manufacturer instructions (e.g., dilution, storage, shelf-life, contact time, PPE)	❑ Yes ❑ No	
D. Regulated medical waste is handled and disposed of according to local, state, and federal regulations	❑ Yes ❑ No	
E. DHCP engaged in environmental cleaning wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection) **Note:** *The correct type of PPE depends on infectious or chemical agent and anticipated type of exposure.*	❑ Yes ❑ No	

II.8 Dental Unit Water Quality

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. Dental unit waterline treatment products/devices are used to ensure water meets EPA regulatory standards for drinking water (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria) for routine dental treatment output water	❑ Yes ❑ No	
B. Product manufacturer instructions (i.e., waterline treatment product, dental unit manufacturer) are followed for monitoring the water quality	❑ Yes ❑ No	
C. Sterile saline or sterile water is used as a coolant/irrigant when performing surgical procedures **Note:** *Use devices specifically designed for delivering sterile irrigating fluids (e.g., sterile bulb syringe, single-use disposable products, and sterilizable tubing).* **Note:** *Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.*	❑ Yes ❑ No	

Appendix B

Relevant Recommendations Published by CDC Since 2003

Administrative Measures

1. Develop and maintain written infection prevention policies and procedures appropriate for the services provided by the facility and based upon evidence-based guidelines, regulations, or standards.
2. Infection prevention policies and procedures are reassessed at least annually or according to state or federal requirements.
3. Assign at least one individual trained in infection prevention responsibility for coordinating the program.
4. Provide supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, safer devices to reduce percutaneous injuries, personal protective equipment).
5. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter.

References

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care

http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html

Infection Prevention Education and Training

1. Maintain training records according to state and federal requirements.

Reference

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Respiratory Hygiene/Cough Etiquette

1. Implement measures to contain respiratory secretions in patients and accompanying individuals who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing throughout the visit.
2. Post signs at entrances with instructions to patients with symptoms of respiratory infection to—
   - Cover their mouths/noses when coughing or sneezing.
   - Use and dispose of tissues.
   - Perform hand hygiene after hands have been in contact with respiratory secretions.
3. Provide tissues and no-touch receptacles for disposal of tissues.
4. Provide resources for performing hand hygiene in or near waiting areas.
5. Offer masks to coughing patients and other symptomatic persons when they enter the dental setting.
6. Provide space and encourage persons with symptoms of respiratory infections to sit as far away from others as possible. If available, facilities may wish to place these patients in a separate area while waiting for care.
7. Educate DHCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens when examining and caring for patients with signs and symptoms of a respiratory infection.

Reference

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Safe Injection Practices

1. Prepare injections using aseptic technique in a clean area.
2. Disinfect the rubber septum on a medication vial with alcohol before piercing.
3. Do not reuse needles or syringes to enter a medication vial or solution, even when obtaining additional doses for the same patient.
4. Do not use single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution for more than one patient.
5. Dedicate multidose vials to a single patient whenever possible.
6. If multidose vials will be used for more than one patient, they should be kept in a centralized medication area and should not enter the immediate patient treatment area to prevent inadvertent contamination.
7. If a multidose vial enters the immediate patient treatment area it should be dedicated for single-patient use and discarded immediately after use.
8. Date multidose vials when first opened and discard within 28 days unless the manufacturer specifies a shorter or longer date for that opened vial.

References

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

CDC: Injection Safety, Information for Providers
www.cdc.gov/injectionsafety/providers.html

Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care

http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html

Sterilization and Disinfection of Patient-Care Items and Devices

1. Have manufacturer instructions for reprocessing reusable dental instruments/equipment readily available, ideally in or near the reprocessing area.
2. Label sterilized items with the sterilizer used, the cycle or load number, the date of sterilization, and (if applicable) the expiration date.
3. Ensure routine maintenance for sterilization equipment is performed according to manufacturer instructions and maintenance records are available.

Reference

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Appendix C

Selected References and Additional Resources by Topic Area

Administrative Measures

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Table 1: Suggested work restrictions for health care personnel infected with or exposed to major infectious diseases in health care settings, in the absence of state and local regulations

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Guideline for Infection Control in Healthcare Personnel, 1998
www.cdc.gov/hicpac/pdf/InfectControl98.pdf

Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis
http://stacks.cdc.gov/view/cdc/20711

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis
www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management
www.cdc.gov/mmwr/PDF/rr/rr6210.pdf

Infection Prevention Education and Training

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Organization for Safety, Asepsis, and Prevention (OSAP) Knowledge Center
http://www.osap.org/?page=KnowledgeCenter

Association for Professionals in Infection Control and Epidemiology (APIC)
Practice Guidance for Infection Prevention
http://apic.org/Professional-Practice/Overview

Dental Health Care Personnel Safety

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Guideline for Infection Control in Healthcare Personnel, 1998
www.cdc.gov/hicpac/pdf/InfectControl98.pdf

Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

Influenza Vaccination of Health-Care Personnel
www.cdc.gov/mmwr/PDF/rr/rr55e209.pdf

Influenza Vaccination Information for Health Care Workers
www.cdc.gov/flu/healthcareworkers.htm

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis *in Health-Care Settings, 2005*
www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens and Needlestick Prevention Standards
www.osha.gov/SLTC/bloodbornepathogens/index.html

Program Evaluation

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf
Table 5: Examples of methods for evaluating infection control programs

Example of an audit tool used by federal surveyors in ambulatory surgical centers (including dental)
www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

Measuring Hand Hygiene Adherence: Overcoming the Challenges
www.cdc.gov/handhygiene/Measurement.html

Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care
www.cdc.gov/oralhealth/infectioncontrol/index.htm
Appendix A: Infection Prevention Checklist for Dental Settings: Basic Expectations for Safe Care

Standard Precautions

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006
www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf

Harte JA. Standard and transmission-based precautions: An update for dentistry. *J Am Dent Assoc.* 141(5):572-581; 2010.

jada.ada.org/article/S0002-8177(14)61533-6/abstract

Hand Hygiene

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf
Table 2: Hand-hygiene methods and indications

Guideline for Hand Hygiene in Health-Care Settings
www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

CDC Hand Hygiene in Healthcare Settings Educational Materials
www.cdc.gov/handhygiene/

Personal Protective Equipment

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Guidance for the Selection and Use of Personal Protective Equipment in Healthcare Settings: Slides and Posters
www.cdc.gov/hai/prevent/ppe.html

Respiratory Hygiene/Cough Etiquette

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

CDC Influenza (Flu) Resources for Health Care Facilities
www.cdc.gov/flu/professionals/infectioncontrol/

CDC Respiratory Hygiene/Cough Etiquette in Healthcare Settings
www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm

Sharps Safety

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program
www.cdc.gov/sharpssafety

CDC Sample Screening and Device Evaluation Forms for Dentistry
www.cdc.gov/OralHealth/infectioncontrol/forms.htm

Safe Injection Practices

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

CDC Injection Safety: Information for Providers—includes a list of frequently asked questions for providers and injection safety training video.
www.cdc.gov/injectionsafety

One and Only Campaign
www.oneandonlycampaign.org

Sterilization and Disinfection of Patient-Care Items and Devices

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Table 4: Infection-control categories of patient-care instruments

Appendix C: Methods for Sterilizing and Disinfecting Patient-Care Items and Environmental Surfaces

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Resources to assist in the event of a reprocessing error/failure

CDC Health Care Associated Infections, Outbreaks and Patient Notifications
www.cdc.gov/hai/outbreaks/outbreak-resources.html

Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in health care settings. *Am J Infect Control.* 2008;36:685–690.

Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol* 2007;28:146—155.

Environmental Infection Prevention and Control

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Guidelines for Environmental Infection Control in Health-Care Facilities
www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

EPA Medical Waste Frequent Questions
www.epa.gov/osw/nonhaz/industrial/medical/mwfaqs.htm

EPA Where You Live—State Medical Waste Programs and Regulations
www.epa.gov/osw/nonhaz/industrial/medical/programs.htm

Dental Unit Water Quality

Guidelines for Infection Control in Dental Health-Care Settings—2003
www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

CDC Boil-Water Advisories and the Dental Office
http://www.cdc.gov/oralhealth/infectioncontrol/faq/dentalunitwaterquality.htm

For more information please contact

Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30329-4027
Telephone: 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov
Web: www.cdc.gov/oralhealth

Publication date: March 2016

CS 258389A

818-012-0040

Infection Control Guidelines

In determining what constitutes unacceptable patient care with respect to infection control, the Board may consider current infection control guidelines such as those of the Centers for Disease Control and Prevention and the American Dental Association. Additionally, licensees must comply with the following requirements:

(1) Disposable gloves shall be worn whenever placing fingers into the mouth of a patient or when handling blood or saliva contaminated instruments or equipment. Appropriate hand hygiene shall be performed prior to gloving.

(2) Masks and protective eyewear or chin-length shields shall be worn by licensees and other dental care workers when spattering of blood or other body fluids is likely.

(3) Between each patient use, instruments or other equipment that come in contact with body fluids shall be sterilized.

(4) Heat sterilizing devices shall be tested for proper function by means of a biological monitoring system that indicates micro-organisms kill each calendar week in which scheduled patients are treated. Testing results shall be retained by the licensee for the current calendar year and the two preceding calendar years.

(5) Environmental surfaces that are contaminated by blood or saliva shall be disinfected with a chemical germicide which is mycobactericidal at use.

(6) Impervious backed paper, aluminum foil, or plastic wrap may be used to cover surfaces that may be contaminated by blood or saliva and are difficult or impossible to disinfect. The cover shall be replaced between patients.

(7) All contaminated wastes and sharps shall be disposed of according to any governmental requirements.

Stat. Auth.: ORS 679.120, 679.250(7), 680.075 & 680.150
Stats. Implemented: ORS 679.140, 679.140(4) & 680.100
Hist.: DE 1-1988, f. 12-28-88, cert. ef. 2-1-89; DE 1-1989, f. 1-27-89, cert. ef. 2-1-89; DE 2-1992, f. & cert. ef. 6-24-92; OBD 1-2004, f. 5-27-04, cert. ef. 6-1-04; OBD 1-2008, f. 11-10-08, cert. ef. 12-1-08; OBD 3-2013, f. 10-24-13, cert. ef. 1-1-14; OBD 1-2014, f. 7-2-14, cert. ef. 8-1-14

Tab 7. Request a letter be sent to WREB approving Kathleen Herzog, R.D.H. to become WREB Examiner

Pursuant to WREB's requirements licensees who wish to become a WREB Examiner must be approved by the State Board in which they practice. Ms. Kathleen Herzog (Attachment 1) is requesting the Board approve her to become WREB Examiner.

For All Other Practicing, Non-Educator Dentists and Dental Hygienists:
1) Provide a current CV
2) Provide 2 professional letters of recommendation including one letter from a current WREB examiner
3) Be approved by the State Board in which they practice.
4) Must observe one WREB exam at own expense, with prior approval of the WREB office. Observation includes participating in a full calibration day as well as one clinical day of the exam.
5) Be a licensed practitioner and actively practicing for 5 years in the state that is approving them.

Dental Hygiene Educators:
1) Receive a letter of approval as an examiner from the State Board in the state where they teach and a recommendation from the Director or Program Chair of the school where they teach

OR
2) Have served on a WREB Committee and receive a recommendation from the Director or Program Chair at the School where they teach.

AND
3) Must observe one WREB exam at their expense, with prior approval of the WREB office. Observation includes participating in a full calibration day as well as one clinical day of the exam.

WREB does not guarantee that all designated examiners will be assigned to examine. WREB will create teams in the manner that provides the most equitable balance among the key factors considered in the examination assignment process.

Probationary Period
All examiners are considered to be probationary for the first year that they examine and may be dismissed at any time without cause and at the discretion of WREB. Examiners will be notified if issues arise that will cause WREB to discontinue using their services, such as failure to be prepared, follow WREB criteria, or meet the minimum commitment for attendance at exams.

RECEIVED
MAY 16 2016
Oregon Board
of Dentistry

Kathleen Herzog
3625 NW 181st Pl.
Portland, OR 97229
(971)506-0929

Oregon Board of Dentistry
1500 SW 1st Ave., Ste. # 770
Portland, OR 97201

Please consider letter is a formal request to be reviewed and considered for recommendation to WREB.

My clinical years of practice include experience in private practice and community based health settings. I have a strong foundation of our profession and would like to be part of a team that helps calibrate our future professionals.

My strengths include working well within a team setting, organizing and implementing rules, following procedures and critiquing details that effect patient care and flow.

Since August of 2015 I have been working with Virginia Garcia. During my employment I have worked within a team to evaluate and establish protocols for their school sealant program and school based health centers.

My background also includes working closely with Pacific University's students at Virginia Garcia and have had past experience as a clinical instructor for Pacific's senior clinic setting.

I look forward to your consideration and review.

Please feel free to contact me with any additional questions or requests.

Thank you for your time,

Kathleen Herzog, RDH
H5492

KATHLEEN HERZOG, RDH

3625 North West 181st Place, Portland, OR 97229 | | C: (971)506-0929 kachirdon@hotmail.com

Professional Summary

As a clinician I have a passion for dental hygiene that includes accurate and efficient patient care. I place a strong emphasis on individualized patient assessment, appropriate treatment planning, patient/research based education and proper treatment implementation.

Comprehensive clinical background including direct patient care, supervision of hygiene students in clinical a setting and program evaluation/construction/implementation.

Certifications and Licenses

State of Oregon - September 2008-2016
Local Anesthesia, Nitrous Oxide 2008-2016
Expanded Practice Permit 2013-2016
CPR - February 2015-2017

Skill Highlights

Advanced treatment planning with team setting, Scaling and root planning, sealants, caries control, digital radiographs/intra oral photography, pain control/working with anxious patients and holistic health management.

Professional Experience

Virginia Garcia Memorial Health Center, Dr. Lisa Bozzetti
August 2015- Present

Portsmouth Dental Care, Dr. James Frohnmayer
March 2009 to August 2015

Kirkland Dentistry, Dr. Bill Kirkland
May 2011 to Jan 2012

Pacific University
August 2009 to July 2010

Dr. Jill Price & Associates
September 2008-December 2008

Education and Training

Bachelor of Science, Dental Health Science
Pacific University - Forest Grove, OR 2008

Bachelor of Science, General Science/ Minor Biology
Portland State University - Portland, OR 2006

Associate of Science
Portland Community College - Portland, OR 2004

References

Dr. Lisa Bozzetti, DDS
(909)496-4358

Dr. Bill Kirkland, DDS
(503)533-8383

Gail Aamodt, Assistant Professor & Clinical Education Coordinator, Pacific University
(503)352-7242

Stephanie Brown, RDH
(951)813-0110

Letters of recommendation available upon request

Public Health Division
Office of the State Public Health Director
Kate Brown, Governor

Oregon Health Authority

800 NE Oregon St
Portland, OR 97232
Voice 971-673-1222
FAX 971-673-1299
TTY 711
healthoregon.org/opioids

May 9, 2016

Stephen Prisby
Executive Director, Oregon Board of Dentistry

Dear Mr. Prisby,

I would like to invite you as a representative of the Oregon Board of Dentistry to become a member of a task force to develop statewide opioid prescribing guidelines. These guidelines will support Oregon's initiative to address the epidemic of opioid use, misuse, and overdose by optimizing care, improving patient safety, and providing a consistent framework for endorsement and implementation at the local level.

Your service will help ensure that decisions and recommendations are based on the best and most current science and best practices.

Specific areas that the Oregon Opioid Prescribing Guidelines Task Force will address include:

1. Recommendations for clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
2. Recommendations for adopting guidelines with specific patient populations, including legacy patients and other high MED patients
3. Dissemination and communication planning
4. Implementation across various providers and settings

The task force will build on the CDC Guideline for Prescribing Opioids for Chronic Pain to develop statewide opioid prescribing guidelines, with an initial focus on recommendations for clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

Membership and Time Commitment
Task Force members represent a variety of organizational stakeholders from around the state, including relevant boards and associations, providers, payers, advocacy organizations and others.

The task force will next convene on June 3, 2016, from 9:00am to 12:00pm, in room 1-B at 800 NE Oregon Street, 97232. Subsequent meetings will occur once a month for 6-9 months until the guidelines are launched, with each meeting lasting approximately three hours. The meetings will be held in person in Portland, with travel reimbursement provided. All meetings will be open to the public and will include time for public comment.

We very much appreciate your potential willingness to serve on the Oregon Opioid Prescribing Guidelines Task Force. I will be happy to answer any questions you might have regarding this task force; you can contact me by phone (971-673-1050) or email (katrina.hedberg@state.or.us).

Sincerely,

Katrina Hedberg, MD, MPH
Health Officer & State Epidemiologist
Oregon Public Health Division
800 NE Oregon St., Suite 930
Portland, Oregon 97232

Last updated: May 9, 2016

Charter: Oregon Opioid Prescribing Guidelines Task Force

Purpose and Background

In Oregon and across the nation, there has been a dramatic increase in overdose deaths and hospitalizations due to prescription opioid pain medications. Since 2000, a steep increase in prescribing opioids for pain has paralleled this increase in deaths and hospitalizations.

This charter establishes the Oregon Opioid Prescribing Guidelines Task Force. The task force will build on the CDC Guideline for Prescribing Opioids for Chronic Pain to develop statewide opioid prescribing guidelines, with an initial focus on recommendations for clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

This effort will support Oregon's initiative to address the epidemic of opioid use, misuse, and overdose by optimizing care, improving patient safety, and providing a consistent framework for endorsement and implementation at the local level.

Task Force end date: 11/30/2016

Scope

Specific areas that the Oregon Opioid Guidelines Task Force will address include:

1. Recommendations for clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
2. Recommendations for adopting guidelines with specific patient populations, including legacy patients and other high MED patients
3. Dissemination and communication planning
4. Implementation across various providers and settings

Authority

The Oregon Health Authority, Public Health Division's mission is "Promoting health and preventing the leading causes of death, disease and injury in Oregon." Working to reduce deaths, hospitalizations, and emergency department visits related to drug overdose is in alignment with this mission.

Membership/ Decision-making

The Opioid Prescribing Guidelines Task Force will include members representing the following organizations/ agencies:

Executive sponsors

OHA Public Health Division State Epidemiologist and State Health Officer: Katrina Hedberg, MD, MPH
OHA Chief Medical Officer: Jim Rickards, MD

Members

American College of Emergency Medicine, Oregon Chapter: Michael Henstrom, MD, FACEP
American College of Physicians - Oregon Chapter: Thomas Cooney, MD, MACP
American Society of Addiction Medicine, Oregon Chapter: Karen Weisman, MD

Co-author, CDC Guideline for Prescribing Opioids for Chronic Pain: Roger Chou, MD
Co-author, OHSU Guideline for Safe Chronic Opioid Therapy Prescribing for Patients with Chronic Non-Cancer Pain: Melissa Weimer, DO, MCR
Federally Qualified Health Center, Central City Concern: Rachel Solotaroff, MD
Federally Qualified Health Center, Clackamas Health Centers: Andrew Suchocki, MD, MPH
Local Public Health Authority, Jackson County: Jim Shames, MD
Local Public Health Authority, Multnomah County: Paul Lewis, MD, MPH
Medical Directors, Coordinated Care Organizations: David Labby, MD
Medical Directors, Coordinated Care Organizations: Kevin Ewanchyna, MD
Medical Directors, Coordinated Care Organizations: Anna Stern, MD
Oregon Academy of Family Physicians: Glenn Rodriguez, MD
Oregon Association of Hospitals and Health Systems: Barbara Wade, MS, BSN, RN, CPHQ
Oregon Association of Hospitals and Health Systems: Lee Milligan, MD
Oregon Association of Hospitals and Health Systems: Tim Herrmann, RN
Oregon Board of Dentistry: *TBD*
Oregon Board of Pharmacy: Marcus Watt, RPh
Oregon Coalition for Responsible Use of Medications (OrCRM): Dwight Holton, JD
Oregon Dental Association: *TBD*
Oregon Health Leadership Council: Susan Kirchoff, MBA
Oregon Medical Association: Andris Antoniskis, MD
Oregon Medical Board: Joe Thaler, MD
Oregon Nurses Association: Larlene Dunsmuir, DNP, FNP, ANP-C
Oregon Oral Health Coalition: Gary Allen, DMD, MS
Oregon Pain Management Commission: Catriona Buist, PsyD
Oregon Primary Care Association: Irma Murauskas, MPH
Oregon State Pharmacy Association: Joshua Free, PharmD, MBA
Oregon Workers' Compensation Division: *TBD*
Pharmacy Directors, Coordinated Care Organizations: Caryn Mickelson, PharmD
Portland Area Indian Health Service (IHS): Thomas Weiser, MD
Portland VA Medical Center: Steven Dobscha, MD
Regional opioids task force, Central Oregon Pain Standards Task Force: Kim Swanson, PhD
Regional opioids task force, Portland Tri-County Prescription Opioid Safety Coalition: Amit Shah, MD

Decision-making will be by consensus when possible. If consensus cannot be reached, a vote of members will be taken and the results will be recorded, along with statements of concurrence or disagreement if necessary.

Deliverables/Outputs – Reports/Metrics

Task Force discussions and recommendations will be documented in meeting minutes. The task force will produce a summary document of the Oregon Opioid Prescribing Guidelines, with specific recommendations for providers.

Meeting/Meeting Support

Oregon Health Authority employees will staff this Task Force. Meetings will adhere to public meeting policies and procedures. Meeting materials (agendas, minutes) will be available at the OHA opioids website: healthoregon.org/opioids

Dear Oregon Prescribing Guidelines Task Force,
As promised, here is the revised Motion that was passed at today's meeting (June 3, 2016). Please use this language for your respective organizations to endorse. Let me know if you have any questions, and we look forward to hearing back from those of you who are holding your vote.

The Oregon Opioid Prescribing Guidelines Task Force adopts the *CDC Guideline for Prescribing Opioids for Chronic Pain* as the foundation for opioid prescribing for Oregon. The Task Force further encourages more discussion at state, regional and organizational levels regarding how the guidelines will be disseminated, communicated to patients and providers, and implemented.

Thanks,
Lisa

Lisa Shields
Injury Prevention Program Coordinator
Public Health Division
healthoregon.org/opioids
healthoregon.org/fallprevention
lisa.m.shields@state.or.us
971-673-1036

Acute Pain Flow Sheet

FOR THE EVALUATION AND TREATMENT OF ACUTE PAIN

Begin

ASSESSMENT

- Patient presents after an acute injury (trauma, surgical procedure).
- Evaluate the clinical situation and determine your expected recovery time based on clinical evaluation, literature, your experience, and the patient's general condition.
- Educate the patient regarding expectations for healing and duration and intensity of pain. Some pain is to be expected, and it will diminish over time.

Green Light

NON-OPIOID OPTIONS

- Advise appropriate behavioral modifications, for example, initial rest followed by graded exercise of the affected body area.
- Provide external pain-reducing modalities, for example, immobilization, heat/cold, and elevation.
- Advise appropriate OTC medications with specific medications, doses, and duration, as you would any pharmacologic modality.

Caution

OPIOID TREATMENT

- If considering opioids, first ask about risks for opioid misuse, for example, previous addiction history, overdose history, and suicidality.
- If opioids are contraindicated, clearly state to the patient and document in the chart note that the risks of treatment overshadow the benefits. Stress other modalities of pain modification.
- When prescribing opioids, use the lowest possible dose for the shortest amount of time. Most acute painful situations will resolve themselves in three to seven days. In most cases, three days of opioids will be sufficient.

Stop!

STOP AND REASSESS

- If the patient asks for additional opioids, and you have prescribed the amount that in your professional judgment should have sufficed, have the patient return for an evaluation. At that follow up visit, you or your staff should:
  - Be sure there is no unforeseen complication requiring further testing or treatment.
  - Be sure there is no evidence of substance use complicating treatment. A PDMP query is advised and a UDS might be indicated at this time.
  - Only prescribe additional opioids if you feel it is clinically appropriate. Otherwise, continue to reinforce non-opioid modalities of pain control.

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Chronic Pain Flow Sheet

FOR THE EVALUATION AND TREATMENT OF CHRONIC NON-CANCER PAIN

Begin

ASSESSMENT

- Evaluate the original tissue injury and determine nociceptive, neuropathic, or central characteristics of the pain perception.
- Assess the risk of prescribing opioids to a patient through assessment tools: ACE, pain catastrophizing scale, PHQ-15, STOP-BANG, functional (e.g. Oswestry) or abuse (e.g. ORT) assessments, and trauma/PTSD screening.
- Obtain and review prior records, or for an established patient, re-familiarize yourself with your patient's past history and evaluations.
- A UDS and query of the PDMP prior to assuming prescribing and periodically thereafter, but no less than yearly.

Green Light

NON-OPIOID OPTIONS

- Exercise, restorative sleep, and behavioral supports should be a major component to any pain-management program.
- A team approach to care is essential to achieve functional improvement and improved quality of life.

Ongoing

ONGOING MONITORING

- Monitor all patients on chronic opioids.
- Every visit:
  - Evaluate progress toward functional goals. Strongly consider weaning in the absence of functional improvement on opioids.
  - Screen for appropriate medication use.
- Periodic assessment (no less than annually):
  - Urine drug screening
  - Pill counts
  - Callbacks
  - PDMP query

Caution

OPIOID TREATMENT

- Rarely prescribe opioids on the first visit.
- Discuss the risks vs. benefit of opioids and get a signed material risk notice.
- Create a care plan that includes functional goals.
- Discuss and plan for dose reduction (see tapering section in the OPG guidelines).
- Co-prescribe naloxone rescue kit to a loved one or family member.

Stop!

STOP AND REASSESS

- Benzodiazepines should not be taken at the same time as opioids.
- Methadone should be used rarely, and if so, in low doses (< 30 mg/d).
- Respiratory disease (COPD, sleep apnea, etc.) narrows the window of safety with opioids.
- Evidence of substance abuse, past or present.
- Illegal activities regarding medication or illicit drugs.
- Lack of functional improvement.

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Please note: An erratum has been published for this issue. To view the erratum, please click here.

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 65 / No. 1

March 18, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Disclosure of Relationship

The Core Expert Group (CEG) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Pam Archer discloses authorship of the Oklahoma Emergency Department and Urgent Care Clinic Opioid Prescribing Guidelines and the Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office Based Setting; Bonnie Burman discloses authorship of the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain; Jane Ballantyne discloses that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC, and has special advisory committee responsibilities on the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies committee; Phillip Coffin discloses that in 2012 he provided expert testimony to the California State Assembly regarding a bill to expand naloxone access and reports that he is the principal investigator on a research study of methamphetamine dependence that receives donated injectable naltrexone from Alkermes, Inc.; Gary Franklin discloses authorship of the AMDG Interagency Guideline on Prescribing Opioids for Pain; Erin Krebs discloses that she represented the American College of Physicians at a 2014 Food and Drug Administration meeting on Abuse Deterrent Opioid Formulations; Lewis Nelson discloses his ad-hoc membership on the FDA Drug Safety and Risk Management Advisory Committee; Trupti Patel discloses authorship of the Arizona Opioid Prescribing Guidelines; Robert "Chuck" Rich discloses that he was an author of the 2013 American Academy of Family Physicians position paper on opioids and pain management; Joanna Starrels discloses that she received honoraria from the Betty Ford Institute; Thomas Tape discloses that he was an author of the 2013 American College of Physicians policy position paper on prescription drug abuse. CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support. No foundation or industry support was accepted.

The Opioid Guideline Workgroup (OGW) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Anne Burns discloses that she participated in a congressional briefing sponsored by Reps. Carter and DeSaulnier on the pharmacist's role of furnishing Naloxone and that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit. Chinazo Cunningham discloses that her husband is employed by Quest Diagnostics and Dr. Cunningham was recused from any discussion related to urine drug testing. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Erin Krebs discloses that she served on the CDC Opioid Prescribing Guideline CEG. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG. Greg Terman discloses that he serves as the President of the American Pain Society. Mark Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone formulation to treat acute postoperative pain and Dr. Wallace was recused form any discussion related to abuse-deterrent drugs.

The NCIPC Board of Scientific Counselors (BSC) members disclose that they have no financial conflicts of interest. Two BSC members, Traci Green and Christina Porucznik, served on the Opioid Guideline Workgroup. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG.

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Suggested citation: [Author names; first three, then et al., if more than six.] [Title]. MMWR Recomm Rep 2016;65(No. RR-#):[inclusive page numbers].

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Please note: An erratum has been published for this issue. To view the erratum, please click here.

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Prepared by
Deborah Dowell, MD[1]
Tamara M. Haegerich, PhD[1]
Roger Chou, MD[1]
[1]*Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, Atlanta, Georgia*

Summary

This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.

Introduction

Background

Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription (*1*). In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills (*2*). Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties (*3*). Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication (*2*).

Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients, particularly members of racial and ethnic minority groups, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment (*4*). Patients can experience persistent pain that is not well controlled. There are clinical, psychological, and social consequences associated with chronic pain including limitations in complex activities, lost work productivity, reduced quality of life, and stigma, emphasizing the importance of appropriate and compassionate patient care (*4*). Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options.

Chronic pain has been variably defined but is defined within this guideline as pain that typically lasts >3 months or past the time of normal tissue healing (*5*). Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (*4*). Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated that 14.6% of adults have current widespread or localized pain lasting at least 3 months (*6*). Based on a survey conducted during 2001–2003 (*7*), the overall prevalence of common, predominantly musculoskeletal pain conditions (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the

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United States, although minimum duration of symptoms was not specified. Most recently, analysis of data from the 2012 National Health Interview Study showed that 11.2% of adults report having daily pain (*8*). Clinicians should consider the full range of therapeutic options for the treatment of chronic pain. However, it is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Evidence supports short-term efficacy of opioids for reducing pain and improving function in noncancer nociceptive and neuropathic pain in randomized clinical trials lasting primarily ≤12 weeks (*9*,*10*), and patients receiving opioid therapy for chronic pain report some pain relief when surveyed (*11*–*13*). However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later (*14*). On the basis of data available from health systems, researchers estimate that 9.6–11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005 (*15*).

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States (*16*). In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly (*17*). Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths (*18*). The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available (*19*). Although clinical criteria have varied over time, opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home (*20*). This diagnosis has also been referred to as "abuse or dependence" and "addiction" in the literature, and is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped), both of which can exist without a diagnosed disorder. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (*21*). Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder (*22*–*24*), highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years receiving opioids for chronic noncancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose (*25*).

This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. Although the guideline does not focus broadly on pain management, appropriate use of long-term opioid therapy must be considered within the context of all pain management strategies (including nonopioid pain medications and nonpharmacologic treatments). CDC's recommendations are made on the basis of a systematic review of the best available evidence, along with input from experts, and further review and deliberation by a federally chartered advisory committee. The guideline is intended to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Rationale

Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids (*26*). Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain (*27*). These attitudes and beliefs, combined with increasing trends in opioid-related overdose, underscore the need for better clinician guidance on opioid prescribing. Clinical practice guidelines focused on prescribing can improve clinician knowledge, change prescribing practices (*28*), and ultimately benefit patient health.

Professional organizations, states, and federal agencies (e.g., the American Pain Society/American Academy of Pain Medicine, 2009; the Washington Agency Medical Directors Group, 2015; and the U.S. Department of Veterans Affairs/Department of Defense, 2010) have developed guidelines for opioid prescribing (*29–31*). Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest (*32*). Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

This CDC guideline offers clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain) (*24*,*33*,*34*). Using guidelines to address problematic prescribing has the potential to optimize care and improve patient safety based on evidence-based practice (*28*), as well as reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic.

Scope and Audience

This guideline is intended for primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians has been above average (*3*). Primary care clinicians include physicians as well as nurse practitioners and physician assistants. Although the focus is on primary care clinicians, because clinicians work within team-based care, the recommendations refer to and promote integrated pain management and collaborative working relationships with other providers (e.g., behavioral health providers, pharmacists, and pain management specialists). Although the transition from use of opioid therapy for acute pain to use for chronic pain is hard to predict and identify, the guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.

This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms (*35*). End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. Patients within the scope of this guideline include cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, and are under cancer surveillance only. The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant women) and in populations with conditions posing special risks (e.g., a history of substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and harms of long-term opioid therapy in children and adolescents is limited, and few opioid medications provide information on the label regarding safety and effectiveness in pediatric patients. However, observational research shows significant increases in opioid prescriptions for pediatric populations from 2001 to 2010 (*36*), and a large proportion of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries (e.g., in one study, 50% of adolescents presenting with headache received a prescription for an opioid pain medication [*37*,*38*]). Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions (*39*), with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs (*40*). Use of prescribed opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse (*41*). Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use (*42*). Thus, risk of opioid medication use in pediatric populations is of great concern. Additional clinical trial and observational research is needed,

and encouraged, to inform development of future guidelines for this critical population.

The recommendations are not intended to provide guidance on use of opioids as part of medication-assisted treatment for opioid use disorder. Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline. Readers are referred to other sources for prescribing recommendations within acute care settings and in dental practice, such as the American College of Emergency Physicians' guideline for prescribing of opioids in the emergency department (*43*); the American Society of Anesthesiologists' guideline for acute pain management in the perioperative setting (*44*); the Washington Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Part II: Prescribing Opioids in the Acute and Subacute Phase (*30*); and the Pennsylvania Guidelines on the Use of Opioids in Dental Practice (*45*). In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (*46*).

Guideline Development Methods

Guideline Development Using the Grading of Recommendations Assessment, Development, and Evaluation Method

CDC developed this guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (http://www.gradeworkinggroup.org). This method specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. The method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP) (*47*). CDC has applied the ACIP translation of the GRADE framework in this guideline. Within the ACIP GRADE framework, the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence in the effect of a clinical action on health outcomes. The categories include type 1 evidence (randomized clinical trials or overwhelming evidence from observational studies), type 2 evidence (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 evidence (observational studies or randomized clinical trials with notable limitations), and type 4 evidence (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). Type of evidence is categorized by study design as well as limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and a constellation of plausible biases that could change observations of effects. Type 1 evidence indicates that one can be very confident that the true effect lies close to that of the estimate of the effect; type 2 evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; type 3 evidence means that confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect; and type 4 evidence indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect (*47*,*48*). When no studies are present, evidence is considered to be insufficient. The ACIP GRADE framework places recommendations in two categories, Category A and Category B. Four major factors determine the category of the recommendation: the quality of evidence, the balance between desirable and undesirable effects, values and preferences, and resource allocation (cost). Category A recommendations apply to all persons in a specified group and indicate that most patients should receive the recommended course of action. Category B recommendations indicate that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (*47*). According to the GRADE methodology, a particular quality of evidence does not necessarily imply a particular strength of recommendation (*48–50*). Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs. Category B recommendations are made when the advantages and disadvantages of a clinical action are more balanced. GRADE methodology is discussed extensively elsewhere (*47*,*51*). The U.S. Preventive Services Task Force (USPSTF) follows different methods for developing and categorizing recommendations (http://www.uspreventiveservicestaskforce.org). USPSTF recommendations focus on preventive services and are categorized as A, B, C, D, and I. Under the Affordable Care Act, all "nongrandfathered" health plans (that is, those health plans not in existence prior to March 23, 2010 or those with significant changes to their coverage) and expanded Medicaid plans are required to cover

preventive services recommended by USPSTF with a category A or B rating with no cost sharing. The coverage requirements went into effect September 23, 2010. Similar requirements are in place for vaccinations recommended by ACIP, but do not exist for other recommendations made by CDC, including recommendations within this guideline.

A previously published systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness and risks of long-term opioid treatment of chronic pain (*14*,*52*) initially served to directly inform the recommendation statements. This systematic clinical evidence review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk-prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, addiction, abuse, or misuse. For the current guideline development, CDC conducted additional literature searches to update the evidence review to include more recently available publications and to answer an additional clinical question about the effect of opioid therapy for acute pain on long-term use. More details about the literature search strategies and GRADE methods applied are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026). CDC developed GRADE evidence tables to illustrate the quality of the evidence for each clinical question.

As identified in the AHRQ-sponsored clinical evidence review, the overall evidence base for the effectiveness and risks of long-term opioid therapy is low in quality per the GRADE criteria. Thus, contextual evidence is needed to provide information about the benefits and harms of nonpharmacologic and nonopioid pharmacologic therapy and the epidemiology of opioid pain medication overdose and inform the recommendations. Further, as elucidated by the GRADE Working Group, supplemental information on clinician and patient values and preferences and resource allocation can inform judgments of benefits and harms and be helpful for translating the evidence into recommendations. CDC conducted a contextual evidence review to supplement the clinical evidence review based on systematic searches of the literature. The review focused on the following four areas: effectiveness of nonpharmacologic and nonopioid pharmacologic treatments; benefits and harms related to opioid therapy (including additional studies not included in the clinical evidence review such as studies that evaluated outcomes at any duration or used observational study designs related to specific opioid pain medications, high-dose opioid therapy, co-prescription of opioids with other controlled substances, duration of opioid use, special populations, risk stratification/mitigation approaches, and effectiveness of treatments for addressing potential harms of opioid therapy); clinician and patient values and preferences; and resource allocation. CDC constructed narrative summaries of this contextual evidence and used the information to support the clinical recommendations. More details on methods for the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

On the basis of a review of the clinical and contextual evidence (review methods are described in more detail in subsequent sections of this report), CDC drafted recommendation statements focused on determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. To help assure the draft guideline's integrity and credibility, CDC then began a multistep review process to obtain input from experts, stakeholders, and the public to help refine the recommendations.

Solicitation of Expert Opinion

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology.* CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

Prior to their participation, CDC asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Experts could not serve if they had conflicts that might have a direct and predictable effect on the recommendations. CDC excluded experts who had a financial or promotional relationship with a company

* A list of the members appears at the end of this report. The recommendations and all statements included in this guideline are those of CDC and do not necessarily represent the official position of any persons or organizations providing comments on the draft guideline.

that makes a product that might be affected by the guideline. CDC reviewed potential nonfinancial conflicts carefully (e.g., intellectual property, travel, public statements or positions such as congressional testimony) to determine if the activities would have a direct and predictable effect on the recommendations. CDC determined the risk of these types of activities to be minimal for the identified experts. All experts completed a statement certifying that there was no potential or actual conflict of interest. Activities that did not pose a conflict (e.g., participation in Food and Drug Administration [FDA] activities or other guideline efforts) are disclosed.

CDC provided to each expert written summaries of the scientific evidence (both the clinical and contextual evidence reviews conducted for this guideline) and CDC's draft recommendation statements. Experts provided individual ratings for each draft recommendation statement based on the balance of benefits and harms, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC hosted an in-person meeting of the experts that was held on June 23–24, 2015, in Atlanta, Georgia, to seek their views on the evidence and draft recommendations and to better understand their premeeting ratings. CDC sought the experts' individual opinions at the meeting. Although there was widespread agreement on some of the recommendations, there was disagreement on others. Experts did not vote on the recommendations or seek to come to a consensus. Decisions about recommendations to be included in the guideline, and their rationale, were made by CDC. After revising the guideline, CDC sent written copies of it to each of the experts for review and asked for any additional comments; CDC reviewed these written comments and considered them when making further revisions to the draft guideline. The experts have not reviewed the final version of the guideline.

Federal Partner Engagement

Given the scope of this guideline and the interest of agencies across the federal government in appropriate pain management, opioid prescribing, and related outcomes, CDC invited its National Institute of Occupational Safety and Health and CDC's federal partners to observe the expert meeting, provide written comments on the full draft guideline after the meeting, and review the guideline through an agency clearance process; CDC reviewed comments and incorporated changes. Interagency collaboration will be critical for translating these recommendations into clinical practice. Federal partners included representatives from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, FDA, the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, AHRQ, and the Office of National Drug Control Policy.

Stakeholder Comment

Given the importance of the guideline for a wide variety of stakeholders, CDC also invited review from a Stakeholder Review Group (SRG) to provide comment so that CDC could consider modifications that would improve the recommendations' specificity, applicability, and ease of implementation. The SRG included representatives from professional organizations that represent specialties that commonly prescribe opioids (e.g., pain medicine, physical medicine and rehabilitation), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organizations with interests in pain management and opioid prescribing.* Representatives from each of the SRG organizations were provided a copy of the guideline for comment. Each of these representatives provided written comments. Once input was received from the full SRG, CDC reviewed all comments and carefully considered them when revising the draft guideline.

Constituent Engagement

To obtain initial perspectives from constituents on the recommendation statements, including clinicians and prospective patients, CDC convened a constituent engagement webinar and circulated information about the webinar in advance through announcements to partners. CDC hosted the webinar on September 16 and 17, 2015, provided information about the methodology for developing the guideline, and presented the key recommendations. A fact sheet was posted on the CDC Injury Center website (http://www.cdc.gov/injury) summarizing the guideline development process and clinical practice areas addressed in the guideline; instructions were included on how to submit comments via email. CDC received comments during and for 2 days following the first webinar. Over 1,200 constituent comments were received. Comments were reviewed and carefully considered when revising the draft guideline.

Peer Review

Per the final information quality bulletin for peer review (https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf), peer review requirements applied to this guideline because it provides influential

scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations.* CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified. CDC placed the names of peer reviewers on the CDC and the National Center for Injury Prevention and Control Peer Review Agenda websites that are used to provide information about the peer review of influential documents. CDC reviewed peer review comments and revised the draft guideline accordingly.

Public Comment

To obtain comments from the public on the full guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the guideline and the supporting clinical and contextual evidence reviews for public comment. The comment period closed January 13, 2016. CDC received more than 4,350 comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when revising the draft guideline.

Federal Advisory Committee Review and Recommendation

The National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) is a federal advisory committee that advises and makes recommendations to the Secretary of the Department of Health and Human Services, the Director of CDC, and the Director of NCIPC.* The BSC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. CDC sought the BSC's advice on the draft guideline. BSC members are special government employees appointed as CDC advisory committee members; as such, all members completed an OGE Form 450 to disclose relevant interests. BSC members also reported on their disclosures during meetings. Disclosures for the BSC are reported in the guideline.

To assist in guideline review, on December 14, 2015, via Federal Register notice, CDC announced the intent to form an Opioid Guideline Workgroup (OGW) to provide observations on the draft guideline to the BSC. CDC provided the BSC with the draft guideline as well as summaries of comments provided to CDC by stakeholders, constituents, and peer reviewers, and edits made to the draft guideline in response. During an open meeting held on January 7, 2016, the BSC recommended the formation of the OGW. The OGW included a balance of perspectives from audiences directly affected by the guideline, audiences that would be directly involved with implementing the recommendations, and audiences qualified to provide representation. The OGW comprised clinicians, subject matter experts, and a patient representative, with the following perspectives represented: primary care, pain medicine, public health, behavioral health, substance abuse treatment, pharmacy, patients, and research.* Additional sought-after attributes were appropriate academic and clinical training and relevant clinical experience; high scientific standing; and knowledge of the patient, clinician, and caregiver perspectives. In accordance with CDC policy, two BSC committee members also served as OGW members, with one serving as the OGW Chair. The professional credentials and interests of OGW members were carefully reviewed to identify possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Only OGW members whose interests were determined to be minimal were selected. When an activity was perceived as having the potential to affect a specific aspect of the recommendations, the activity was disclosed, and the OGW member was recused from discussions related to that specific aspect of the recommendations (e.g., urine drug testing and abuse-deterrent formulations). Disclosures for the OGW are reported. CDC and the OGW identified ad-hoc consultants to supplement the workgroup expertise, when needed, in the areas of pediatrics, occupational medicine, obstetrics and gynecology, medical ethics, addiction psychiatry, physical medicine and rehabilitation, guideline development methodology, and the perspective of a family member who lost a loved one to opioid use disorder or overdose.

The BSC charged the OGW with reviewing the quality of the clinical and contextual evidence reviews and reviewing each of the recommendation statements and accompanying rationales. For each recommendation statement, the OGW considered the quality of the evidence, the balance of benefits and risks, the values and preferences of clinicians and patients, the cost feasibility, and the category designation

Please note: An erratum has been published for this issue. To view the erratum, please click here.

of the recommendation (A or B). The OGW also reviewed supplementary documents, including input provided by the CEG, SRG, peer reviewers, and the public. OGW members discussed the guideline accordingly during virtual meetings and drafted a summary report of members' observations, including points of agreement and disagreement, and delivered the report to the BSC.

NCIPC announced an open meeting of the NCIPC BSC in the Federal Register on January 11, 2015. The BSC met on January 28, 2016, to discuss the OGW report and deliberate on the draft guideline itself. Members of the public provided comments at this meeting. After discussing the OGW report, deliberating on specific issues about the draft guideline identified at the meeting, and hearing public comment, the BSC voted unanimously: to support the observations made by the OGW; that CDC adopt the guideline recommendations that, according to the workgroup's report, had unanimous or majority support; and that CDC further consider the guideline recommendations for which the group had mixed opinions. CDC carefully considered the OGW observations, public comments, and BSC recommendations, and revised the guideline in response.

Summary of the Clinical Evidence Review

Primary Clinical Questions

CDC conducted a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain, consistent with the GRADE approach (*47*,*48*). Long-term opioid therapy is defined as use of opioids on most days for >3 months. A previously published AHRQ-funded systematic review on the effectiveness and risks of long-term opioid therapy for chronic pain comprehensively addressed four clinical questions (*14*,*52*). CDC, with the assistance of a methodology expert, searched the literature to identify newly published studies on these four original questions. Because long-term opioid use might be affected by use of opioids for acute pain, CDC subsequently developed a fifth clinical question (last in the series below), and in collaboration with a methodologist conducted a systematic review of the scientific evidence to address it. In brief, five clinical questions were addressed:

- The effectiveness of long-term opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for long term (≥1 year) outcomes related to pain, function, and quality of life, and how effectiveness varies according to the type/cause of pain, patient demographics, and patient comorbidities (Key Question [KQ] 1).
- The risks of opioids versus placebo or no opioids on abuse, addiction, overdose, and other harms, and how harms vary according to the type/cause of pain, patient demographics, patient comorbidities, and dose (KQ2).
- The comparative effectiveness of opioid dosing strategies (different methods for initiating and titrating opioids; immediate-release versus ER/LA opioids; different ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled, continuous versus as-needed dosing; dose escalation versus dose maintenance; opioid rotation versus maintenance; different strategies for treating acute exacerbations of chronic pain; decreasing opioid doses or tapering off versus continuation; and different tapering protocols and strategies) (KQ3).
- The accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse; the effectiveness of risk mitigation strategies (use of risk prediction instruments); effectiveness of risk mitigation strategies including opioid management plans, patient education, urine drug testing, prescription drug monitoring program (PDMP) data, monitoring instruments, monitoring intervals, pill counts, and abuse-deterrent formulations for reducing risk for opioid overdose, addiction, abuse, or misuse; and the comparative effectiveness of treatment strategies for managing patients with addiction (KQ4).
- The effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain on long-term use (KQ5).

The review was focused on the effectiveness of long-term opioid therapy on long-term (>1 year) outcomes related to pain, function, and quality of life to ensure that findings are relevant to patients with chronic pain and long-term opioid prescribing. The effectiveness of short-term opioid therapy has already been established (*10*). However, opioids have unique effects such as tolerance and physical dependence that might influence assessments of benefit over time. These effects raise questions about whether findings on short-term effectiveness of opioid therapy can be extrapolated to estimate benefits of long-term therapy for chronic pain. Thus, it is important to consider studies that provide data on long-term benefit. For certain opioid-related harms (overdose, fractures, falls, motor vehicle crashes), observational studies were included with outcomes measured at shorter intervals because such outcomes can occur early during opioid therapy, and such harms are not captured well in short-term clinical trials. A detailed listing of the key questions is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Clinical Evidence Systematic Review Methods

Complete methods and data for the 2014 AHRQ report, upon which this updated systematic review is based, have been published previously (*14*,*52*). Study authors developed the protocol using a standardized process (*53*) with input from experts and the public and registered the protocol in the PROSPERO database (*54*). For the 2014 AHRQ report, a research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL for English-language articles published January 2008 through August 2014, using search terms for opioid therapy, specific opioids, chronic pain, and comparative study designs. Also included were relevant studies from an earlier review (*10*) in which searches were conducted without a date restriction, reference lists were reviewed, and ClinicalTrials.gov was searched. CDC updated the AHRQ literature search using the same search strategies as in the original review including studies published before April, 2015. Seven additional studies met inclusion criteria and were added to the review. CDC used the GRADE approach outlined in the ACIP Handbook for Developing Evidence-Based Recommendations (*47*) to rate the quality of evidence for the full body of evidence (evidence from the 2014 AHRQ review plus the update) for each clinical question. Evidence was categorized into the following types: type 1 (randomized clinical trials or overwhelming evidence from observational studies), type 2 (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 (observational studies, or randomized clinical trials with notable limitations), or type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). When no studies were present, evidence was considered to be insufficient. Per GRADE methods, type of evidence was categorized by study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects. Results were synthesized qualitatively, highlighting new evidence identified during the update process. Meta-analysis was not attempted due to the small numbers of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of the studies. More detailed information about data sources and searches, study selection, data extraction and quality assessment, data synthesis, and update search yield and new evidence for the current review is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Summary of Findings for Clinical Questions

The main findings of this updated review are consistent with the findings of the 2014 AHRQ report (*14*). In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly ≤12 weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events (*10*).

The GRADE evidence summary with type of evidence ratings for the five clinical questions for the current evidence review are outlined (Table 1). This summary is based on studies included in the AHRQ 2014 review (35 studies) plus additional studies identified in the updated search (seven studies). Additional details on findings from the original review are provided in the full 2014 AHRQ report (*14*,*52*). Full details on the clinical evidence review findings supporting this guideline are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Effectiveness

For KQ1, no study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for chronic pain evaluated long-term (≥1 year) outcomes related to pain, function, or quality of life. Most placebo-controlled randomized clinical trials were ≤6 weeks in duration. Thus, the body of evidence for KQ1 is rated as insufficient (0 studies contributing) (*14*).

Harms

For KQ2, the body of evidence is rated as type 3 (12 studies contributing; 11 from the original review plus one new study). One fair-quality cohort study found that long-term opioid therapy is associated with increased risk for an opioid abuse or dependence diagnosis (as defined by ICD-9-CM codes) versus no opioid prescription (*22*). Rates of opioid abuse or dependence diagnosis ranged from 0.7% with lower-dose (≤36 MME) chronic therapy to 6.1% with higher-dose (≥120 MME) chronic therapy, versus 0.004% with no opioids prescribed. Ten fair-quality uncontrolled studies reported estimates of opioid abuse, addiction, and related outcomes (*55*–*65*). In primary care settings, prevalence of opioid dependence

(using DSM-IV criteria) ranged from 3% to 26% (*55*,*56*,*59*). In pain clinic settings, prevalence of addiction ranged from 2% to 14% (*57*,*58*,*60*,*61*,*63–65*).

Factors associated with increased risk for misuse included history of substance use disorder, younger age, major depression, and use of psychotropic medications (*55*,*62*). Two studies reported on the association between opioid use and risk for overdose (*66*,*67*). One large fair-quality retrospective cohort study found that recent opioid use was associated with increased risk for any overdose events and serious overdose events versus nonuse (*66*). It also found higher doses associated with increased risk. Relative to 1–19 MME/day, the adjusted hazard ratio (HR) for any overdose event (consisting of mostly nonfatal overdose) was 1.44 for 20 to 49 MME/day, 3.73 for 50–99 MME/day, and 8.87 for ≥100 MME/day. A similar pattern was observed for serious overdose. A good-quality population-based, nested case-control study also found a dose-dependent association with risk for overdose death (*67*). Relative to 1–19 MME/day, the adjusted odds ratio (OR) was 1.32 for 20–49 MME/day, 1.92 for 50–99 MME/day, 2.04 for 100–199 MME/day, and 2.88 for ≥200 MME/day.

Findings of increased fracture risk for current opioid use, versus nonuse, were mixed in two studies (*68*,*69*). Two studies found an association between opioid use and increased risk for cardiovascular events (*70*,*71*). Indirect evidence was found for endocrinologic harms (increased use of medications for erectile dysfunction or testosterone from one previously included study; laboratory-defined androgen deficiency from one newly reviewed study) (*72*,*73*). One study found that opioid dosages ≥20 MME/day were associated with increased odds of road trauma among drivers (*74*).

Opioid Dosing Strategies

For KQ3, the body of evidence is rated as type 4 (14 studies contributing; 12 from the original review plus two new studies). For initiation and titration of opioids, the 2014 AHRQ report found insufficient evidence from three fair-quality, open-label trials to determine comparative effectiveness of ER/LA versus immediate-release opioids for titrating patients to stable pain control (*75*,*76*). One new fair-quality cohort study of Veterans Affairs patients found initiation of therapy with an ER/LA opioid associated with greater risk for nonfatal overdose than initiation with an immediate-release opioid, with risk greatest in the first 2 weeks after initiation of treatment (*77*).

For comparative effectiveness and harms of ER/LA opioids, the 2014 AHRQ report included three randomized, head-to-head trials of various ER/LA opioids that found no clear differences in 1-year outcomes related to pain or function (*78–80*) but had methodological shortcomings. A fair-quality retrospective cohort study based on national Veterans Health Administration system pharmacy data found that methadone was associated with lower overall risk for all-cause mortality versus morphine (*81*), and a fair-quality retrospective cohort study based on Oregon Medicaid data found no statistically significant differences between methadone and long-acting morphine in risk for death or overdose symptoms (*82*). However, a new observational study (*83*) found methadone associated with increased risk for overdose versus sustained-release morphine among Tennessee Medicaid patients. The observed inconsistency in study findings suggests that risks of methadone might vary in different settings as a function of different monitoring and management protocols, though more research is needed to understand factors associated with safer methadone prescribing.

For dose escalation, the 2014 AHRQ report included one fair-quality randomized trial that found no differences between more liberal dose escalation and maintenance of current doses after 12 months in pain, function, all-cause withdrawals, or withdrawals due to opioid misuse (*84*). However, the difference in opioid dosages prescribed at the end of the trial was relatively small (mean 52 MME/day with more liberal dosing versus 40 MME/day). Evidence on other comparisons related to opioid dosing strategies (ER/LA versus immediate-release opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled continuous dosing versus as-needed dosing; or opioid rotation versus maintenance of current therapy; long-term effects of strategies for treating acute exacerbations of chronic pain) was not available or too limited to determine effects on long-term clinical outcomes. For example, evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies (*85–87*).

Risk Assessment and Mitigation

For KQ4, the body of evidence is rated as type 3 for the accuracy of risk assessment tools and insufficient for the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms (six studies contributing; four from the original review plus two new studies). The 2014 AHRQ report included four studies (*88–91*) on the accuracy of risk assessment instruments, administered prior to opioid therapy initiation, for predicting opioid abuse or misuse. Results for the Opioid Risk Tool (ORT) (*89–91*) were extremely inconsistent; evidence for other risk assessment instruments was very sparse, and studies had serious methodological shortcomings. One additional fair-quality (*92*) and one poor-quality (*93*) study identified for this update compared the predictive accuracy of the ORT, the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview.

For the ORT, sensitivity was 0.58 and 0.75 and specificity 0.54 and 0.86; for the SOAPP-R, sensitivity was 0.53 and 0.25 and specificity 0.62 and 0.73; and for the Brief Risk Interview, sensitivity was 0.73 and 0.83 and specificity 0.43 and 0.88. For the ORT, positive likelihood ratios ranged from noninformative (positive likelihood ratio close to 1) to moderately useful (positive likelihood ratio >5). The SOAPP-R was associated with noninformative likelihood ratios (estimates close to 1) in both studies.

No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.

Effects of Opioid Therapy for Acute Pain on Long-Term Use

For KQ5, the body of evidence is rated as type 3 (two new studies contributing). Two fair-quality retrospective cohort studies found opioid therapy prescribed for acute pain associated with greater likelihood of long-term use. One study evaluated opioid-naïve patients who had undergone low-risk surgery, such as cataract surgery and varicose vein stripping (*94*). Use of opioids within 7 days of surgery was associated with increased risk for use at 1 year. The other study found that among patients with a workers' compensation claim for acute low back pain, compared to patients who did not receive opioids early after injury (defined as use within 15 days following onset of pain), patients who did receive early opioids had an increased likelihood of receiving five or more opioid prescriptions 30–730 days following onset that increased with greater early exposure. Versus no early opioid use, the adjusted OR was 2.08 (95% CI = 1.55–2.78) for 1–140 MME/day and increased to 6.14 (95% confidence interval [CI] = 4.92–7.66) for ≥450 MME/day (*95*).

Summary of the Contextual Evidence Review

Primary Areas of Focus

Contextual evidence is complementary information that assists in translating the clinical research findings into recommendations. CDC conducted contextual evidence reviews on four topics to supplement the clinical evidence review findings:

- Effectiveness of nonpharmacologic (e.g., cognitive behavioral therapy [CBT], exercise therapy, interventional treatments, and multimodal pain treatment) and nonopioid pharmacologic treatments (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, and anticonvulsants), including studies of any duration.
- Benefits and harms of opioid therapy (including additional studies not included in the clinical evidence review, such as studies that were not restricted to patients with chronic pain, evaluated outcomes at any duration, performed ecological analyses, or used observational study designs other than cohort and case-cohort control studies) related to specific opioids, high-dose therapy, co-prescription with other controlled substances, duration of use, special populations, and potential usefulness of risk stratification/mitigation approaches, in addition to effectiveness of treatments associated with addressing potential harms of opioid therapy (opioid use disorder).
- Clinician and patient values and preferences related to opioids and medication risks, benefits, and use.
- Resource allocation including costs and economic efficiency of opioid therapy and risk mitigation strategies.

CDC also reviewed clinical guidelines that were relevant to opioid prescribing and could inform or complement the CDC recommendations under development (e.g., guidelines on nonpharmacologic and nonopioid pharmacologic treatments and guidelines with recommendations related to specific clinician actions such as urine drug testing or opioid tapering protocols).

Contextual Evidence Review Methods

CDC conducted a contextual evidence review to assist in developing the recommendations by providing an assessment of the balance of benefits and harms, values and preferences, and cost, consistent with the GRADE approach. Given the public health urgency for developing opioid prescribing recommendations, a rapid review was required for the contextual evidence review for the current guideline. Rapid reviews are used when there is a need to streamline the systematic review process to obtain evidence quickly (*96*). Methods used to streamline the process include limiting searches by databases, years, and languages considered, and truncating quality assessment and data abstraction protocols. CDC conducted "rapid reviews" of the contextual evidence on nonpharmacologic and nonopioid pharmacologic treatments, benefits and harms, values and preferences, and resource allocation.

Detailed information about contextual evidence data sources and searches, inclusion criteria, study selection, and

data extraction and synthesis are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). In brief, CDC conducted systematic literature searches to identify original studies, systematic reviews, and clinical guidelines, depending on the topic being searched. CDC also solicited publication referrals from subject matter experts. Given the need for a rapid review process, grey literature (e.g., literature by academia, organizations, or government in the forms of reports, documents, or proceedings not published by commercial publishers) was not systematically searched. Database sources, including MEDLINE, PsycINFO, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews, varied by topic. Multiple reviewers scanned study abstracts identified through the database searches and extracted relevant studies for review. CDC constructed narrative summaries and tables based on relevant articles that met inclusion criteria, which are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Findings from the contextual reviews provide indirect evidence and should be interpreted accordingly. CDC did not formally rate the quality of evidence for the studies included in the contextual evidence review using the GRADE method. The studies that addressed benefits and harms, values and preferences, and resource allocation most often employed observational methods, used short follow-up periods, and evaluated selected samples. Therefore the strength of the evidence from these contextual review areas was considered to be low, comparable to type 3 or type 4 evidence. The quality of evidence for nonopioid pharmacologic and nonpharmacologic pain treatments was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines (e.g., for treatment of chronic neuropathic pain, low back pain, osteoarthritis, and fibromyalgia). Similarly, the quality of evidence on pharmacologic and psychosocial opioid use disorder treatment was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines.

Summary of Findings for Contextual Areas

Full narrative reviews and tables that summarize key findings from the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Effectiveness of Nonpharmacologic and Nonopioid Pharmacologic Treatments

Several nonpharmacologic and nonopioid pharmacologic treatments have been shown to be effective in managing chronic pain in studies ranging in duration from 2 weeks to 6 months. For example, CBT that trains patients in behavioral techniques and helps patients modify situational factors and cognitive processes that exacerbate pain has small positive effects on disability and catastrophic thinking (*97*). Exercise therapy can help reduce pain and improve function in chronic low back pain (*98*), improve function and reduce pain in osteoarthritis of the knee (*99*) and hip (*100*), and improve well-being, fibromyalgia symptoms, and physical function in fibromyalgia (*101*). Multimodal and multidisciplinary therapies (e.g., therapies that combine exercise and related therapies with psychologically based approaches) can help reduce pain and improve function more effectively than single modalities (*102*,*103*). Nonopioid pharmacologic approaches used for pain include analgesics such as acetaminophen, NSAIDs, and cyclooxygenase 2 (COX-2) inhibitors; selected anticonvulsants; and selected antidepressants (particularly tricyclics and serotonin and norepinephrine reuptake inhibitors [SNRIs]). Multiple guidelines recommend acetaminophen as first-line pharmacotherapy for osteoarthritis (*104*–*109*) or for low back pain (*110*) but note that it should be avoided in liver failure and that dosage should be reduced in patients with hepatic insufficiency or a history of alcohol abuse (*109*). Although guidelines also recommend NSAIDs as first-line treatment for osteoarthritis or low back pain (*106*,*110*), NSAIDs and COX-2 inhibitors do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks (*111*). FDA has recently strengthened existing label warnings that NSAIDs increase risks for heart attack and stroke, including that these risks might increase with longer use or at higher doses (*112*). Several guidelines agree that first- and second-line drugs for neuropathic pain include anticonvulsants (gabapentin or pregabalin), tricyclic antidepressants, and SNRIs (*113*–*116*). Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain (*117*–*119*). Epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (*120*).

Benefits and Harms of Opioid Therapy

Balance between benefits and harms is a critical factor influencing the strength of clinical recommendations. In particular, CDC considered what is known from the epidemiology research about benefits and harms related to specific opioids and formulations, high dose therapy, co-prescription with other controlled substances, duration of use, special populations, and risk stratification and mitigation approaches. Additional information on benefits and harms of long-term opioid therapy from studies meeting rigorous selection criteria is provided in the clinical evidence review (e.g., see KQ2). CDC also considered the number of persons experiencing chronic pain, numbers potentially benefiting

from opioids, and numbers affected by opioid-related harms. A review of these data is presented in the background section of this document, with detailed information provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). Finally, CDC considered the effectiveness of treatments that addressed potential harms of opioid therapy (opioid use disorder).

Regarding specific opioids and formulations, as noted by FDA, there are serious risks of ER/LA opioids, and the indication for this class of medications is for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain (*121*). Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study (*122*). Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (*123*).

Regarding high-dose therapy, several epidemiologic studies that were excluded from the clinical evidence review because patient samples were not restricted to patients with chronic pain also examined the association between opioid dosage and overdose risk (*23*,*24*,*124*–*126*). Consistent with the clinical evidence review, the contextual review found that opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. Two of these studies (*23*,*24*), as well as the two studies in the clinical evidence review (*66*,*67*), evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were between 1.3 (*67*) and 1.9 (*24*) for dosages of 20 to <50 MME/day, between 1.9 (*67*) and 4.6 (*24*) for dosages of 50 to <100 MME/day, and between 2.0 (*67*) and 8.9 (*66*) for dosages of ≥100 MME/day. Compared with dosages of 1–<20 MME/day, absolute risk difference approximation for 50–<100 MME/day was 0.15% for fatal overdose (*24*) and 1.40% for any overdose (*66*), and for ≥100 MME/day was 0.25% for fatal overdose (*24*) and 4.04% for any overdose (*66*). A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day) (*127*). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually (*128*). A listing of common opioid medications and their MME equivalents is provided (Table 2).

Regarding coprescription of opioids with benzodiazepines, epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (*67*,*128*,*129*). In one of these studies (*67*), among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time (*130*). Patients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use (*131*).

Regarding populations potentially at greater risk for harm, risk is greater for patients with sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders. Interpretation of clinical data on the effects of opioids on sleep-disordered breathing is difficult because of the types of study designs and methods employed, and there is no clear consensus regarding association with risk for developing obstructive sleep apnea syndrome (*132*). However, opioid therapy can decrease respiratory drive, a high percentage of patients on long-term opioid therapy have been reported to have an abnormal apnea-hypopnea index (*133*), opioid therapy can worsen central sleep apnea in obstructive sleep apnea patients, and it can cause further desaturation in obstructive sleep apnea patients not on continuous positive airway pressure (CPAP) (*31*). Reduced renal or hepatic function can result in greater peak effect and longer duration of action and reduce the dose at which respiratory depression and overdose occurs (*134*). Age-related changes in patients aged ≥65 years, such as reduced renal function and medication clearance, even in the absence of renal disease (*135*), result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose. Older adults might also be at increased risk for falls and fractures related to opioids (*136*–*138*). Opioids used

in pregnancy can be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with birth defects, including neural tube defects (*139*,*140*), congenital heart defects (*140*), and gastroschisis (*140*); preterm delivery (*141*), poor fetal growth (*141*), and stillbirth (*141*). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome (*142*). Patients with mental health comorbidities and patients with histories of substance use disorders might be at higher risk than other patients for opioid use disorder (*62*,*143*,*144*). Recent analyses found that depressed patients were at higher risk for drug overdose than patients without depression, particularly at higher opioid dosages, although investigators were unable to distinguish unintentional overdose from suicide attempts (*145*). In case-control and case-cohort studies, substance abuse/dependence was more prevalent among patients experiencing overdose than among patients not experiencing overdose (12% versus 6% [*66*], 40% versus 10% [*24*], and 26% versus 9% [*23*]).

Regarding risk stratification approaches, limited evidence was found regarding benefits and harms. Potential benefits of PDMPs and urine drug testing include the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder, and help determine which patients will benefit from greater caution and increased monitoring or interventions when risk factors are present. For example, one study found that most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose (*124*,*146*) that are available to prescribers in the PDMP (*124*). However, limited evaluation of PDMPs at the state level has revealed mixed effects on changes in prescribing and mortality outcomes (*28*). Potential harms of risk stratification include underestimation of risks of opioid therapy when screening tools are not adequately sensitive, as well as potential overestimation of risk, which could lead to inappropriate clinical decisions.

Regarding risk mitigation approaches, limited evidence was found regarding benefits and harms. Although no studies were found to examine prescribing of naloxone with opioid pain medication in primary care settings, naloxone distribution through community-based programs providing prevention services for substance users has been demonstrated to be associated with decreased risk for opioid overdose death at the community level (*147*).

Concerns have been raised that prescribing changes such as dose reduction might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (*148*) or interference with appropriate pain treatment (*149*). With the exception of a study noting an association between an abuse-deterrent formulation of OxyContin and heroin use, showing that some patients in qualitative interviews reported switching to another opioid, including heroin, for many reasons, including cost and availability as well as ease of use (*150*), CDC did not identify studies evaluating these potential outcomes.

Finally, regarding the effectiveness of opioid use disorder treatments, methadone and buprenorphine for opioid use disorder have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin (*151*–*153*). Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy; for example, by reducing opioid misuse and increasing retention during maintenance therapy, and improving compliance after detoxification (*154*,*155*).

Clinician and Patient Values and Preferences

Clinician and patient values and preferences can inform how benefits and harms of long-term opioid therapy are weighted and estimate the effort and resources required to effectively provide implementation support. Many physicians lack confidence in their ability to prescribe opioids safely (*156*), to predict (*157*) or detect (*158*) prescription drug abuse, and to discuss abuse with their patients (*158*). Although clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (*159*), most consider prescription drug abuse to be a "moderate" or "big" problem in their community, and large proportions are "very" concerned about opioid addiction (55%) and death (48%) (*160*). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs (*161*,*162*), urine drug testing (*163*), and opioid treatment agreements (*164*). This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems) (*165*), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results (*166*).

Many patients do not have an opinion about "opioids" or know what this term means (*167*). Most are familiar with the term "narcotics." About a third associated "narcotics" with addiction or abuse, and about half feared "addiction" from long-term "narcotic" use (*168*). Most patients taking opioids experience side effects (73% of patients taking hydrocodone for noncancer pain [*11*], 96% of patients taking opioids for chronic pain [*12*]), and side effects, rather than pain relief,

have been found to explain most of the variation in patients' preferences related to taking opioids (*12*). For example, patients taking hydrocodone for noncancer pain commonly reported side effects including dizziness, headache, fatigue, drowsiness, nausea, vomiting, and constipation (*11*). Patients with chronic pain in focus groups emphasized effectiveness of goal setting for increasing motivation and functioning (*168*). Patients taking high dosages report reliance on opioids despite ambivalence about their benefits (*169*) and regardless of pain reduction, reported problems, concerns, side effects, or perceived helpfulness (*13*).

Resource Allocation

Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. CDC searched for evidence on opioid therapy compared with other treatments; costs of misuse, abuse, and overdose from prescription opioids; and costs of specific risk mitigation strategies (e.g., urine drug testing). Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids (*170*); $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids (*171*); and $20.4 billion for direct and indirect costs related to opioid-related overdose alone (*172*). In 2012, total expenses for outpatient prescription opioids were estimated at $9.0 billion, an increase of 120% from 2002 (*173*). Although there are perceptions that opioid therapy for chronic pain is less expensive than more time-intensive nonpharmacologic management approaches, many pain treatments, including acetaminophen, NSAIDs, tricyclic antidepressants, and massage therapy, are associated with lower mean and median annual costs compared with opioid therapy (*174*). COX-2 inhibitors, SNRIs, anticonvulsants, topical analgesics, physical therapy, and CBT are also associated with lower median annual costs compared with opioid therapy (*174*). Limited information was found on costs of strategies to decrease risks associated with opioid therapy; however, urine drug testing, including screening and confirmatory tests, has been estimated to cost $211–$363 per test (*175*).

Recommendations

The recommendations are grouped into three areas for consideration:

- Determining when to initiate or continue opioids for chronic pain.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
- Assessing risk and addressing harms of opioid use.

There are 12 recommendations (Box 1). Each recommendation is followed by a rationale for the recommendation, with considerations for implementation noted. In accordance with the ACIP GRADE process, CDC based the recommendations on consideration of the clinical evidence, contextual evidence (including benefits and harms, values and preferences, resource allocation), and expert opinion. For each recommendation statement, CDC notes the recommendation category (A or B) and the type of the evidence (1, 2, 3, or 4) supporting the statement (Box 2). Expert opinion is reflected within each of the recommendation rationales. While there was not an attempt to reach consensus among experts, experts from the Core Expert Group and from the Opioid Guideline Workgroup ("experts") expressed overall, general support for all recommendations. Where differences in expert opinion emerged for detailed actions within the clinical recommendations or for implementation considerations, CDC notes the differences of opinion in the supporting rationale statements.

Category A recommendations indicate that most patients should receive the recommended course of action; category B recommendations indicate that different choices will be appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations. Consistent with the ACIP (*47*) and GRADE process (*48*), category A recommendations were made, even with type 3 and 4 evidence, when there was broad agreement that the advantages of a clinical action greatly outweighed the disadvantages based on a consideration of benefits and harms, values and preferences, and resource allocation. Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation. All recommendations are category A recommendations, with the exception of recommendation 10, which is rated as category B. Recommendations were associated with a range of evidence types, from type 2 to type 4.

In summary, the categorization of recommendations was based on the following assessment:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

BOX 2. Interpretation of recommendation categories and evidence type

Recommendation Categories

Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).

Category A recommendation: Applies to all persons; most patients should receive the recommended course of action.

Category B recommendation: Individual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

Evidence Type

Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.

Type 1 evidence: Randomized clinical trials or overwhelming evidence from observational studies.

Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.

Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.

Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3).**

Patients with pain should receive treatment that provides the greatest benefits relative to risks. The contextual evidence review found that many nonpharmacologic therapies, including physical therapy, weight loss for knee osteoarthritis, psychological therapies such as CBT, and certain interventional procedures can ameliorate chronic pain. There is high-quality evidence that exercise therapy (a prominent modality in physical therapy) for hip (*100*) or knee (*99*) osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months. Previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*). Exercise therapy also can help reduce pain and improve function in low back pain and can improve global well-being and physical function in fibromyalgia (*98*,*101*). Multimodal therapies and multidisciplinary biopsychosocial rehabilitation-combining approaches (e.g., psychological therapies with exercise) can reduce long-term pain and disability compared with usual care and compared with physical treatments (e.g., exercise) alone. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients. Interventional approaches such as arthrocentesis and intraarticular glucocorticoid injection for pain associated with rheumatoid arthritis (*117*) or osteoarthritis (*118*) and subacromial corticosteroid injection for rotator cuff disease (*119*) can provide short-term improvement in pain and function. Evidence is insufficient to determine the extent to which repeated glucocorticoid injection increases potential risks such as articular cartilage changes (in osteoarthritis) and sepsis (*118*). Serious adverse events are rare but have been reported with epidural injection (*120*).

Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain. Selected anticonvulsants such as pregabalin and gabapentin can improve pain in diabetic neuropathy and post-herpetic neuralgia (contextual evidence review). Pregabalin, gabapentin, and carbamazepine are FDA-approved for treatment of certain neuropathic pain conditions, and pregabalin is FDA approved for fibromyalgia management. In patients with or without depression, tricyclic antidepressants and SNRIs provide effective analgesia for neuropathic pain conditions including diabetic neuropathy and post-herpetic neuralgia, often at lower dosages and with a shorter time to onset of effect than for treatment of depression (see contextual evidence review). Tricyclics and SNRIs can also relieve fibromyalgia symptoms. The SNRI duloxetine is FDA-approved for the treatment of diabetic neuropathy and fibromyalgia. Because patients with chronic pain often suffer from concurrent depression (*144*), and depression can exacerbate physical symptoms including pain (*177*), patients with co-occurring pain and depression are especially likely to benefit from antidepressant medication (see Recommendation 8). Nonopioid pharmacologic therapies

are not generally associated with substance use disorder, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review). For example, acetaminophen, NSAIDs, and opioid pain medication were involved in 881, 228, and 16,651 pharmaceutical overdose deaths in the United States in 2010 (*178*). However, nonopioid pharmacologic therapies are associated with certain risks, particularly in older patients, pregnant patients, and patients with certain co-morbidities such as cardiovascular, renal, gastrointestinal, and liver disease (see contextual evidence review). For example, acetaminophen can be hepatotoxic at dosages of >3–4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease (*109*). NSAID use has been associated with gastritis, peptic ulcer disease, cardiovascular events (*111*,*112*), and fluid retention, and most NSAIDs (choline magnesium trilisate and selective COX-2 inhibitors are exceptions) interfere with platelet aggregation (*179*). Clinicians should review FDA-approved labeling including boxed warnings before initiating treatment with any pharmacologic therapy.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy (KQ1). While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury (KQ2). At a population level, more than 165,000 persons in the United States have died from opioid pain-medication-related overdoses since 1999 (see Contextual Evidence Review).

Integrated pain management requires coordination of medical, psychological, and social aspects of health care and includes primary care, mental health care, and specialist services when needed (*180*). Nonpharmacologic physical and psychological treatments such as exercise and CBT are approaches that encourage active patient participation in the care plan, address the effects of pain in the patient's life, and can result in sustained improvements in pain and function without apparent risks. Despite this, these therapies are not always or fully covered by insurance, and access and cost can be barriers for patients. For many patients, aspects of these approaches can be used even when there is limited access to specialty care. For example, previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*) and maintenance of activity for patients with low back pain (*110*). A randomized trial found no difference in reduced chronic low back pain intensity, frequency or disability between patients assigned to relatively low-cost group aerobics and individual physiotherapy or muscle reconditioning sessions (*181*). Low-cost options to integrate exercise include brisk walking in public spaces or use of public recreation facilities for group exercise. CBT addresses psychosocial contributors to pain and improves function (*97*). Primary care clinicians can integrate elements of a cognitive behavioral approach into their practice by encouraging patients to take an active role in the care plan, by supporting patients in engaging in beneficial but potentially anxiety-provoking activities, such as exercise (*179*), or by providing education in relaxation techniques and coping strategies. In many locations, there are free or low-cost patient support, self-help, and educational community-based programs that can provide stress reduction and other mental health benefits. Patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, can be referred for formal therapy with a mental health specialist (e.g., psychologist, psychiatrist, clinical social worker). Multimodal therapies should be considered for patients not responding to single-modality therapy, and combinations should be tailored depending on patient needs, cost, and convenience.

To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Detailed recommendations on diagnosis are provided in other guidelines (*110*,*179*), but evaluation should generally include a focused history, including history and characteristics of pain and potentially contributing factors (e.g., function, psychosocial stressors, sleep) and physical exam, with imaging or other diagnostic testing only if indicated (e.g., if severe or progressive neurologic deficits are present or if serious underlying conditions are suspected) (*110*,*179*). For complex pain syndromes, pain specialty consultation can be considered to assist with diagnosis as well as management. Diagnosis can help identify disease-specific interventions to reverse or ameliorate pain; for example, improving glucose control to prevent progression of diabetic neuropathy; immune-modulating agents for rheumatoid arthritis; physical or occupational therapy to address posture, muscle weakness, or repetitive occupational motions that contribute to musculoskeletal pain; or surgical intervention to relieve mechanical/compressive pain (*179*). The underlying mechanism for most pain syndromes can be categorized as neuropathic (e.g., diabetic neuropathy, postherpetic neuralgia, fibromyalgia), or nociceptive (e.g., osteoarthritis, muscular back pain). The diagnosis and pathophysiologic mechanism of pain have implications for symptomatic pain treatment with medication. For example, evidence is limited or insufficient

for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain (*182*), headache (*183*), and fibromyalgia (*184*). Although NSAIDs can be used for exacerbations of nociceptive pain, other medications (e.g., tricyclics, selected anticonvulsants, or transdermal lidocaine) generally are recommended for neuropathic pain. In addition, improvement of neuropathic pain can begin weeks or longer after symptomatic treatment is initiated (*179*). Medications should be used only after assessment and determination that expected benefits outweigh risks given patient-specific factors. For example, clinicians should consider falls risk when selecting and dosing potentially sedating medications such as tricyclics, anticonvulsants, or opioids, and should weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults as well as patients with hypertension, renal insufficiency, or heart failure, or those with risk for peptic ulcer disease or cardiovascular disease. Some guidelines recommend topical NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) over oral NSAIDs in patients aged ≥75 years to minimize systemic effects (*176*).

Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care, given small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms; although evidence on long-term benefits of nonopioid therapies is also limited, these therapies are also associated with short-term benefits, and risks are much lower. This does not mean that patients should be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., headache or fibromyalgia), expected benefits of initiating opioids are unlikely to outweigh risks regardless of previous nonpharmacologic and nonopioid pharmacologic therapies used. In other situations (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. In addition, when opioid pain medication is used, it is more likely to be effective if integrated with nonpharmacologic therapy. Nonpharmacologic approaches such as exercise and CBT should be used to reduce pain and improve function in patients with chronic pain. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be combined with nonpharmacologic therapy to reduce pain and improve function. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

2. **Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent. In addition, studies on currently available risk assessment instruments were sparse and showed inconsistent results (KQ4). The clinical evidence review for the current guideline considered studies with outcomes examined at ≥1 year that compared opioid use versus nonuse or placebo. Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves (*185*). These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients. Opioid therapy should not be initiated without consideration of an "exit strategy" to be used if the therapy is unsuccessful.

Experts agreed that before opioid therapy is initiated for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should determine how effectiveness will be evaluated and should establish treatment goals with patients. Because the line between acute pain and initial chronic pain is not always clear, it might be difficult for clinicians to determine when they are initiating opioids for chronic pain rather than treating acute pain. Pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition) is generally no longer considered acute. However, establishing treatment goals with a patient who has already received opioid therapy for 3 months would defer this discussion well past the point of

initiation of opioid therapy for chronic pain. Clinicians often write prescriptions for long-term use in 30-day increments, and opioid prescriptions written for ≥30 days are likely to represent initiation or continuation of long-term opioid therapy. Before writing an opioid prescription for ≥30 days, clinicians should establish treatment goals with patients. Clinicians seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy. Although the clinical evidence review did not find studies evaluating the effectiveness of written agreements or treatment plans (KQ4), clinicians and patients who set a plan in advance will clarify expectations regarding how opioids will be prescribed and monitored, as well as situations in which opioids will be discontinued or doses tapered (e.g., if treatment goals are not met, opioids are no longer needed, or adverse events put the patient at risk) to improve patient safety.

Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). However, there are some clinical circumstances under which reductions in pain without improvement in physical function might be a more realistic goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma). Experts noted that function can include emotional and social as well as physical dimensions. In addition, experts emphasized that mood has important interactions with pain and function. Experts agreed that clinicians may use validated instruments such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) to track patient outcomes. Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function (*187*). Monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities) can also contribute to the assessment of functional improvement. Clinicians should use these goals in assessing benefits of opioid therapy for individual patients and in weighing benefits against risks of continued opioid therapy (see Recommendation 7, including recommended intervals for follow-up). Because depression, anxiety, and other psychological co-morbidities often coexist with and can interfere with resolution of pain, clinicians should use validated instruments to assess for these conditions (see Recommendation 8) and ensure that treatment for these conditions is optimized. If patients receiving opioid therapy for chronic pain do not experience meaningful improvements in both pain and function compared with prior to initiation of opioid therapy, clinicians should consider working with patients to taper and discontinue opioids (see Recommendation 7) and should use nonpharmacologic and nonopioid pharmacologic approaches to pain management (see Recommendation 1).

3. **Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).**

The clinical evidence review did not find studies evaluating effectiveness of patient education or opioid treatment plans as risk-mitigation strategies (KQ4). However, the contextual evidence review found that many patients lack information about opioids and identified concerns that some clinicians miss opportunities to effectively communicate about safety. Given the substantial evidence gaps on opioids, uncertain benefits of long-term use, and potential for serious harms, patient education and discussion before starting opioid therapy are critical so that patient preferences and values can be understood and used to inform clinical decisions. Experts agreed that essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.

Clinicians should involve patients in decisions about whether to start or continue opioid therapy. Given potentially serious risks of long-term opioid therapy, clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives to opioids before starting or continuing opioid therapy. Clinicians are encouraged to have open and honest discussions with patients to inform mutual decisions about whether to start or continue opioid therapy. Important considerations include the following:

- Be explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely (clinical evidence review, KQ1).
- Emphasize improvement in function as a primary goal and that function can improve even when pain is still present.
- Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
- Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase

hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.

- Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
- Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
- Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.
- Discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient, and that young children are susceptible to unintentional ingestion. Discuss storage of opioids in a secure, preferably locked location and options for safe disposal of unused opioids (*188*).
- Discuss the importance of periodic reassessment to ensure that opioids are helping to meet patient goals and to allow opportunities for opioid discontinuation and consideration of additional nonpharmacologic or nonopioid pharmacologic treatment options if opioids are not effective or are harmful.
- Discuss planned use of precautions to reduce risks, including use of prescription drug monitoring program information (see Recommendation 9) and urine drug testing (see Recommendation 10). Consider including discussion of naloxone use for overdose reversal (see Recommendation 8).
- Consider whether cognitive limitations might interfere with management of opioid therapy (for older adults in particular) and, if so, determine whether a caregiver can responsibly co-manage medication therapy. Discuss the importance of reassessing safer medication use with both the patient and caregiver.

Given the possibility that benefits of opioid therapy might diminish or that risks might become more prominent over time, it is important that clinicians review expected benefits and risks of continued opioid therapy with patients periodically, at least every 3 months (see Recommendation 7).

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. The clinical evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids (*77*). The clinical evidence review did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/LA opioids reduces risks for opioid misuse or addiction (KQ3).

In 2014, the FDA modified the labeling for ER/LA opioid pain medications, noting serious risks and recommending that ER/LA opioids be reserved for "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment" when "alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain" and not used as "as needed" pain relievers (*121*). FDA has also noted that some ER/LA opioids are only appropriate for opioid-tolerant patients, defined as patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week (*189*). Time-scheduled opioid use can be associated with greater total average daily opioid dosage compared with intermittent, as-needed opioid use (contextual evidence review). In addition, experts indicated that there was not enough evidence to determine the safety of using immediate-release opioids for breakthrough pain when ER/LA opioids are used for chronic pain outside of active cancer pain, palliative care, or end-of-life care, and that this practice might be associated with dose escalation.

Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (*190*), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent

opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

In comparing different ER/LA formulations, the clinical evidence review found inconsistent results for overdose risk with methadone versus other ER/LA opioids used for chronic pain (KQ3). The contextual evidence review found that methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for chronic pain. In addition, methadone is associated with cardiac arrhythmias along with QT prolongation on the electrocardiogram, and it has complicated pharmacokinetics and pharmacodynamics, including a long and variable half-life and peak respiratory depressant effect occurring later and lasting longer than peak analgesic effect. Experts noted that the pharmacodynamics of methadone are subject to more inter-individual variability than other opioids. In regard to other ER/LA opioid formulations, experts noted that the absorption and pharmacodynamics of transdermal fentanyl are complex, with gradually increasing serum concentration during the first part of the 72-hour dosing interval, as well as variable absorption based on factors such as external heat. In addition, the dosing of transdermal fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing. Experts thought that these complexities might increase the risk for fatal overdose when methadone or transdermal fentanyl is prescribed to a patient who has not used it previously or by clinicians who are not familiar with its effects.

Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, clinicians should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance. Clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to patients with renal or hepatic dysfunction because decreased clearance of drugs among these patients can lead to accumulation of drugs to toxic levels and persistence in the body for longer durations. Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

- Methadone should not be the first choice for an ER/LA opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to educate and closely monitor their patients, including risk assessment for QT prolongation and consideration of electrocardiographic monitoring, should consider prescribing methadone for pain. A clinical practice guideline that contains further guidance regarding methadone prescribing for pain has been published previously (*191*).
- Because dosing effects of transdermal fentanyl are often misunderstood by both clinicians and patients, only clinicians who are familiar with the dosing and absorption properties of transdermal fentanyl and are prepared to educate their patients about its use should consider prescribing it.

5. **When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3).**

Benefits of high-dose opioids for chronic pain are not established. The clinical evidence review found only one study (*84*) addressing effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. (These groups were prescribed average dosages of 52 and 40 MME/day, respectively, at the end of the trial.) At the same time, risks for serious harms

related to opioid therapy increase at higher opioid dosage. The clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose (KQ2). The clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50–<100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–<20 MME/day, and that dosages ≥100 MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–<20 MME/day. In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose (*127*).

The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages. Experts agreed that lower dosages of opioids reduce the risk for overdose, but that a single dosage threshold for safe opioid use could not be identified. Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks, that dosages <50 MME/day are safer than dosages of 50–100 MME/day, and that dosages <20 MME/day are safer than dosages of 20–50 MME/day. One expert thought that a specific dosage at which the benefit/risk ratio of opioid therapy decreases could not be identified. Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function and that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosages to ≥50 MME/day. Most experts also agreed that opioid dosages should not be increased to ≥90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.

When opioids are used for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should start opioids at the lowest possible effective dosage (the lowest starting dosage on product labeling for patients not already taking opioids and according to product labeling guidance regarding tolerance for patients already taking opioids). Clinicians should use additional caution when initiating opioids for patients aged ≥65 years and for patients with renal or hepatic insufficiency because decreased clearance of drugs in these patients can result in accumulation of drugs to toxic levels. Clinicians should use caution when increasing opioid dosages and increase dosage by the smallest practical amount because overdose risk increases with increases in opioid dosage. Although there is limited evidence to recommend specific intervals for dosage titration, a previous guideline recommended waiting at least five half-lives before increasing dosage and waiting at least a week before increasing dosage of methadone to make sure that full effects of the previous dosage are evident (*31*). Clinicians should re-evaluate patients after increasing dosage for changes in pain, function, and risk for harm (see Recommendation 7). Before increasing total opioid dosage to ≥50 MME/day, clinicians should reassess whether opioid treatment is meeting the patient's treatment goals (see Recommendation 2). If a patient's opioid dosage for all sources of opioids combined reaches or exceeds 50 MME/day, clinicians should implement additional precautions, including increased frequency of follow-up (see Recommendation 7) and considering offering naloxone and overdose prevention education to both patients and the patients' household members (see Recommendation 8). Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at ≥90 MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids (see Recommendation 7), and consider consulting a pain specialist. Some states require clinicians to implement clinical protocols at specific dosage levels. For example, before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington state must obtain consultation from a pain specialist who agrees that this is indicated and appropriate (*30*). Clinicians should be aware of rules related to MME thresholds and associated clinical protocols established by their states.

Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is

now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (see Recommendation 7). Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages. Clinicians should remain alert to signs of anxiety, depression, and opioid use disorder (see Recommendations 8 and 12) that might be unmasked by an opioid taper and arrange for management of these co-morbidities. For patients agreeing to taper to lower opioid dosages as well as for those remaining on high opioid dosages, clinicians should establish goals with the patient for continued opioid therapy (see Recommendation 2), maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1), and consider consulting a pain specialist as needed to assist with pain management.

6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4).**

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (*192–194*) and other settings (*195*,*196*) have recommended prescribing ≤3 days of opioids in most cases, whereas others have recommended ≤7 days (*197*) or <14 days (*30*). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days' supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (*198*). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, nonsurgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (*30*). Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

7. **Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).**

Although the clinical evidence review did not find studies evaluating the effectiveness of more frequent monitoring intervals (KQ4), it did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder (KQ2); therefore, follow-up earlier than 3 months might be necessary to provide the greatest opportunity to prevent the development of opioid use disorder. In addition, risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment (KQ3). The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months. Although evidence is insufficient to determine at what point within the first 3 months of opioid therapy the risks for opioid use disorder increase, reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications. Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when methadone or transdermal fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.

Clinicians should evaluate patients to assess benefits and harms of opioids within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Clinicians should consider follow-up intervals within the lower end of this range when ER/LA opioids are started or increased or when total daily opioid dosage is ≥50 MME/day. Shorter follow-up intervals (within 3 days) should be strongly considered when starting or increasing the dosage of methadone. At follow up, clinicians should assess benefits in function, pain control, and quality of life using tools such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) and/or asking patients about progress toward functional goals that have meaning for them (see Recommendation 2). Clinicians should also ask patients about common adverse effects such as constipation and drowsiness (see Recommendation 3), as well as asking about and assessing for effects that might be early warning signs for more serious problems such as overdose (e.g., sedation or slurred speech) or opioid use disorder (e.g., craving, wanting to take opioids in greater quantities or more frequently than prescribed, or difficulty controlling use). Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.

Because of potential changes in the balance of benefits and risks of opioid therapy over time, clinicians should regularly reassess all patients receiving long-term opioid therapy, including patients who are new to the clinician but on long-term opioid therapy, at least every 3 months. At reassessment, clinicians should determine whether opioids continue to meet treatment goals, including sustained improvement in pain and function, whether the patient has experienced common or serious adverse events or early warning signs of serious adverse events, signs of opioid use disorder (e.g., difficulty controlling use, work or family problems related to opioid use), whether benefits of opioids continue to outweigh risks, and whether opioid dosage can be reduced or opioids can be discontinued. Ideally, these reassessments would take place in person and be conducted by the prescribing clinician. In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other issues make follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through video and audio could be conducted, with in-person visits occurring at least once per year. Clinicians should re-evaluate patients who are exposed to greater risk of opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking ≥50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. If clinically meaningful improvements in pain and function are not sustained, if patients are taking high-risk regimens (e.g., dosages ≥50 MME/day or opioids combined with benzodiazepines) without evidence of benefit, if patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation, or if patients experience overdose or other serious adverse events (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events, clinicians should work with patients to reduce opioid dosage or to discontinue opioids when possible. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to assist with pain management.

Considerations for Tapering Opioids

Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued (KQ3), tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines (*199*), and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose (*30*). Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years). Opioid withdrawal during pregnancy has been associated with spontaneous abortion and premature labor.

When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point; experts agreed that tapering plans may be individualized based on patient goals and concerns. Experts noted that at times, tapers might have to be paused and restarted again when the patient is ready and might have to be slowed once patients reach low dosages. Tapers may be considered successful as long as the patient is making progress. Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped when taken less frequently than once a day. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced overdose on their current dosage). Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (*200*). Clinicians should access appropriate expertise if considering tapering opioids during pregnancy because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal. Patients who are not taking opioids (including patients who are diverting all opioids they obtain) do not require tapers. Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose. Primary care clinicians should collaborate with mental health providers and with other specialists as needed to optimize nonopioid pain management (see Recommendation 1), as well as psychosocial support for anxiety related to the taper. More detailed guidance on tapering, including management of withdrawal symptoms has been published previously (*30*,*201*). If a patient exhibits signs of opioid use disorder, clinicians should offer or arrange for treatment of opioid use disorder (see Recommendation 12) and consider offering naloxone for overdose prevention (see Recommendation 8).

Assessing Risk and Addressing Harms of Opioid Use

8. **Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities (KQ2). However, based on the contextual evidence review and expert opinion, certain risk factors are likely to increase susceptibility to opioid-associated harms and warrant incorporation of additional strategies into the management plan to mitigate risk. Clinicians should assess these risk factors periodically, with frequency varying by risk factor and patient characteristics. For example, factors that vary more frequently over time, such as alcohol use, require more frequent follow up. In addition, clinicians should consider offering naloxone, re-evaluating patients more frequently (see Recommendation 7), and referring to pain and/or behavioral health specialists when factors that increase risk for harm, such as history of overdose, history of substance use disorder, higher dosages of opioids (≥50 MME/day), and concurrent use of benzodiazepines with opioids, are present.

Patients with Sleep-Disordered Breathing, Including Sleep Apnea

Risk factors for sleep-disordered breathing include congestive heart failure, and obesity. Experts noted that careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. Clinicians should avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing whenever possible to minimize risks for opioid overdose (contextual evidence review).

Pregnant Women

Opioids used in pregnancy might be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with stillbirth, poor fetal growth, pre-term delivery, and birth defects (contextual evidence review). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome. Clinicians and patients together should carefully weigh risks and benefits when making decisions

about whether to initiate opioid therapy for chronic pain during pregnancy. In addition, before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any future pregnancy. For pregnant women already receiving opioids, clinicians should access appropriate expertise if considering tapering opioids because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal (see Recommendation 7). For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine or methadone has been associated with improved maternal outcomes and should be offered (*202*) (see Recommendation 12). Clinicians caring for pregnant women receiving opioids for pain or receiving buprenorphine or methadone for opioid use disorder should arrange for delivery at a facility prepared to monitor, evaluate for, and treat neonatal opioid withdrawal syndrome. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for neonatal opioid withdrawal syndrome, and transfer the newborn for additional treatment if needed. Neonatal toxicity and death have been reported in breast-feeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breast feeding and, if used, should be limited to the lowest possible dose and to a 4-day supply (*203*).

Patients with Renal or Hepatic Insufficiency

Clinicians should use additional caution and increased monitoring (see Recommendation 7) to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, given their decreased ability to process and excrete drugs, susceptibility to accumulation of opioids, and reduced therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review; see Recommendations 4, 5, and 7).

Patients Aged ≥65 Years

Inadequate pain treatment among persons aged ≥65 years has been documented (*204*). Pain management for older patients can be challenging given increased risks of both nonopioid pharmacologic therapies (see Recommendation 1) and opioid therapy in this population. Given reduced renal function and medication clearance even in the absence of renal disease, patients aged ≥65 years might have increased susceptibility to accumulation of opioids and a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review). Some older adults suffer from cognitive impairment, which can increase risk for medication errors and make opioid-related confusion more dangerous. In addition, older adults are more likely than younger adults to experience co-morbid medical conditions and more likely to receive multiple medications, some of which might interact with opioids (such as benzodiazepines). Clinicians should use additional caution and increased monitoring (see Recommendations 4, 5, and 7) to minimize risks of opioids prescribed for patients aged ≥65 years. Experts suggested that clinicians educate older adults receiving opioids to avoid risky medication-related behaviors such as obtaining controlled medications from multiple prescribers and saving unused medications. Clinicians should also implement interventions to mitigate common risks of opioid therapy among older adults, such as exercise or bowel regimens to prevent constipation, risk assessment for falls, and patient monitoring for cognitive impairment.

Patients with Mental Health Conditions

Because psychological distress frequently interferes with improvement of pain and function in patients with chronic pain, using validated instruments such as the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for anxiety, post-traumatic stress disorder, and/or depression (*205*), might help clinicians improve overall pain treatment outcomes. Experts noted that clinicians should use additional caution and increased monitoring (see Recommendation 7) to lessen the increased risk for opioid use disorder among patients with mental health conditions (including depression, anxiety disorders, and PTSD), as well as increased risk for drug overdose among patients with depression. Previous guidelines have noted that opioid therapy should not be initiated during acute psychiatric instability or uncontrolled suicide risk, and that clinicians should consider behavioral health specialist consultation for any patient with a history of suicide attempt or psychiatric disorder (*31*). In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose (see Recommendation 11). Clinicians should ensure that treatment for depression and other mental health conditions is optimized, consulting with behavioral health specialists when needed. Treatment for depression can improve pain symptoms as well as depression and might decrease overdose risk (contextual evidence review). For treatment of chronic pain in patients with depression, clinicians should strongly consider using tricyclic or SNRI antidepressants for analgesic as well as antidepressant effects if these medications are not otherwise contraindicated (see Recommendation 1).

Patients with Substance Use Disorder

Illicit drugs and alcohol are listed as contributory factors on a substantial proportion of death certificates for opioid-related overdose deaths (contextual evidence review). Previous guidelines have recommended screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids. However, the clinical evidence review found that currently available risk-stratification tools (e.g., Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain Version 1, SOAPP-R, and Brief Risk Interview) show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse (KQ4). Clinicians should always exercise caution when considering or prescribing opioids for any patient with chronic pain outside of active cancer, palliative, and end-of-life care and should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.

Clinicians should ask patients about their drug and alcohol use. Single screening questions can be used (*206*). For example, the question "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview (*207*). Validated screening tools such as the Drug Abuse Screening Test (DAST) (*208*) and the Alcohol Use Disorders Identification Test (AUDIT) (*209*) can also be used. Clinicians should use PDMP data (see Recommendation 9) and drug testing (see Recommendation 10) as appropriate to assess for concurrent substance use that might place patients at higher risk for opioid use disorder and overdose. Clinicians should also provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol (see Recommendation 3) and ensure that patients receive effective treatment for substance use disorders when needed (see Recommendation 12).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder (KQ2), although a history of substance use disorder was associated with misuse. Similarly, based on contextual evidence, patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. If clinicians consider opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care for patients with drug or alcohol use disorders, they should discuss increased risks for opioid use disorder and overdose with patients, carefully consider whether benefits of opioids outweigh increased risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed. Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse. Experts also noted that clinicians should communicate with patients' substance use disorder treatment providers if opioids are prescribed.

Patients with Prior Nonfatal Overdose

Although studies were not identified that directly addressed the risk for overdose among patients with prior nonfatal overdose who are prescribed opioids, based on clinical experience, experts thought that prior nonfatal overdose would substantially increase risk for future nonfatal or fatal opioid overdose. If patients experience nonfatal opioid overdose, clinicians should work with them to reduce opioid dosage and to discontinue opioids when possible (see Recommendation 7). If clinicians continue opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care in patients with prior opioid overdose, they should discuss increased risks for overdose with patients, carefully consider whether benefits of opioids outweigh substantial risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed.

Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

Naloxone is an opioid antagonist that can reverse severe respiratory depression; its administration by lay persons, such as friends and family of persons who experience opioid overdose, can save lives. Naloxone precipitates acute withdrawal among patients physically dependent on opioids. Serious adverse effects, such as pulmonary edema, cardiovascular instability, and seizures, have been reported but are rare at doses consistent with labeled use for opioid overdose (*210*). The contextual evidence review did not find any studies on effectiveness of prescribing naloxone for overdose prevention among patients prescribed opioids for chronic pain. However, there is evidence for effectiveness of naloxone provision in preventing opioid-related overdose death at the community level through community-based distribution (e.g., through overdose education and naloxone distribution programs in community service agencies) to persons at risk for overdose

(mostly due to illicit opiate use), and it is plausible that effectiveness would be observed when naloxone is provided in the clinical setting as well. Experts agreed that it is preferable not to initiate opioid treatment when factors that increase risk for opioid-related harms are present. Opinions diverged about the likelihood of naloxone being useful to patients and the circumstances under which it should be offered. However, most experts agreed that clinicians should consider offering naloxone when prescribing opioids to patients at increased risk for overdose, including patients with a history of overdose, patients with a history of substance use disorder, patients taking benzodiazepines with opioids (see Recommendation 11), patients at risk for returning to a high dose to which they are no longer tolerant (e.g., patients recently released from prison), and patients taking higher dosages of opioids (≥50 MME/day). Practices should provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households. Experts noted that naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists. Resources for prescribing naloxone in primary care settings can be found through Prescribe to Prevent at http://prescribetoprevent.org.

9. **Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).**

PDMPs are state-based databases that collect information on controlled prescription drugs dispensed by pharmacies in most states and, in select states, by dispensing physicians as well. In addition, some clinicians employed by the federal government, including some clinicians in the Indian Health Care Delivery System, are not licensed in the states where they practice, and do not have access to PDMP data. Certain states require clinicians to review PDMP data prior to writing each opioid prescription (see state-level PDMP-related policies on the National Alliance for Model State Drug Laws website at http://www.namsdl.org/prescription-monitoring-programs.cfm). The clinical evidence review did not find studies evaluating the effectiveness of PDMPs on outcomes related to overdose, addiction, abuse, or misuse (KQ4). However, even though evidence is limited on the effectiveness of PDMP implementation at the state level on prescribing and mortality outcomes (*28*), the contextual evidence review found that most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages; information on both of these risk factors for overdose are available to prescribers in the PDMP. PDMP data also can be helpful when patient medication history is not otherwise available (e.g., for patients from other locales) and when patients transition care to a new clinician. The contextual evidence review also found that PDMP information could be used in a way that is harmful to patients. For example, it has been used to dismiss patients from clinician practices (*211*), which might adversely affect patient safety.

The contextual review found variation in state policies that affect timeliness of PDMP data (and therefore benefits of reviewing PDMP data) as well as time and workload for clinicians in accessing PDMP data. In states that permit delegating access to other members of the health care team, workload for prescribers can be reduced. These differences might result in a different balance of benefits to clinician workload in different states. Experts agreed that PDMPs are useful tools that should be consulted when starting a patient on opioid therapy and periodically during long-term opioid therapy. However, experts disagreed on how frequently clinicians should check the PDMP during long-term opioid therapy, given PDMP access issues and the lag time in reporting in some states. Most experts agreed that PDMP data should be reviewed every 3 months or more frequently during long-term opioid therapy. A minority of experts noted that, given the current burden of accessing PDMP data in some states and the lack of evidence surrounding the most effective interval for PDMP review to improve patient outcomes, annual review of PDMP data during long-term opioid therapy would be reasonable when factors that increase risk for opioid-related harms are not present.

Clinicians should review PDMP data for opioids and other controlled medications patients might have received from additional prescribers to determine whether a patient is receiving high total opioid dosages or dangerous combinations (e.g., opioids combined with benzodiazepines) that put him or her at high risk for overdose. Ideally, PDMP data should be reviewed before every opioid prescription. This is recommended in all states with well-functioning PDMPs and where PDMP access policies make this practicable (e.g., clinician and delegate access permitted), but it is not currently possible in states without functional PDMPs or in those that do not permit certain prescribers to access them. As vendors and practices facilitate integration of PDMP information into regular clinical workflow (e.g., data made available in electronic health records), clinicians' ease of access in reviewing PDMP data is expected to improve.

In addition, improved timeliness of PDMP data will improve their value in identifying patient risks.

If patients are found to have high opioid dosages, dangerous combinations of medications, or multiple controlled substance prescriptions written by different clinicians, several actions can be taken to augment clinicians' abilities to improve patient safety:

- Clinicians should discuss information from the PDMP with their patient and confirm that the patient is aware of the additional prescriptions. Occasionally, PDMP information can be incorrect (e.g., if the wrong name or birthdate has been entered, the patient uses a nickname or maiden name, or another person has used the patient's identity to obtain prescriptions).
- Clinicians should discuss safety concerns, including increased risk for respiratory depression and overdose, with patients found to be receiving opioids from more than one prescriber or receiving medications that increase risk when combined with opioids (e.g., benzodiazepines) and consider offering naloxone (see Recommendation 8).
- Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care (see Recommendation 11).
- Clinicians should calculate the total MME/day for concurrent opioid prescriptions to help assess the patient's overdose risk (see Recommendation 5). If patients are found to be receiving high total daily dosages of opioids, clinicians should discuss their safety concerns with the patient, consider tapering to a safer dosage (see Recommendations 5 and 7), and consider offering naloxone (see Recommendation 8).
- Clinicians should discuss safety concerns with other clinicians who are prescribing controlled substances for their patient. Ideally clinicians should first discuss concerns with their patient and inform him or her that they plan to coordinate care with the patient's other prescribers to improve the patient's safety.
- Clinicians should consider the possibility of a substance use disorder and discuss concerns with their patient (see Recommendation 12).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal (see Recommendations 7 and 10). A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result (see Recommendation 10).

Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder [see Recommendation 12]).

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. Urine drug tests do not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain (KQ4). The contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care). Routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use. Although random drug testing also might destigmatize urine drug testing, experts thought that truly random testing was not feasible in clinical practice. Some clinics obtain a urine specimen at every visit, but only send it for testing on a random schedule. Experts noted that in addition to direct costs of urine drug testing, which often are not covered fully by insurance and can be a burden for patients, clinician time is needed to interpret, confirm, and communicate results.

Experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should

use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. There was some difference of opinion among experts as to whether this recommendation should apply to all patients, or whether this recommendation should entail individual decision making with different choices for different patients based on values, preferences, and clinical situations. While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up interval should be left to the discretion of the clinician. Previous guidelines have recommended more frequent urine drug testing in patients thought to be at higher risk for substance use disorder (*30*). However, experts thought that predicting risk prior to urine drug testing is challenging and that currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance use disorder.

In most situations, initial urine drug testing can be performed with a relatively inexpensive immunoassay panel for commonly prescribed opioids and illicit drugs. Patients prescribed less commonly used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard immunoassays or on the presence of unexpected urine drug test results. Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. For example, a positive "opiates" immunoassay detects morphine, which might reflect patient use of morphine, codeine, or heroin, but this immunoassay does not detect synthetic opioids (e.g., fentanyl or methadone) and might not detect semisynthetic opioids (e.g., oxycodone). However, many laboratories use an oxycodone immunoassay that detects oxycodone and oxymorphone. In some cases, positive results for specific opioids might reflect metabolites from opioids the patient is taking and might not mean the patient is taking the specific opioid for which the test was positive. For example, hydromorphone is a metabolite of hydrocodone, and oxymorphone is a metabolite of oxycodone. Detailed guidance on interpretation of urine drug test results, including which tests to order and expected results, drug detection time in urine, drug metabolism, and other considerations has been published previously (*30*). Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahyrdocannabinol (THC). In addition, restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of urine drug testing, given the substantial costs associated with confirmatory testing methods. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results. Clinicians should explain to patients that urine drug testing is intended to improve their safety and should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient). Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs. Clinicians should discuss unexpected results with the local laboratory or toxicologist and with the patient. Discussion with patients prior to specific confirmatory testing can sometimes yield a candid explanation of why a particular substance is present or absent and obviate the need for expensive confirmatory testing on that visit. For example, a patient might explain that the test is negative for prescribed opioids because she felt opioids were no longer helping and discontinued them. If unexpected results are not explained, a confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted to clarify the situation.

Clinicians should use unexpected results to improve patient safety (e.g., change in pain management strategy [see Recommendation 1], tapering or discontinuation of opioids [see Recommendation 7], more frequent re-evaluation [see Recommendation 7], offering naloxone [see Recommendation 8], or referral for treatment for substance use disorder [see Recommendation 12], all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper. Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently

whenever possible (recommendation category: A, evidence type: 3).

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. The clinical evidence review did not address risks of benzodiazepine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzodiazepine use in large proportions of opioid-related overdose deaths, and a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone (*212*). Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. In addition, given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9) and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants. Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first (see Recommendation 7). Clinicians should taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death (contextual evidence review). A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (*213*,*214*). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper (*213*). If benzodiazepines prescribed for anxiety are tapered or discontinued, or if patients receiving opioids require treatment for anxiety, evidence-based psychotherapies (e.g., CBT) and/or specific anti-depressants or other nonbenzodiazepine medications approved for anxiety should be offered. Experts emphasized that clinicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 2).

Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year (http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf) (*20*).

The clinical evidence review found prevalence of opioid dependence (using DSM-IV diagnosis criteria) in primary care settings among patients with chronic pain on opioid therapy to be 3%–26% (KQ2). As found in the contextual evidence review and supported by moderate quality evidence, opioid agonist or partial agonist treatment with methadone maintenance therapy or buprenorphine has been shown to be more effective in preventing relapse among patients with opioid use disorder (*151*–*153*). Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification (*154*,*155*); behavioral therapies are also recommended by clinical practice guidelines (*215*). The cited studies primarily evaluated patients with a history of illicit opioid use, rather than prescription opioid use for chronic pain. Recent studies among patients with prescription opioid dependence (based on DSM-IV criteria) have found maintenance therapy with buprenorphine and buprenorphine-naloxone effective in preventing relapse (*216*,*217*). Treatment need in a community is often not met by capacity to provide buprenorphine or methadone maintenance therapy (*218*), and patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited (*219*). Oral or long-acting injectable formulations of naltrexone can also be used as medication-assisted treatment for opioid use disorder in nonpregnant adults, particularly for highly motivated persons (*220*,*221*). Experts agreed that clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community and should work together to ensure sufficient treatment capacity for opioid use disorder at the practice level.

If clinicians suspect opioid use disorder based on patient concerns or behaviors or on findings in prescription drug monitoring program data (see Recommendation 9) or from urine drug testing (see Recommendation 10), they should discuss their concern with their patient and provide an opportunity for the patient to disclose related concerns or problems. Clinicians should assess for the presence of opioid use disorder using DSM-5 criteria (*20*). Alternatively, clinicians can arrange for a substance use disorder treatment specialist to assess for the presence of opioid use disorder. For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies. Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in non-pregnant adults. Naltrexone blocks the effects of opioids if they are used but requires adherence to daily oral therapy or monthly injections. For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine (without naloxone) or methadone has been associated with improved maternal outcomes and should be offered (see Recommendation 8). Clinicians should also consider offering naloxone for overdose prevention to patients with opioid use disorder (see Recommendation 8). For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids (see Recommendation 7). For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.

Physicians not already certified to provide buprenorphine in an office-based setting can undergo training to receive a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that allows them to prescribe buprenorphine to treat patients with opioid use disorder. Physicians prescribing opioids in communities without sufficient treatment capacity for opioid use disorder should strongly consider obtaining this waiver. Information about qualifications and the process to obtain a waiver are available from SAMHSA (*222*). Clinicians do not need a waiver to offer naltrexone for opioid use disorder as part of their practice.

Additional guidance has been published previously (*215*) on induction, use, and monitoring of buprenorphine treatment (see Part 5) and naltrexone treatment (see Part 6) for opioid use disorder and on goals, components of, and types of effective psychosocial treatment that are recommended in conjunction with pharmacological treatment of opioid use disorder (see Part 7). Clinicians unable to provide treatment themselves should arrange for patients with opioid use disorder to receive care from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider, or from an opioid treatment program certified by SAMHSA to provide supervised medication-assisted treatment for patients with opioid use disorder. Clinicians should assist patients in finding qualified treatment providers and should arrange for patients to follow up with these providers, as well as arranging for ongoing coordination of care. Clinicians should not dismiss patients from their practice because of a substance use disorder because this can adversely affect patient safety and could represent patient abandonment. Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment. In addition, although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use nonpharmacologic and nonopioid pharmacologic pain treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to provide optimal pain management.

Resources to help with arranging for treatment include SAMHSA's buprenorphine physician locator (http://buprenorphine.samhsa.gov/bwns_locator); SAMHSA's Opioid Treatment Program Directory (http://dpt2.samhsa.gov/treatment/directory.aspx); SAMHSA's Provider Clinical Support System for Opioid Therapies (http://pcss-o.org), which offers extensive experience in the treatment of substance use disorders and specifically of opioid use disorder, as well as expertise on the interface of pain and opioid misuse; and SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (http://pcssmat.org), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings. CDC will translate this guideline into user-friendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and clinicians and engage in dissemination efforts. CDC has provided a

checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025), additional resources such as fact sheets (http://www.cdc.gov/drugoverdose/prescribing/resources.html), and will provide a mobile application to guide clinicians in implementing the recommendations. CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic health records to assist clinicians' treatment decisions at the point of care; identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice. In addition, policy initiatives that address barriers to implementation of the guidelines, such as increasing accessibility of PDMP data within and across states, e-prescribing, and availability of clinicians who can offer medication-assisted treatment for opioid use disorder, are strategies to consider to enhance implementation of the recommended practices. CDC will work with federal partners and payers to evaluate strategies such as payment reform and health care delivery models that could improve patient health and safety. For example, strategies might include strengthened coverage for nonpharmacologic treatments, appropriate urine drug testing, and medication-assisted treatment; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care.

As highlighted in the forthcoming report on the National Pain Strategy, an overarching federal effort that outlines a comprehensive population-level health strategy for addressing pain as a public health problem, clinical guidelines complement other strategies aimed at preventing illnesses and injuries that lead to pain. A draft of the National Pain Strategy has been published previously (*180*). These strategies include strengthening the evidence base for pain prevention and treatment strategies, reducing disparities in pain treatment, improving service delivery and reimbursement, supporting professional education and training, and providing public education. It is important that overall improvements be made in developing the workforce to address pain management in general, in addition to opioid prescribing specifically. This guideline also complements other federal efforts focused on addressing the opioid overdose epidemic including prescriber training and education, improving access to treatment for opioid use disorder, safe storage and disposal programs, utilization management mechanisms, naloxone distribution programs, law enforcement and supply reduction efforts, prescription drug monitoring program improvements, and support for community coalitions and state prevention programs.

This guideline provides recommendations that are based on the best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. To inform future guideline development, more research is necessary to fill in critical evidence gaps. The evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy. As highlighted by an expert panel in a recent workshop sponsored by the National Institutes of Health on the role of opioid pain medications in the treatment of chronic pain, "evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain" (*223*). The National Institutes of Health panel recommended that research is needed to improve our understanding of which types of pain, specific diseases, and patients are most likely to be associated with benefit and harm from opioid pain medications; evaluate multidisciplinary pain interventions; estimate cost-benefit; develop and validate tools for identification of patient risk and outcomes; assess the effectiveness and harms of opioid pain medications with alternative study designs; and investigate risk identification and mitigation strategies and their effects on patient and public health outcomes. It is also important to obtain data to inform the cost feasibility and cost-effectiveness of recommended actions, such as use of nonpharmacologic therapy and urine drug testing. Research that contributes to safer and more effective pain treatment can be implemented across public health entities and federal agencies (*4*). Additional research can inform the development of future guidelines for special populations that could not be adequately addressed in this guideline, such as children and adolescents, where evidence and guidance is needed but currently lacking. CDC is committed to working with partners to identify the highest priority research areas to build the evidence base. Yet, given that chronic pain is recognized as a significant public health problem, the risks associated with long-term opioid therapy, the availability of effective nonpharmacological and nonopioid pharmacologic treatment options for pain, and the potential for improvement in the quality of health care with the implementation of recommended practices, a guideline for prescribing is warranted with the evidence that is currently available. The balance between the benefits and the risks of long-term opioid therapy for chronic pain based on both clinical and contextual evidence is strong enough to support the issuance of category A recommendations in most cases.

CDC will revisit this guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the guideline. Until this research is conducted, clinical practice guidelines will have to be based on the best available evidence and expert opinion. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

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TABLE 1. Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness and comparative effectiveness (KQ1)							
Effectiveness of long-term opioid therapy versus placebo or no opioid therapy for long-term (≥1 year) outcomes							
Pain, function, and quality of life	None	—[†]	—	—	Insufficient	—	No evidence
Harms and adverse events (KQ2)							
Risks of opioids versus placebo or no opioids on opioid abuse, addiction, and related outcomes; overdose; and other harms							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found long-term use of prescribed opioids associated with an increased risk of abuse or dependence diagnosis versus no opioid use (adjusted OR ranged from 14.9 to 122.5, depending on dose).
Abuse or addiction	10 uncontrolled studies (n = 3,780)	Very serious limitations	Very serious inconsistency	No imprecision	4	None identified	In primary care settings, prevalence of opioid abuse ranged from 0.6% to 8% and prevalence of dependence from 3% to 26%. In pain clinic settings, prevalence of misuse ranged from 8% to 16% and addiction from 2% to 14%. Prevalence of aberrant drug-related behaviors ranged from 6% to 37%.
Overdose	1 cohort study (n = 9,940)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Current opioid use associated with increased risk of any overdose events (adjusted HR 5.2, 95% CI = 2.1–12) and serious overdose events (adjusted HR 8.4, 95% CI = 2.5–28) versus current nonuse.
Fractures	1 cohort study (n = 2,341) and 1 case–control study (n = 21,739 case patients)	Serious limitations	No inconsistency	No imprecision	3	None identified	Opioid use associated with increased risk of fracture in 1 cohort study (adjusted HR 1.28, 95% CI = 0.99–1.64) and 1 case-control study (adjusted OR 1.27, 95% CI = 1.21–1.33).
Myocardial infarction	1 cohort study (n = 426,124) and 1 case–control study (n = 11,693 case patients)	No limitations	No inconsistency	No imprecision	3	None identified	Current opioid use associated with increased risk of myocardial infarction versus nonuse (adjusted OR 1.28, 95% CI = 1.19–1.37 and incidence rate ratio 2.66, 95% CI = 2.30–3.08).
Endocrinologic harms	1 cross-sectional study (n = 11,327)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Long-term opioid use associated with increased risk for use of medications for erectile dysfunction or testosterone replacement versus nonuse (adjusted OR 1.5, 95% CI = 1.1–1.9).
How do harms vary depending on the opioid dose used?							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found higher doses of long-term opioid therapy associated with increased risk of opioid abuse or dependence than lower doses. Compared to no opioid prescription, the adjusted odds ratios were 15 (95% CI = 10–21) for 1 to 36 MME/day, 29 (95 % CI = 20–41) for 36 to120 MME/day, and 122 (95 % CI = 73–205) for ≥120 MME/day.
Overdose	1 cohort study (n = 9,940) and 1 case–control study (n = 593 case patients in primary analysis)	Serious limitations	No inconsistency	No imprecision	3	Magnitude of effect, dose response relationship	Versus 1 to <20 MME/day, one cohort study found an adjusted HR for an overdose event of 1.44 (95% CI = 0.57–3.62) for 20 to <50 MME/day that increased to 8.87 (95% CI = 3.99–19.72) at ≥100 MME/day; one case-control study found an adjusted OR for an opioid-related death of 1.32 (95% CI = 0.94–1.84) for 20 to 49 MME/day that increased to 2.88 (95% CI = 1.79–4.63) at ≥200 MME/day.
Fractures	1 cohort study (n = 2,341)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Risk of fracture increased from an adjusted HR of 1.20 (95% CI = 0.92–1.56) at 1 to <20 MME/day to 2.00 (95% CI = 1.24–3.24) at ≥50 MME/day; the trend was of borderline statistical significance.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Myocardial infarction	1 cohort study (n = 426,124)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Relative to a cumulative dose of 0 to 1,350 MME during a 90-day period, the incidence rate ratio for myocardial infarction for 1350 to <2700 MME was 1.21 (95% CI = 1.02–1.45), for 2,700 to <8,100 MME was 1.42 (95% CI = 1.21–1.67), for 8,100 to <18,000 MME was 1.89 (95% CI = 1.54–2.33), and for ≥18,000 MME was 1.73 (95% CI = 1.32–2.26).
Motor vehicle crash injuries	1 case–control study (n = 5,300 case patients)	No limitations	Unknown (1 study)	No imprecision	3	None identified	No association between opioid dose and risk of motor vehicle crash injuries even though opioid doses >20 MME/day were associated with increased odds of road trauma among drivers.
Endocrinologic harms	1 cross-sectional study (n = 11,327) New for update: 1 additional cross-sectional study (n=1,585)	Serious limitations	Consistent	No imprecision	3	None identified	Relative to 0 to <20 MME/day, the adjusted OR for ≥120 MME/day for use of medications for erectile dysfunction or testosterone replacement was 1.6 (95% CI = 1.0–2.4). One new cross-sectional study found higher-dose long-term opioid therapy associated with increased risk of androgen deficiency among men receiving immediate-release opioids (adjusted OR per 10 MME/day 1.16, 95% CI = 1.09–1.23), but the dose response was very weak among men receiving ER/LA opioids.
Dosing strategies (KQ3)							
Comparative effectiveness of different methods for initiating opioid therapy and titrating doses							
Pain	3 randomized trials (n = 93)	Serious limitations	Serious inconsistency	Very serious imprecision	4	None identified	Trials on effects of titration with immediate-release versus ER/LA opioids reported inconsistent results and had additional differences between treatment arms in dosing protocols (titrated versus fixed dosing) and doses of opioids used.
Overdose	New for update: 1 cohort study (n = 840,606)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One new cross-sectional study found initiation of therapy with an ER/LA opioid associated with increased risk of overdose versus initiation with an immediate-release opioid (adjusted HR 2.33, 95% CI = 1.26–4.32).
Comparative effectiveness of different ER/LA opioids							
Pain and function	3 randomized trials (n = 1,850)	Serious limitations	No inconsistency	No imprecision	3	None identified	No differences
All-cause mortality	1 cohort study (n = 108,492) New for update: 1 cohort study (n = 38,756)	Serious limitations	Serious inconsistency	No imprecision	4	None identified	One cohort study found methadone to be associated with lower all-cause mortality risk than sustained-release morphine in a propensity-adjusted analysis (adjusted HR 0.56, 95% CI = 0.51–0.62) and one cohort study among Tennessee Medicaid patients found methadone to be associated with higher risk of all-cause mortality than sustained-release morphine (adjusted HR 1.46, 95% CI = 1.17–1.73).
Abuse and related outcomes	1 cohort study (n = 5,684)	Serious limitations	Unknown (1 study)	Serious imprecision	4	None identified	One cohort study found some differences between ER/LA opioids in rates of adverse outcomes related to abuse, but outcomes were nonspecific for opioid-related adverse events, precluding reliable conclusions.
ER/LA versus immediate-release opioids							
Endocrinologic harms	New for update: 1 cross-sectional study (n = 1,585)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One cross-sectional study found ER/LA opioids associated with increased risk of androgen deficiency versus immediate-release opioids (adjusted OR 3.39, 95% CI = 2.39–4.77).

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Dose escalation versus dose maintenance or use of dose thresholds							
Pain, function, or withdrawal due to opioid misuse	1 randomized trial (n = 140)	Serious limitations	Unknown (1 study)	Very serious imprecision	3	None identified	No difference between more liberal dose escalation versus maintenance of current doses in pain, function, or risk of withdrawal due to opioid misuse, but there was limited separation in opioid doses between groups (52 versus 40 MME/day at the end of the trial).
Immediate-release versus ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled and continuous versus as-needed dosing of opioids; or opioid rotation versus maintenance of current therapy							
Pain, function, quality of life, and outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of decreasing or tapering opioid doses versus continuation of opioid therapy							
Pain and function	1 randomized trial (n = 10)	Very serious limitations	Unknown (1 study)	Very serious imprecision	4	None identified	Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine.
Comparative effectiveness of different tapering protocols and strategies							
Opioid abstinence	2 nonrandomized trials (n = 150)	Very serious limitations	No inconsistency	Very serious imprecision	4	None identified	No clear differences between different methods for opioid discontinuation or tapering in likelihood of opioid abstinence after 3–6 months
Risk assessment and risk mitigation strategies (KQ4)							
Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse among patients with chronic pain being considered for long-term opioid therapy							
Opioid risk tool	3 studies of diagnostic accuracy (n = 496) New for update: 2 studies of diagnostic accuracy (n = 320)	Serious limitations	Very serious inconsistency	Serious imprecision	4	None identified	Based on a cutoff score of >4 (or unspecified), five studies (two fair-quality, three poor-quality) reported sensitivity that ranged from 0.20 to 0.99 and specificity that ranged from 0.16 to 0.88.
Screener and Opioid Assessment for Patients with Pain, Version 1	2 studies of diagnostic accuracy (n = 203)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of ≥8, sensitivity was 0.68 and specificity was 0.38 in one study, for a positive likelihood ratio of 1.11 and a negative likelihood ratio of 0.83. Based on a cutoff score of >6, sensitivity was 0.73 in one study.
Screener and Opioid Assessment for Patients with Pain-Revised	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of >3 or unspecified, sensitivity was 0.25 and 0.53 and specificity was 0.62 and 0.73 in two studies, for likelihood ratios close to 1.
Brief Risk Interview	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a "high risk" assessment, sensitivity was 0.73 and 0.83 and specificity was 0.43 and 0.88 in two studies, for positive likelihood ratios of 1.28 and 7.18 and negative likelihood ratios of 0.63 and 0.19.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of opioid therapy for acute pain on long-term use (KQ5)							
Long-term opioid use	New for update: 2 cohort studies (n = 399,852)	Serious limitations	No inconsistency	No imprecision	3	None identified	One study found use of opioids within 7 days of low-risk surgery associated with increased likelihood of opioid use at 1 year (adjusted OR 1.44, 95% CI = 1.39–1.50), and one study found use of opioids within 15 days of onset of low back pain among workers with a compensation claim associated with increased risk of late opioid use (adjusted OR 2.08, 95% CI = 1.55–2.78 for 1 to 140 MME/day and OR 6.14, 95% CI = 4.92–7.66 for ≥450 MME/day).

Abbreviations: CI = confidence interval; ER/LA = extended release/long-acting; HR = hazard ratio; MME = morphine milligram equivalents; OR = odds ratio.
* Ratings were made per GRADE quality assessment criteria; "no limitations" indicates that limitations assessed through the GRADE method were not identified.
† Not applicable as no evidence was available for rating.

TABLE 2. Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf).

* Multiply the dose for each opioid by the conversion factor to determine the dose in MMEs. For example, tablets containing hydrocodone 5 mg and acetaminophen 300 mg taken four times a day would contain a total of 20 mg of hydrocodone daily, equivalent to 20 MME daily; extended-release tablets containing oxycodone 10mg and taken twice a day would contain a total of 20mg of oxycodone daily, equivalent to 30 MME daily. The following cautions should be noted: 1) All doses are in mg/day except for fentanyl, which is mcg/hr. 2) Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics. 3) Do not use the calculated dose in MMEs to determine the doses to use when converting opioid to another; when converting opioids the new opioid is typically dosed at substantially lower than the calculated MME dose to avoid accidental overdose due to incomplete cross-tolerance and individual variability in opioid pharmacokinetics. 4) Use particular caution with methadone dose conversions because the conversion factor increases at higher doses. 5) Use particular caution with fentanyl since it is dosed in mcg/hr instead of mg/day, and its absorption is affected by heat and other factors.

† Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

Please note: An erratum has been published for this issue. To view the erratum, please click here.

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Pain Treatment Guidelines

A Provider and Community Resource

OPG

OREGON PAIN GUIDANCE

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INTRODUCTION

For the past few decades, a conceptual shift has taken place regarding the treatment of chronic pain. Opioids have been encouraged for the treatment of all types of pain. In particular, chronic non-cancer pain was suggested as a treatable condition necessitating long-acting medications, without solid scientific evidence supporting that practice. As a society, we are reaping the consequences of that change in prescribing habits with an increase in opioid dependency, accidental drug overdoses, and heroin use. The expectation on the part of the public that there is a pill to be prescribed for any discomfort is harder to quantify but no less important.[1,2,3]

The community consequences of excessive opioid prescribing are manifest. In addition to the mortality and quality-of-life consequences previously mentioned, we are facing an increase in communicable diseases associated with substance-use disorders (HIV, hepatitis, syphilis), strains on the court system and treatment programs, and a "lost generation" of patients dependent upon opioids who are a challenge to treat humanely and effectively.

The message embodied in this document is that opioids are powerful drugs that can create calm and relief when used wisely but can cause great harm when prescribed injudiciously. Every encounter with a patient in pain will require the same analysis, and patient safety should guide all treatment recommendations.

- What is the etiology of the pain, and would non-opioid treatment suffice?
- Are there risk factors present that would make the use of opioids unsafe for this patient?
- What is the usual expectation for pain for this condition? Is my patient's response outside that expected range?
- Is there a medical justification for this dose of opioid, for this length of time, for this condition, in this patient?

Practicing outside those parameters puts your patient, or your patient's family, or the community at large, at risk. Too many pills prescribed for a given situation can create dependency in your patient, or if they are stolen or diverted, can feed the illicit habit of others.

This is an iatrogenic public health crisis, and all of us in the healthcare profession have to assume responsibility in fixing it.[4]

The Oregon Pain Guidance Group (OPG)

In southern Oregon, we have been working on a community response to this opioid crisis for several years. We continue to adjust our recommendations as information concerning safe practice evolves. For example, we now advocate prescribing less than 50 mg/d MED (morphine equivalent dose), and a ceiling of 90 mg/d MED, rather than the 120 mg/d MED mentioned in our previous version. Likewise, we have reduced the maximum safe methadone dose from 40 mg/d to 30 mg/d, reflecting the increase in overdose deaths associated with methadone use for pain treatment.

To achieve genuine and lasting practice change, our entire community has to be educated concerning our current understanding of the appropriate management of pain. All of us need to understand the science that underlies current best-practice recommendations. Our patients and families need to hear the same message. We felt the best approach would be to promote a grassroots effort, achieving regional, broad support for these guidelines. Providers would share common understanding, our patients would hear a consistent message, and the community at large would support these efforts.

The OPG is a group of physicians, nurse practitioners, physician assistants, nurses, pharmacists, medical directors, insurance providers, emergency room providers, pain medicine specialists, mental health counselors, substance abuse professionals, public health professionals, and others. We are a large group of 200+ individuals. We average 40 attendees from Southern Oregon who meet monthly by videoconference. We hold monthly Continuing Medical Education (CME) supported meetings over dinner, and have an agenda that is set by a steering committee that meets every two weeks. Our group process has evolved over the past five years, but includes didactic learning, small group discussion, case presentations, and updates on community activities. The OPG group—and in particular the steering committee—promotes community education, our annual pain conference, the website, and the production of these guidelines.

OPG Guidelines Authors and Contributors

With the release of the CDC guidelines,[5] we have focused our attention on operationalizing these nationally recognized best practices. Our goal in the development of the revised OPG guidelines is to provide real-world tools and advice to practicing clinicians as they seek to comply with this excellent national guidance document. The OPG guidelines have been influenced by the work of the Washington State Medical Directors Group,[6] the CDC, and many other leaders in the state of Oregon and nationally in the field of safe opioid prescribing. These guidelines have been debated and edited by our colleagues in the OPG and elsewhere, and not every participant agrees with every component of this document. We have created the OPG guidelines for everyone who manages patients with pain: prescribers, behavioral professionals, those who dispense pain medications, and those who pay for them.

Credit for the creation of these guidelines belongs first to the members of the OPG group who developed a series of OPG guidelines over several years that reflected agreed community standards of care. The last major release was two years ago in 2014. Since that time, two major guidelines have been released, the Washington state AMDG guidelines (June 2015) and the CDC guidelines (March 2016). We have done our best to incorporate and be consistent with recommendations in both these guidelines.

The majority of the drafting and revisions were done by three individuals: Jim Shames, MD, Medical Director and Health Officer of Jackson County Health and Human Services; John Kolsbun, MD, Medical Director of AllCare Health, and Mark Stephens, a healthcare consultant. Other significant contributors were Laura Heesacker, LCSW; Sara Smith, RN; Rachel Vossen, PharmD; Mark Kantor, RPh; and Paul Coelho, MD; as well as other members of the OPG group who added additional content. Other experts in “Pain” have reviewed and commented on these guidelines as well. We are very grateful for all the contributors who helped produce these guidelines.

CDC Guidelines

In March 2016, the CDC issued new guidelines on opioid prescribing.[5] The importance of these guidelines cannot be overstated as they establish national recommendations for the use of opioids for treatment of chronic pain. We completely support and endorse these new guidelines. This is a summary of the 12 CDC recommendations. We have modified the OPG guidelines to ensure they are in compliance with and support these guidelines.

Determining when to initiate or continue opioids for chronic pain

1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid selection, dosage, duration, follow-up, and discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MED) per day, and should avoid increasing dosage to ≥90 MED/day or carefully justify a decision to titrate dosage to ≥90 MED/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or fewer will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing risk and addressing harms of opioid use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance-use disorder, higher opioid dosages (≥50 MED/day), or concurrent benzodiazepine use are present.
9. Clinicians should review the patient's history of controlled-substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put the patient at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug screening before starting opioid therapy and consider urine drug screening at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines (BZPs) concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid-use disorder.

Axioms of Pain Treatment

The Axioms of Pain Treatment are a contribution from Gary Franklin, MD, MPH, University of Washington and Michael Von Korff, Senior Investigator, Group Health Research Institute. It provides current best practices regarding acute and chronic pain management. Along with the Chronic Pain, Acute Pain, and Tapering Flow Sheets, we hope to bring tools to the practicing clinician that make compliance with appropriate pain management accessible and easy to follow.

Acute pain

- For most injuries and minor procedures (e.g., dental extraction, sports injuries), prescribe no more than a three-day supply or 10 doses of a short-acting opioid.
- For more severe injuries (e.g., fractures), prescribe no more than a seven-day supply of a short-acting opioid.
- Do not prescribe extended-release opioids for acute pain.

Chronic conditions with acute pain flares

- Do not use opioids for acute flares of non-specific musculoskeletal pain, headaches, or fibromyalgia.
- For acute flares of other chronic conditions (e.g., osteoarthritis, sickle cell anemia), limit prescribing to a three-day supply of a short-acting opioid. In rare instances, up to a seven-day supply may be appropriate.
- Check the state Prescription Drug Monitoring Program (PDMP) with any first opioid prescription.

Subacute (6–12 weeks) opioid use and transition to chronic opioid therapy (>12 weeks)

- Don't start long-term use of opioids without a visit devoted to evaluation of suitability of long-term opioid use and discussion of all opioid risks and realistic expectations of benefits.
- Use non-opioid alternatives (non-opioid analgesics, graded exercise, cognitive behavioral therapy, mindfulness, and relaxation techniques).
- Unless opioid use has resulted in clinically meaningful improvement in pain and function (at least 30% improvement documented with validated instruments), discontinue prescribing.
- If opioid use results in clinically meaningful improvement in pain and function, use best-practice screenings (e.g., UDS substance-use disorder, depression, PDMP) for opioid-related risks. Assess signs of prescription opioid-use disorder by asking the patient or family members about history of substance abuse. Discuss risks and benefits of long-term opioid use and document via a signed informed consent form.
- At every prescribing visit for opioids, the total opioid dose should be recorded using an online calculator and measures of pain and function using brief validated instruments.

Chronic opioid use (>12 weeks)

- Do not prescribe chronic opioids for non-specific musculoskeletal pain, headache or fibromyalgia.
- Do not combine opioids with benzodiazepines, muscle relaxants, or sedative hypnotics.

- Repeat PDMP check and urine drug screen (UDS) periodically, based on risk.
- Avoid exceeding 90 mg/day MED. For patients with one or more risk factors (e.g., history of substance-use disorder, tobacco users, mental health disorders, cannabis-use disorder), do not prescribe more than 50 mg/day MED.
- Non-pharmacological alternatives to opioids should be used and incented for most chronic-pain conditions, especially multimodal use of reactivation methods (e.g., graded exercise, activity diaries, mindfulness, and relaxation techniques) in combination with brief interventions, such as cognitive behavioral therapy, that can effectively address psychosocial barriers to recovery (e.g., fear avoidance, catastrophizing, low expectations of recovery).
- Periodically ask if the patient would like to consider trying a gradual opioid taper to reduce dose or discontinue use.

Tapering chronic opioid therapy

- Discontinue opioids if patient has not achieved clinically meaningful improvement, had an overdose event, develops a serious adverse outcome (e.g., endocrine dysfunction, severe dependence or opioid-use disorder), demonstrates aberrant behaviors or requests a taper.
- Tapering to zero can be accomplished in most cases by reducing the dose up to 10% per week, with pauses as needed, with or without adjuvant medications (e.g., clonidine, buprenorphine)
- A list of helpful medications to help decrease many of the side effects of opioid tapering is in Appendix R, Opioid Withdrawal Attenuation Cocktail.
- Refer patients with symptoms of severe dependence or opioid-use disorder for evaluation and treatment. If indicated, help patients get medication-assisted treatment along with behavioral therapy.

Perioperative opioid use

- For patients on chronic opioid therapy, develop a coordinated treatment plan, including a timeline for tapering opioids post-operatively. Doses by six weeks post-operatively should not exceed preoperative doses.
- For minor surgeries (e.g., carpal tunnel release), discharge patients with acetaminophen, NSAIDs, or a limited supply (two or three days) of short-acting opioids.
- For patients undergoing elective surgery who are opioid naïve, opioids should only be prescribed if required to manage severe pain and they should be discontinued as soon as pain is tolerable (not when the patient is pain-free), no later than six weeks post-operatively.

Team Approach to Pain Management

As you read this document, it should become clear that chronic pain management can be challenging—and rewarding. The evaluation requires attention to history and physical findings as well as the use of assessment tools that may require additional time to administer and interpret. Treatment often utilizes behavioral, motivational and other ancillary modalities. Follow-up requires attention to safety monitoring such as PDMP, UDS, and pill counts. Most experts agree that pain management is best accomplished in a team-based care model, not unlike the approach of the treatment of other chronic diseases such as diabetes, congestive heart failure, and the like.

Larger clinics can access nurses, counselors, OT/PT, and peers within their organization. Smaller medical practices should develop strong relationships with local specialists who have expertise in the treatment of pain.

Just as your patients often need help from their support network, providers also need help from others to institute the chronic disease model of care in the management of chronic pain.

How to Use these Guidelines

We understand that practitioners providing care for individuals living with pain need readily accessible guidance and simple best-practice management tools. This document has been created for these practitioners.

The OPG Guidelines are divided into sections that can stand alone for quick reference. In this document, we tried to address the real-world situations practitioners face in daily patient care.

We encourage healthcare organizations large and small to use these tools along with other excellent resources, many of which are referenced in this document, to create treatment guidelines of their own. On request, we are happy to provide a Microsoft Word version of this document.

Treatment and tapering flow sheets

There are four flow sheets that can be laminated and used as a quick reference for the most common situations you encounter. They are the treatment essentials for Acute Pain (page 15), Chronic Pain (page 21), Opioid Tapering (page 44), and Benzodiazepine Tapering (page 48). Each of these flow sheets has a corresponding section in the document that provides more in-depth guidance if needed.

Tools

We have collected tools that are useful to the practicing clinician and placed them in the appendices of this document. In addition, they may be printed directly from the website in the Tools section.

Website

Beyond the OPG guidelines, the website can serve as an up-to-date resource for you as well as your patients. Links to other guidelines, videos, scholarly articles, events, news stories, and more are all accessible through www.oregonpainguidance.org.

Permission for reprints

An electronic copy of these guidelines is available on the OPG website. We give permission for anyone to download the PDF and reprint copies.

Morphine Equivalent Dose (MED)

MED is referred to in this document frequently. MED calculators (not all of which agree with each other) can help you determine the dosage equivalency of one opioid when compared to another. It is wise to use MED calculations very conservatively and use 25 to 50% of the calculated dose when switching between opioids.

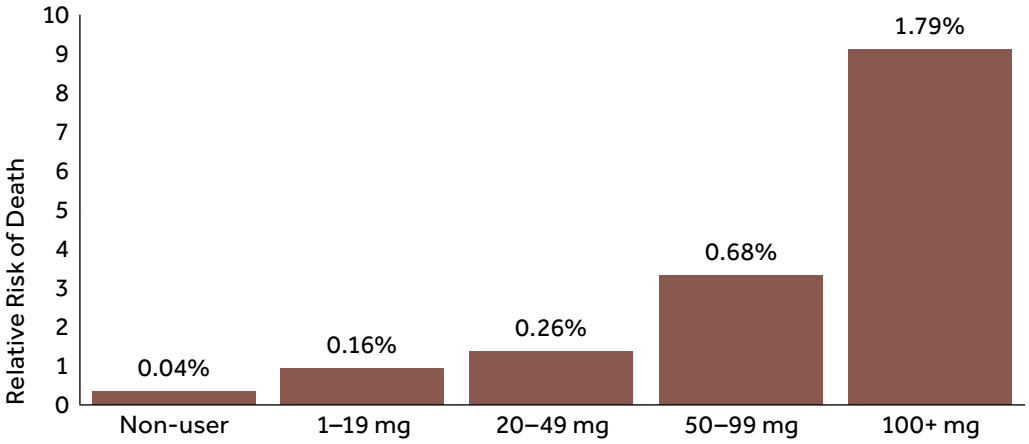
When using such calculators, be aware that methadone is a complex drug in terms of its metabolism. As the dose escalates, the MED escalates in an accelerated fashion. It is critical to understand methadone's unique MED status to safely switch between methadone and other opioids, and vice versa.

The following graph illustrates the importance of keeping your patient's MED as low as possible. It is also reveals the logic behind the CDC recommended opioid dose ceiling of 50 mg/d MED.

The Importance of MED

Significant Increment in Risk p<0.05

Source: Dunn et al, Annals of Int Med, 2010



MED for Selected Opioids

Opioid	Approximate Equianalgesic Dose (oral and transdermal)
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Methadone Chronic	4mg
Oxycodone	20mg
Oxymorphone	10mg
Tapentodol	75mg
Tramadol	300mg

An electronic MED calculator is available at: www.agencymeddirectors.wa.gov/Files/DosingCalc.xls.

Risk Stratification

Separating your patients into high, medium, and low-risk categories is a common approach to determining the level of scrutiny to apply to a given individual. The advantage to risk stratification is that it allows you to provide additional scrutiny to individuals who are more likely to fail opioid therapy. The disadvantage is that all chronic opioid therapy (COT) patients are at risk for complications of treatment and risk-stratifying your patients may provide a false sense of security to the clinician. Here are some generally accepted guidelines:

Red flags or conditions that require additional scrutiny on the part of the provider (Source: David Tauben, MD, Chief of Pain Medicine at the University of Washington):

Red flags upon intake

- Evidence of PDMP irregularities
- Benzodiazepine use
- Use of two or more psychoactive drugs
- Methadone use
- Buprenorphine use
- MED ≥ 90
- History of prior non-fatal overdose
- History of current or active opioid or substance abuse
- Opioid Risk Tool (ORT) ≥8
- Active alcohol misuse by AUDIT-3
- Patients with severe depression (PHQ-9 ≥15), anxiety (GAD-7 ≥12), or PTSD (PC-PTSD >2)
- Patients with a listed diagnosis in the medical record of bipolar disorder, personality disorder, or schizophrenia

Current patient red flags

- Losing prescriptions, running out early or borrowing opioids
- Illicit use of prescription or use of illicit substances
- Running out of medication early
- Recurring ED visits
- Demanding opioids
- Obtaining opioids from multiple prescribers
- Multiple pharmacies used
- Unexpected UDS results
- Non-compliance with clinic policies

Response to red flags

- If continued prescribing puts your patient at risk or puts you at risk of violating the law, then you may need to discontinue prescribing immediately.
- You rarely will need to "fire" a patient from your practice. You can discontinue prescribing while still maintaining a therapeutic and professional relationship.
- Increased scrutiny is often helpful to delineate whether you are dealing with substance-use disorder versus other treatment issues. This may be useful:
  - Increasing the frequency of UDS
  - Instituting pill counts and/or "callbacks" (asking a patient to return to the clinic within 24 hours to evaluate and count remaining medication)
  - Frequent query of the PDMP
  - Increase the prescription refill frequency

TREATING ACUTE PAIN
(0–7 Days Following Trauma or Surgery)

In most cases, acute pain can be treated effectively with non-opioid or non-pharmacological options (e.g., elevation, ice). With more severe acute injury (e.g., significant trauma, fracture, crush injury, postoperative pain, extensive burns), short-term use of opioids may be appropriate. Initial opioid prescriptions should not exceed seven days for most situations, and two to three days of opioid medication will often suffice.[7,8,9,10,11] If an individual needs medication beyond three days (or beyond the average expected time for initial healing) a reevaluation of the patient should be performed prior to further opioid prescribing. Physical dependence on opioids can occur within only a few weeks of continuous use, so great caution needs to be exercised during this critical recovery period.

Assessment

- Review medical history, including records from previous providers, when available.
- Administer a physical exam to determine diagnosis and appropriate care. Document baseline function and baseline pain.
- Determine whether the injury can be treated without opioids or if the severity of the injury justifies the risks of opioid therapy.

Non-Opioid Treatment

- Help patients set reasonable expectations concerning recovery from the injury. Educate them about the healing process and the benefits of appropriate activity.
- Reassure the patient that some pain is to be expected and that it will subside in time. Over-the-counter (OTC) medications will provide significant relief from pain in many situations and can be relied upon for ongoing pain relief after the acute period is over.
- Patients should improve in function and pain and resume their normal activities in a matter of days to weeks, depending upon the diagnosis. Reevaluate those who do not follow the normal course of recovery.

Opioid Treatment

- If the severity of the injury indicates that limited opioid treatment is appropriate, *before prescribing,* you:
  - Should perform a simple screen for substance abuse (e.g., ORT). Individuals in active recovery are at high risk of being "triggered" by even small amounts of opioids, and you can inadvertently put them in harm's way with your prescription. Those with a history of attempted suicide or overtaking opioids should be prescribed the least amount of medication necessary.

- Should identify other prescribed medications or conditions that would preclude co-prescribing opioids. Benzodiazepines have a synergistic effect with opioids.[12]
- Must inform the patient about the risks and side effects of opioids. Many young people who became dependent on opioids say they never were informed of its risks.
- May want to have the patient sign a treatment agreement if the patient returns requesting a refill of opioids. A urine drug screen and PDMP query should be performed prior to writing the second prescription. Continued prescribing might indicate the need for the patient to sign a treatment agreement.

› Opioid prescriptions should be for the shortest appropriate period of time, usually two to three days of treatment post injury or surgery, followed by over-the-counter treatments if further medications are indicated.

› Opioid overprescribing puts your patients at risk. Four out of five recent heroin initiates (79.5 percent) previously used prescription pain killers.[13]

› Some major surgeries, injuries, and certain disease states may require longer periods of opioid treatment. Justification for prescribing outside the guidelines should be documented in the patient record.

› If pain continues, a reevaluation is usually indicated because:

- Pain beyond the expected timeframe may indicate a complication (e.g., infection, re-injury, displacement, dehiscence).
- Complaint of ongoing pain may indicate an unrecognized substance-use disorder, which may require greater scrutiny and an alternative treatment modality.

› At each follow-up visit, assess and document pain and function, educate the patient on the importance of self-management and appropriate activity.

Patient Instructions

› Dosage instructions need to clear. PRN prescribing should be only as liberal as necessary, as it can lead to inadvertent large doses (e.g., hydrocodone/acetaminophen 5/325 one to two every three to six hours can be as much as 50 mg MED a day—a lot of medication for an opioid-naïve individual).

› The number of pills you prescribe sets up "dosing expectations" for the patient. Prescribing #40 pills for a time-limited painful experience may send an inadvertent message to the patient, giving permission for the casual use of opioids.

Tools

› Screening tools for substance abuse: ORT (Appendix A), and SOAPP-R (Appendix B)

› Screening tools for function: Oswestry Disability Index (ODI) (Appendix M) and PEG-3 (Krebs et al 2009) (Appendix N)

› Screening tools for co-occurring mental health conditions: PHQ-4, GAD-7

› Prescription Drug Monitoring Program (PDMP) (See http://www.orpdmp.com/PDMP_2015v02262015.pdf, page 15)

Acute Pain Flow Sheet

FOR THE EVALUATION AND TREATMENT OF ACUTE PAIN

Begin

ASSESSMENT

- Patient presents after an acute injury (trauma, surgical procedure).
- Evaluate the clinical situation and determine your expected recovery time based on clinical evaluation, literature, your experience, and the patient's general condition.
- Educate the patient regarding expectations for healing and duration and intensity of pain. Some pain is to be expected, and it will diminish over time.

Green Light

NON-OPIOID OPTIONS

- Advise appropriate behavioral modifications, for example, initial rest followed by graded exercise of the affected body area.
- Provide external pain-reducing modalities, for example, immobilization, heat/cold, and elevation.
- Advise appropriate OTC medications with specific medications, doses, and duration, as you would any pharmacologic modality.

Caution

OPIOID TREATMENT

- If considering opioids, first ask about risks for opioid misuse, for example, previous addiction history, overdose history, and suicidality.
- If opioids are contraindicated, clearly state to the patient and document in the chart note that the risks of treatment overshadow the benefits. Stress other modalities of pain modification.
- When prescribing opioids, use the lowest possible dose for the shortest amount of time. Most acute painful situations will resolve themselves in three to seven days. In most cases, three days of opioids will be sufficient.

Stop!

STOP AND REASSESS

- If the patient asks for additional opioids, and you have prescribed the amount that in your professional judgment should have sufficed, have the patient return for an evaluation. At that follow up visit, you or your staff should:
  - Be sure there is no unforeseen complication requiring further testing or treatment.
  - Be sure there is no evidence of substance use complicating treatment. A PDMP query is advised and a UDS might be indicated at this time.
  - Only prescribe additional opioids if you feel it is clinically appropriate. Otherwise, continue to reinforce non-opioid modalities of pain control.

TREATING CHRONIC PAIN
(Pain Lasting More Than Three Months)

For almost 30 years, common medical wisdom held that most individuals experiencing chronic pain would benefit from daily doses of opioids. Medical knowledge has matured, and our understanding of the risk/benefit of chronic opioid use has changed, such that we now know the risks of chronic use are significant, and the benefits are often modest.[14] Most patients with chronic non-cancer pain can be managed with non-opioid modalities or occasional opioid use.

The problem we now face is the "legacy patients," those who have been on high-dose daily opioids for years, sometimes passing from provider to provider. Many primary care practitioners care for these patients, though they may not have initiated the opioid treatment regimen. These individuals deserve compassionate care and may sincerely believe that they could not cope without continuing their medication regimen. However, current best practice suggests that a slow-dosage reduction will improve the quality of life for the majority of patients.

The characteristics that contribute to dose escalation for chronic pain patients are the same as those which predispose to addiction. When appropriate screening, safe monitoring, and dose reduction are instituted, some of these individuals will be found to have the true diagnosis of substance-use disorder. Co-occurring mental health disorders related to trauma, depression, and anxiety may be revealed, as well. Management of these emerging disorders may require a shift in treatment modalities or a specialty-care referral. A strong partnership with behavioral health experts is essential to managing these patients.[15]

Involvement in daily activities and improved quality of life are the goals of chronic pain treatment. Monitoring function, rather than simply measuring the perception of pain, is the method of assessing patient improvement. Many patients do better after tapering and are grateful to "have their lives back" despite their initial fears of dose reduction.

Categorization of Chronic Pain Patients

It may be helpful to think of chronic pain patients as having pain belonging to one of three broad categories: peripheral (nociceptive), neuropathic, and central (non-nociceptive).

- **Nociceptive pain:** Pain whose etiology is ongoing peripheral inflammation or damage. This pain may be responsive to medications or procedures.

- **Neuropathic pain:** Pain resulting from trauma to peripheral nerves. This pain may be responsive to pharmacotherapy.
- **Central pain:** This phenomenon has many names, such as "pain amplification," "brain pain" and "non-nociception pain." Fibromyalgia syndrome is the classic example of this type of chronic pain. Psychotropic and other non-opioid therapies, including behavioral therapies, can be beneficial. Opioids are contraindicated with central pain etiologies.

All three pain types may coexist and may benefit from non-medication pain-management strategies: cognitive behavioral therapy (CBT), movement therapy, and education.

Nociceptive and Neuropathic Pain

Historically, almost all chronic non-cancer pain (CNCP) was thought to be either nociceptive or neuropathic. In this model of CNCP, the underlying cause of pain was believed to result from stimulation of peripheral pain or sensory nerve fibers located within the painful anatomic region. In this pain schema, peripherally directed therapies such as topical treatments, injections, opioids, and surgery are believed to be helpful. Examples of peripheral nociceptive pain include osteoarthritis, rheumatoid arthritis, and cancer pain. While examples of peripheral neuropathic pain include diabetic neuropathic pain and post-herpetic neuralgia.

However, over the past decade, a body of evidence has accumulated to suggest that a third type of pain, centralized pain, is likely to be much more prevalent than either nociceptive or neuropathic pain amongst working-age adults with CNCP. This distinction is very important to make as centralized pain, unlike nociceptive and neuropathic pain, is not responsive to peripherally directed therapies or opioids.[16]

Central Pain or Central Sensitization (CS)

The prototypical central pain state is fibromyalgia syndrome. But current research suggests that centralized pain is a spectrum disorder, which includes a large family of common chronic non-cancer pain diagnoses. Chronic low back pain, chronic headaches, and fibromyalgia are highly associated with CS.[16,17,18]

Screening for centralized pain syndromes is essential both for successful treatment and to avoid the unnecessary harms of over-medicalization with repeated scans, injections, surgeries, and opioids. Because the examination, imaging, and labs are often unremarkable in centralized pain syndromes, diagnosis rests upon a careful history, review of symptoms, and the use of validated CS screening instruments. Moreover, given the high co-occurrence of depression, anxiety, PTSD, and addictive disorders within individuals with CS, it is recommended that screening for these co-morbidities is also included in the initial evaluation.

If we treat centralized pain syndromes with drugs alone, we will fail. This is akin to treating diabetes with insulin or drugs alone, without any corresponding attempt to modify diet or weight.

Assessment for Chronic Non-Cancer Pain

Prior to assuming responsibility for prescribing for these patients, you should obtain and review the following:

- Prior medical and psychiatric records and (ideally) personal communication with the previous prescriber. It may be important to know why a patient left the previous practice.
- A complete physical exam, including:

- Past medical and psychiatric history, longitudinal pain history, family pain history, substance use history, laboratory, and imaging as appropriate.
- Specific ROS (review of systems) related to CS spectrum: difficulty sleeping, fibromyalgia, headaches, inflammatory bowel syndrome, pelvic pain, memory problems, TMJ, sensory descriptors of pain, i.e., numbness, tingling, pins and needles, etc., and of course, history of childhood trauma.
- Physical exam: A thorough exam will typically rule out undiagnosed nociceptive or neuropathic pain. Physical findings, imaging, and labs are typically unremarkable in controlled substance spectrum disorders.

› A query of the PDMP.

› UDS (POC [in-office point of care] will provide results at the time of the visit)

› Substance-abuse risk screening.

› Mental health screening, for example, adverse childhood experiences (ACEs), PTSD, anxiety, and depression.

› Respiratory disease risk screening.

› Pain and, most important, functional assessment to evaluate progress with treatment over time. (Oswestry, Low Back Pain Intensity, Visual Analog Scale, PEG 3-item scale for pain tracking).

Opioid Treatment

› Rarely will it be possible to prescribe on the first visit. Once you have decided to assume prescribing responsibility for opioid treatment, you should do the following:

- Discuss the material risk notice with the patient, and have it signed in your presence. Many providers also use a controlled substances agreement.
- Consider a lowering of their opioid dose, as many patients will benefit from a dose reduction. If the patient presents with a total MED over 90mg, a taper plan needs to be discussed with the patient, with the understanding that opioid risk is dose related. The safest regimen is the absence of opioids.
- Co-prescribe a naloxone rescue kit. This will require a visit with the patient's loved ones. Most insurance will pay for this modality, and the drug comes as a nasal spray, is easy to use, carries no substantial risks, and has been proven to save lives. (See Naloxone, page 51.)

› Ongoing monitoring should be instituted as clinic policy for *all* patients. Everyone is at increased risk with opioids, not just the ones you identify as problem patients or high-dose patients. Risk stratification (see elsewhere in this document) may have some, albeit limited, usefulness. Monitoring should include episodic evaluation of functional improvement, UDS, PDMP query, callbacks with pill counts, and documentation of any other changes in behavioral or physical conditions that would influence your prescribing decision.

› Opioids and benzodiazepines should not be co-prescribed as they can produce a synergistic effect resulting in respiratory arrest.[20]

› Methadone use should be avoided, and, if prescribed, doses should be kept below 30mg/d because of its high lethality mg for mg.[21] Other rapidly acting opioids, such as fentanyl, are highly addictive.

› Contraindications for opioid treatment:

- Concurrent use of benzodiazepines and other sedative hypnotics (alcohol, muscle relaxants, sleeping medications)

- Increased risk of respiratory depression: severe COPD, sleep apnea, etc.
- Substance-use disorder. Past abuse requires increased scrutiny if any prescribing is undertaken.
- Illegal activities regarding medications.
- Lack of functional improvement while taking opioids.
- Recent—last 12 months—documented prior violation of an opioid treatment agreement with another prescriber.

Non-Opioid Treatment[22,23,24,25]

- A pain rehabilitation program is strongly recommended as an adjunct to treating chronic pain patients. Such programs often include education, movement therapies, behavioral modalities, and peer-to-peer support. Patients should be educated about pain *management* techniques, rather than expecting pain elimination. This is a strategy common to all chronic disease states (diabetes, hypertension, etc.).
- Attendance in a rehabilitation program can be effectively linked to a dose-reduction regimen. A patient agreeing to supportive treatments is likely to succeed with a slow opioid taper. Resistant patients may need to be tapered more rapidly to assure an appropriate risk/benefit balance in a timely manner.
- Over-the-counter pain medications as well as intermittent, brief opioid regimens may be beneficial in selected patients when exacerbations of the chronic state occur.

Patient Instructions

- Dose instructions need to clear. PRN prescribing may lead to inadvertent large doses (e.g., hydrocodone/acetaminophen 5/325 one to two every three to six hours can be as much as 50 mg. MED a day, even though each pill represents a small dose of opioids.)
- The following should be a part of patient/family education concerning opioids:
  - Safe storage to prevent children and others from obtaining the medication.
  - Safe disposal when they are no longer needed.
  - Clinic policy regarding inappropriate behaviors. Many clinics have patients sign a patient contract. Those disallowed behaviors often include: early refills, lost or stolen prescriptions, Friday and weekend refill requests, obtaining controlled substances elsewhere without disclosure, use of illicit drugs, alcohol abuse, and concomitant marijuana use (some providers do not allow).

Tapering

- Many legacy patients are likely to react negatively to a discussion of tapering. Preparation for these difficult conversations can be very helpful, and a section of the guidelines is dedicated to that subject.
- Tapering strategies are discussed elsewhere in this document.
- It is essential that patients be provided resources to assist them with the discomfort and anxiety that often accompanies tapering. Learn what local community resources are available to you.

- Many patients are on both opioids and benzodiazepines simultaneously. It is inappropriate to have patients on both of those drugs, even if you are not the prescriber for both. Patients may be tapered off both simultaneously, but many prefer to taper off one and then the other. Since opioids are more dangerous regarding overdose, and can be tapered more rapidly, we recommend starting your taper with opioids and then tapering the benzodiazepines.
- When patients are exhibiting active addiction behaviors (e.g., use of illicit drugs like heroin) an immediate cessation of prescribing may be indicated and accompanied by an addiction treatment referral.

Additional Concerns

- **Secondary Gain:** Disability payments, legal actions, and illicit financial incentives can complicate the treatment of pain. Practicing safe and appropriate medicine, with thorough documentation, will serve as a starting point, with specialty referral being necessary at times.
- **Suicidality:** Individuals whose lives have revolved around opioids for decades may have significant and legitimate concerns about dose reduction. These individuals need patience and behavioral support. Be sure to ask about suicidal thoughts and provide referrals to counseling when needed.
- **Addiction (opioid-use disorder):** It is sometimes hard to distinguish between patients who take opioids to relieve pain and those who are taking medication obsessively to relieve cravings or to achieve a pleasurable effect. Individuals who have an unnatural focus on their medications and respond poorly to opioid treatment may be identified as either having ineffectively treated pain or having an opioid-use disorder.

You may have patients to whom you were prescribing opioids for the treatment of pain, but who over time showed evidence of addiction. Ideally, if you prescribe opioids for chronic pain, you also have the capability to prescribe buprenorphine (or refer to others with that capability) for your patients who you feel have a substance-use disorder. Regardless of the terminology you use, some patients would be safer being prescribed buprenorphine rather than pure mu agonists.

An in-depth knowledge of your community addiction services is an important component of chronic pain treatment.

Chronic Pain Flow Sheet

FOR THE EVALUATION AND TREATMENT OF CHRONIC NON-CANCER PAIN

Begin

ASSESSMENT

- Evaluate the original tissue injury and determine nociceptive, neuropathic, or central characteristics of the pain perception.
- Assess the risk of prescribing opioids to a patient through assessment tools: ACE, pain catastrophizing scale, PHQ-15, STOP-BANG, functional (e.g. Oswestry) or abuse (e.g. ORT) assessments, and trauma/PTSD screening.
- Obtain and review prior records, or for an established patient, re-familiarize yourself with your patient's past history and evaluations.
- A UDS and query of the PDMP prior to assuming prescribing and periodically thereafter, but no less than yearly.

Green Light

NON-OPIOID OPTIONS

- Exercise, restorative sleep, and behavioral supports should be a major component to any pain-management program.
- A team approach to care is essential to achieve functional improvement and improved quality of life.

Ongoing

ONGOING MONITORING

- Monitor all patients on chronic opioids.
- Every visit:
  - Evaluate progress toward functional goals. Strongly consider weaning in the absence of functional improvement on opioids.
  - Screen for appropriate medication use.
- Periodic assessment (no less than annually):
  - Urine drug screening
  - Pill counts
  - Callbacks
  - PDMP query

Caution

OPIOID TREATMENT

- Rarely prescribe opioids on the first visit.
- Discuss the risks vs. benefit of opioids and get a signed material risk notice.
- Create a care plan that includes functional goals.
- Discuss and plan for dose reduction (see tapering section in the OPG guidelines).
- Co-prescribe naloxone rescue kit to a loved one or family member.

Stop!

STOP AND REASSESS

- Benzodiazepines should not be taken at the same time as opioids.
- Methadone should be used rarely, and if so, in low doses (< 30 mg/d).
- Respiratory disease (COPD, sleep apnea, etc.) narrows the window of safety with opioids.
- Evidence of substance abuse, past or present.
- Illegal activities regarding medication or illicit drugs.
- Lack of functional improvement.

NON-OPIOID OPTIONS

A patient's trauma history, mental health, family, and social situation all can affect the perception of pain. This is why chronic pain is described as a bio-psycho-social phenomenon. Without addressing those behavioral issues, opioid management of chronic pain will not provide the level of relief the patient is seeking, and dose escalation, with its concomitant morbidity and mortality, will often occur.

Studies show that opioids are only moderately successful in relieving pain and, in fact, are inferior to sleep restoration, mindfulness training, and physical exercise in providing long-term benefit.

Treatment Comparisons

Treatment	Reduction in Pain Intensity
Physical fitness	30–60%
CBT/Mindfulness	30–50%
Sleep restoration	30–40%
Opioids	<30%
Tricyclics	<30%
Anti-epileptics	<30%
Cannabis	10–30%
Acupuncture	>10%

Source: David Tauben, MD, Chief of Pain Medicine at the University of Washington.

The following table lists various non-opioid treatment options, including behavioral, movement, and pharmacological treatments. This is not meant to be an exhaustive list but, rather, is intended to show the many empowering ways our patients can use readily accessible resources to help manage their pain.

Non-Opioid Treatment Options

Patient Lifestyle	› Healthy sleep management › Weight reduction › Diet/Nutrition › Stress reduction › Exercise
Physiotherapy Interventions	› Functional therapies ○ Physical therapy (PT) ○ Occupational therapy (OT) ○ Passive modalities
Behavioral Interventions	› Educational groups ○ Preventive ○ Support ○ Peer-to-peer/Living Well workshops ○ Shared medical appointments › Psychotherapy ○ Individual counseling ○ Group therapy ○ Cognitive behavioral therapy › Supportive care ○ Case management › Substance-abuse treatment ○ Residential ○ Outpatient ○ Medication-assisted treatment referral › Trauma-informed care ○ PTSD screening ○ Domestic violence screening ○ Child abuse screening
Medical Interventions	› Non-opioid medications that may aid in chronic pain management ○ NSAIDS, acetaminophen ○ Tricyclic antidepressants (neuropathic pain) ○ Anti-epileptics (neuropathic pain) ○ Antidepressants (treating underlying depression) ○ Topical medications › Minimally invasive surgical procedures ○ Nerve blocks, steroid injections ○ Interventional treatments: ablations, restorative injections, stimulators, implantable devices ○ Surgical treatment › Complementary and alternative treatments ○ Manipulation therapy ○ Acupuncture

Behavioral Treatment Options

Cognitive behavioral therapy (CBT)

- **What is CBT?** CBT is a form of psychotherapy that emphasizes the importance of the causal relationship between our thinking and our feelings and behaviors. The cognitive, or thinking part of our experience, very much affects the behavioral, or action part of our experience. With training, we can change the way we think to affect the way we feel and behave, even if the situation has not changed. CBT has an educational focus and teaches rational self-counseling skills.
- **What does the research say about CBT for the treatment of chronic pain?** Studies show that a patient's report of chronic pain intensity is far more about that individual's capacity to manage his or her pain than it is about stimulation of nociceptors.[26] Additional studies show that patients experience between 30% to 60% reduction in pain intensity by learning and applying CBT techniques. This compares favorably to the estimated efficacy of 30% for chronic opioids.
- **What are some of the key components of CBT for patients with CNCP?** In general, CBT for chronic pain works to reduce patients' pain, distress, and pain behavior while improving their daily functioning. Components of CBT may include helping patients to decrease negative emotional responses to pain and perceptions of disability while increasing their acceptance of pain and orientation toward self-management. CBT helps patients change the way they relate to pain so they can experience life more fully.
- **What is the goal of CBT for patients with CNCP?** Two fundamental concepts are at play. One is that a person must accept the aspects of the pain that cannot be changed, including all the difficult thoughts, feelings, and bodily sensations that come with it. The second is that this acceptance allows for the possibility of the patient opening to the pain and committing to acting in ways that make the patient feel vital and energized. Learning to accept pain to live life is often referred to as "victory by surrender."

Living Well with Chronic Pain

This program is one of a group of validated syllabus-based programs developed at Stanford University for the purpose of empowering individuals living with chronic pain. It is available in many communities around the country and teaches self-management skills concerning the management of chronic diseases, including pain.

Shared medical appointments

One approach for a busy practice to incorporate peer support, education, and behavioral treatment into the office visit is to use a shared medical appointment. The prescriber and a facilitator, often a nurse, can meet with patients as a group to discuss common issues, while simultaneously taking individual patients aside for brief patient-specific evaluations. Many insurance companies will pay for this treatment approach.

Peer-to-peer meetings

Trained peer educators can facilitate groups of pain patients to share successes, set goals, and help overcome common obstacles. Peer educators can work under the auspices of a licensed practitioner or enroll patients independently. Such programs can work in parallel with the other modalities mentioned in this section.

SPECIALTY CARE FOR TREATING CHRONIC PAIN

Pain, in all its manifestations, is an aspect of most illnesses, as well as a normal part of the aging process. As such, its treatment is an essential component of primary care. The treatment of pain, especially acute pain, may at times require the use of opioids, which have significant risks in addition to their benefits. After years of misguided provider education, millions of patients in our healthcare system are on opioids for inappropriate diagnoses and at inappropriate doses (legacy patients or the lost generation). Even the most skilled providers may at times need specialty care to assist in the management of these complex patients. This guideline will address the following questions:

What kinds of patients are most appropriate for specialty care?

What is the screening and evaluation expected for these high-risk patients?

What kind of oversight should exist to assure consistent and safe management of these patients?

Who is a pain specialist?

What kind of services should constitute a specialty-care clinic?

What are the expectations and long-term goals for such patients?

Patient Selection for Pain Specialty Care

- Patients on high doses (>90 mg MED) or unsafe drug combinations (e.g., benzodiazepines + opioids) who either refuse dosage reduction, exhibit substance-use disorder behaviors, or have significant behavioral conditions beyond the scope of the provider, may require referral to a pain specialty program or substance abuse program for evaluation or ongoing care.
- Any chronic pain patient beyond the expertise of the primary care provider.
- The Oregon Medical Board (or similar state boards), UW "Tele-Pain" (or similar regional peer education), can be excellent resources for helping manage difficult patients in lieu of specialty referral.

Screening and Evaluation

All patients being prescribed chronic opioids need screening for behavioral, respiratory, and other psychosocial risks because, by definition, the specialty-referral clients are at higher risk. A more thorough evaluation of such patients is to be expected:

- Ongoing functional evaluation: PEG, Oswestry or similar, monitored over time.
- Respiratory: S T O P B A N G or similar, with appropriate referral or further evaluation as necessary.

- Central sensitization screening including but not limited to Central Sensitivity Index, Pain Catastrophizing Scale (PCS), PHQ-15, etc.
- Validated addiction-screening tests such ORT/SBIRT/DAST-28, appropriate for age and history.
- Query of the PDMP initially and episodically.
- Evaluation for possible unforeseen sources of nociception, such as identification of ongoing tissue destruction.

Oversight

Pain specialists, accredited, self-identified, or working under the license of others, can succumb to lack of time and inadequate resources resulting in a loosening of appropriate safeguards in the management of chronic pain. A process of peer review can provide feedback at the expert level (and can be an educational resource for primary care) to assure quality and consistent care for complex, high-risk patients. This may include:

- Regularly scheduled multi-disciplinary meetings of healthcare professionals, including behavioral specialists, addiction counselors/specialists, pharmacy, case management, and more to facilitate case discussions. Review of treatment data (MED, functional improvement, adherence to risk stratification) in a transparent fashion by the participants is an expected component.
- A committee that could serve as a "brain trust" for others providing pain management in the community.

Pain Specialty

It is clear from the latest research that chronic pain is often, if not largely, a disorder of nociceptive perception and dysregulation.[27,28] Chronic pain patients often represent a subset of the population with specific bio-psycho-social characteristics. This means that a pain specialty clinic needs to have a foundation of understanding and resource accessibility to care for individuals with historical trauma, substance-use disorder, catastrophizing, as well as an understanding of the pharmaco-dynamics of opioids. Chronic pain is often best viewed through the lens of chronic disease management rather than cure. Therefore, to be considered a pain specialty clinic for the purposes of referral and reimbursement, items 1 through 6 will need to be provided by the clinic staff.

Services

A pain specialty clinic should include the following:

1. Clinicians willing to be transparent and share de-identified treatment data.
2. An organization with deeply embedded behavioral health experts to provide evidence-based counseling, education, and substance-use disorder treatment.
3. Prescribers specifically educated concerning the use and abuse of opioids, or who can demonstrate their expertise through an objective testing process.
4. The ability to provide buprenorphine to appropriate patients for the treatment of opioid-use disorder.

5. The ability to provide referral and expert care for complex chronic pain patients. It should be the goal of pain specialty to develop and establish a treatment plan and return the patient to primary care. In extremely complex patient situations, pain specialty should provide direct care until exceptional care needs are addressed, managed, and a care plan is established; at which point the patient should be returned to primary care. It is expected that all providers participating in a patient's care will employ common treatment goals and communicate regularly amongst themselves.
6. The previously listed components are essential for quality chronic pain care. If they are not offered on site, then close collaboration, integration, and management of such services is expected.

Long-Term Management Goals

The evidence supporting long-term benefits of opioids is lacking, while the risks and harms are evident. Tapering opioids after long-term use can be challenging and may elicit preexisting conditions. Patients with underlying trauma, mental health disorders, co-existing benzodiazepine use, and substance-use disorders can be exceptionally challenging when tapering, and specialty care can provide additional structure, expertise and support.

- The OPG guidelines, including < 50 MED for most patients, with an absolute MED maximum of < 90 MED, are appropriate for patients managed by pain specialty, as well.
- It is understood that these complex patients may require additional services, support, and time to achieve those goals. Specialty care, by definition, will provide that level of expertise and care.

TRAUMA-INFORMED CARE (Childhood Trauma, PTSD & Chronic Pain)

It is increasingly recognized that childhood trauma and PTSD affect not only the quality of life of many individuals but also their physical health. Research has increasingly demonstrated that trauma can lead to neurobiological dysregulation, altering the functioning of catecholamine, hypothalamic-pituitary-adrenocorticoid, endogenous opioid, thyroid, immune, and neurotransmitter systems. It is not surprising, therefore, that exposure to traumatic stress is associated with increased health complaints, health-services utilization, morbidity, and mortality.

Trauma and Chronic Pain

The prevalence of trauma is substantially elevated in patients with chronic pain. A current PTSD prevalence of 35% was seen in a sample of chronic pain patients,[29] compared to 3.5% in the general population.[30] In a study of patients with chronic low back pain, 51% of the patients evidenced significant PTSD symptoms.[31] Daniel Claw and others have found a strong association between trauma, childhood sexual abuse in particular, and central sensitization (CS) syndromes.[31] Emotional pain can amplify physical pain perception, and pain itself can actually serve as a reminder of the traumatic event, and thus put the patient at risk for dose escalation.

Screening and Referral Overview

- PTSD symptom screening is an important addition to routine preventive health screening in primary healthcare settings because:
  - Patients are unlikely to report trauma history or symptoms unless directly asked.
  - Trauma exposure is associated with many problems—emotional and physical—that affect health.
  - In patients with long-lasting PTSD, significant improvements in symptoms are unlikely to occur without treatment.
- Gather a thorough bio-psycho-social history and assess the individual for medical and psychiatric problems. Do a risk assessment for suicidal and homicidal ideation. Also ask about substance abuse.
- Assess for PTSD symptoms. There are a number of screening tests that have been designed for use in primary care and other medical settings. See PTSD Screening and Referral: For Health Care Providers for more information.
- Make appropriate referrals for PTSD, depression, other psychiatric disorders, or significant spiritual issues. Likewise, help build up or stabilize the patient's social support network, as this will act as a buffer against the stress they are experiencing.

Trauma-Informed Treatment

- Research suggests that providing CBT treatments to address PTSD symptoms in patients with chronic pain may lead to improvements in pain-related functioning.[33]
- Other useful treatment methods include behavioral regulation methods (imagined or actual exposure to feared activities or circumstances) and physiological strategies (relaxation-response training; movement therapy) that overlap substantially with many aspects of cognitive behavioral therapy used in the treatment of chronic pain.
- Multimodal pain programs, which are trauma informed, also provide a good referral resource for those suffering from PTSD and persistent pain.

What Can Healthcare Providers Do

Healthcare providers can increase the chances of improved health outcomes for their patients by following these steps:

- Identify a PTSD consultant in your community
- Screen for trauma
- Discuss the results openly with your patient
- Provide a referral when appropriate
- Provide educational materials
- Follow up with the patient

Further information can be found on the U.S. Department of Veterans Affairs website: http://www.ptsd.va.gov/professional/co-occurring/chronic-pain-ptsd-providers.asp.

Tools

See Primary Care PTSD Screen (PC-PTSD) in Appendix D.

TREATING PAIN IN CHILDREN AND ADOLESCENTS

The use of opioids to treat pain in infants and children presents challenges. First, with rare exceptions, opioids have not been labeled for use in individuals under 18 years of age. There is a dearth of quality studies on pharmacokinetics, pharmacodynamics, safety, and clinical effectiveness. Acute pain problems in pediatrics have many characteristics in common with adult presentations. Persistent, recurrent, and chronic pain in infants, children, and adolescents are often qualitatively different from chronic pain problems in adults. Treatment approaches may vary accordingly.

Assessment

- Review medical history, including records from previous providers, when available. Be sure to elicit family history of chronic pain syndromes.
- Perform a physical exam to determine diagnosis, baseline function, and pain.
- Carefully assess the degree of injury and the normal healing expectations regarding pain and improved function. Determine the need for opioids versus non-opioid therapies (see Acute Pain section in this document).

Non-Opioid Treatment

- Describe the nature of the injury or disease to the patient and the parent. Be sure to describe the expected course of recovery and convey that some pain is to be expected and that activity and exercise can often provide some pain relief and may improve healing.
- Explain that OTC or over-the-counter pain medications can be highly effective, and be sure they understand dose and frequency recommendations.
- Patients who experience pain extending beyond the expected time of recovery should be reevaluated.

Opioid Treatment

- Only those who understand the differences in pharmacokinetics and pharmacodynamics between children and adults should prescribe opioids for pediatric patients.
- Opioids should be avoided for the vast majority of chronic non-cancer pain in children and adolescents as evidence of safety and efficacy is lacking.
- Opioids are indicated for a small number of persistent, painful conditions, including those with clear pathophysiology and when an endpoint to usage may be defined, such as post-surgical pain and trauma (including burns). Every attempt should be made to limit opiate use to fewer than seven days.

- Opioids may be indicated for some chronic conditions where there is no definable endpoint (like osteogenesis imperfecta or epidermolysis bullosa) or for end-of-life care. Such patients are best treated in a specialty-care setting.
- Put safety first when prescribing opioids to younger patients. Limit the total dispensed and educate parents about dosing, administration, storage and disposal to minimize risks of diversion or accidental ingestion. Adolescents should undergo similar screening for risk of substance-use disorder that one would conduct with adults.

Tools for Adolescents

- Screening tools for substance abuse: ORT, SOAPP-R
- Screening tools for co-occurring mental health conditions: PHQ-9, GAD-7
- Prescription Drug Monitoring Program
- Age and developmentally appropriate screening tools for children such as NIPPS, FLACC, or Bieri-Modified

PAIN CONTROL IN THE ELDERLY AND INDIVIDUALS WITH DEMENTIA

Pain in the elderly patient may be more difficult to assess because of the patient's cognitive and physical impairments. Traditional approaches to pain management may need to be modified because of a sometimes-elusive diagnosis, altered patient physiology, and the risk of more prominent side effects.

The goals of therapy are to decrease pain while increasing function and enhancing quality of life.

Because chronic non-cancer pain can be reduced but not eliminated, ongoing pain reporting is common in patients with dementia.

Chronic Pain in the Elderly Population

- Persistent pain (three to six months) is present in 25–50% of older adults, and increases with age. Nursing home patients may have prevalence as high as 45–80%.[34]
- Chronologic markers for old age are arbitrary; however, various factors such as socioeconomic impacts, health-style choices and medical comorbidities may all factor into a patient's physiologic age.

Evaluation of the Elderly Patient

- Identify the source of the pain and the impact that pain is having on the patient. Assess previous consultations, workups, and imaging studies. Be suspicious of increases in pain above baseline as pathologic pain promoters are much more likely with advanced age.
- Cognitive impairment resulting from delirium, dementia, or other mental health conditions may make both the assessment and management of symptoms more difficult.
- In a patient with complicated emotional issues, they may describe the pain in imprecise, inconsistent terms.
- Poly-pharmacy is common. Be aware of potential adverse effects from multiple medications.
- Imaging should be symptom and examination driven. Avoid duplication of previous testing.
- The management of symptoms in the older patient follows the same principles as that in younger persons. However, the elderly are more sensitive to medication side effects.[35]

Goals of Treatment

- The goals of treatment are to modulate pain, provide the ability to perform valued activities; improve function; feel well enough to socialize; have the additional freedom from chronic, painful conditions; and enhance the quality of life.[36]

- Persistent pain is multifactorial. It is a treatable but not curable condition. Let the patient know that although pain cannot be eliminated, substantial improvement in function is a realistic goal.

Non-Pharmaceutical Approach

- Often beneficial, with low cost and minimal side effects.
- Includes physical therapy, occupational therapy, acupuncture, chiropractic, and massage therapy. When ordering therapies, be sure to specify what conditions you want targeted and your goals of treatment. Monitor the modalities to ensure that they are being applied appropriately (positioning, hot/cold).
- Behavioral – Cognitive behavioral therapy and meditation along with patient education.
- Localized therapy – Joint injections and trigger-point injections.
- Continue these treatments when introducing medications to minimize medications and their side effects.

Pharmaceutical Approach

Non-opioids

Non-opioids are preferred over opioids. Used primarily for nociceptive pain (post-op pain, mechanical low back pain, injuries/trauma, arthritis). Involve a pharmacist for help in reviewing side effects and concomitant medications (including supplements) for drug-drug/supplement interactions.

- Acetaminophen is the first-line approach to mild, persistent pain:
  - Acetaminophen lacks inflammatory activity so, therefore, may be limited in the long-term treatment of inflammatory conditions.
  - Beware of potential drug interactions and drug-dosing limits (determine the doses of all acetaminophen-containing products).
  - Reasonable prescribing: 3 grams/24 hours OR fewer than 2 grams in frail patients, those more than 80 years old or those who use alcohol on a regular basis.
- Non-steroidal, anti-inflammatory drugs (NSAIDs)
  - Start at low doses in the elderly.
  - Use briefly; no more than one to two weeks during periods of increased pain.
  - Tailor the medication to the patient's cardiac and GI risk factors.
  - For those at risk for GI complications, add a gastro-protective agent.
  - Potentially lower GI risk with non-acetylate salicylate or COX-2 inhibitors.
- Antidepressants-for chronic neuropathic pain (postherpetic neuralgia, neuropathic back pain, polyneuropathy, trigeminal neuralgia). All have increased side effects in the elderly.[37]
  - TCAs – Tricyclic antidepressants have been shown to have effectiveness preventing migraine and tension headaches and in treating chronic pain. Common side effects are sedation, cognitive dysfunction, and orthostatic hypotension. Watch for drug interactions.
  - SNRIs – Selective noradrenalin reuptake inhibitors (e.g., duloxetine, venlafaxine) are frequently used in treating neuropathic pain.

- SSRIs – Selective serotonin reuptake inhibitors (e.g., paroxetine, citalopram) have been used in the treatment of neuropathic pain. These agents may be particularly useful in elderly patients because of their favorable side-effect profiles.

- Anticonvulsants – gabapentin, pregabalin and carbamazepine may be effective for neuropathic pain. Use of these medications is frequently limited because of dizziness, somnolence, fatigue and weight gain. Improved tolerance over time. Their side effects and potential for drug-drug interactions limit their utility in older adults.[38]
  - Start at low doses, titrate slowly upward, and taper off when stopping the medication.
- Transdermal lidocaine can be useful in the elderly to treat neuropathic and localized, nociceptive pain and has a low incidence of side effects.
- Muscle relaxants should be avoided in individuals older than 65 because of intolerance to side effects.

Opioids – General Considerations

- Opioid analgesics are the mainstay for the treatment of moderate to severe pain in patients with advanced illness. Long-acting or sustained-release analgesic preparations should be used for continuous pain. Breakthrough pain should be identified and treated by the use of fast-onset, short-acting preparations.
- Elderly are more sensitive to the effects of the opioids, with age-related physiologic changes (e.g., decreased renal or hepatic function and altered body-fat distribution) along with comorbid medical conditions.
- Always consider if there is an alternative therapy that is likely to have an equal or better therapeutic benefit for pain control, functional restoration, and improvement in the quality of life.
- Is the patient (or caregiver) likely to manage the opioid use responsibly?
- Patients may require other forms of medication other than pills. These may be liquid, patch or injections. Try to stay with the least-complicated mode of treatment to help with compliance.
- Opioids can cause mental clouding, which may clear over time. However, there may be persistent sedation, cognitive and psychomotor impairment, hallucinations, dreams and nightmares while on the medication.
- Never initiate opioid therapy with patches or other long-acting opiates in opioid-naïve patients.
- Reasonable dosing recommendations should start at 30% to 50% of the recommended starting dose at the same dosing intervals, and then titrate doses upward in 25% increments for comfort and side-effect tolerance. There is substantial individual variation in the response to the different opioids, and the drug with the most favorable balance between analgesia and side effects cannot be predicted.
- Potential medication choices:
  - Morphine, oxycodone, hydrocodone +/- acetaminophen, hydromorphone, tramadol, fentanyl, buprenorphine. Avoid meperidine and methadone. When choosing a medication, identify the targeted goal of treatment, the preferred route of administration, the patient's frailty and comorbid conditions along with your clinical experience.
  - Opioid side effects:
- Constipation – There is little adjustment to this side effect over time. Constipation is predictable, so start prophylactic laxative therapy when initiating narcotics.
- Balance/Falls
  - Particularly in patients taking poly-pharmacy, who are deconditioned, or who have vision difficulties.

- If there is evidence of risk for falls, consider not starting narcotics.
- Consider a possible referral for PT and mobility aids prior to initiating treatment.
- Ensure a safe environment for the patient with impaired mobility. Consider a home safety evaluation through the appropriate agency.
- Respiratory
- Sleep apnea and sleep-disordered breathing are seen with narcotic use.

› The exaggerated respiratory depression seen with opioid use can be minimized by starting at low doses and with appropriate titration. Use significant caution when increasing doses, especially in elderly individuals with risk factors for sleep apnea.
  - Nausea is common. Nausea can be minimized with a slow titration upward in the narcotic dosing.
  - Depression – Opioids may precipitate or worsen depression, which is a treatable condition that may respond to therapy.
  - Opioids affect the functioning of the hypothalamic-pituitary-adrenal axis, resulting in increased levels of prolactin, decreased levels of sex hormones and, rarely, secondary adrenal insufficiency.

Pain Treatment in Patients with Dementia

› Because chronic, non-cancer pain can be reduced but not eliminated, ongoing pain reporting is common.

› In those with advanced dementia who may be unable to communicate verbally about their pain, you may need to evaluate their condition (and their response to treatment) by facial expressions, verbalizations, body movements, changes in interpersonal interactions, activity patterns and routines such as sleep disruption and appetite suppression. Multiple questionnaires have been developed with variable success rates in eliciting pain levels in persons with dementia, with no general consensus on which one is superior.[39]

› Patients may also exhibit striking out, refusing medications, agitation, delirium, increased restlessness, and social withdrawal. Rule out other potential infectious, metabolic, medication-related, and social-situation changes as possible causes for acute decline.

› Prescribe a trial of scheduled medications (be cautious with scheduled NSAIDs). Use a stepwise approach.
  - Start low, go slow, be aware of possible under treatment.
  - Monitor the patient carefully to balance the risks and benefits of the treatment.

› Be alert to herbal and dietary supplements taken by older patients who may not volunteer this information. They may be prone to drug-supplement interactions.

› Patients who don't respond to one medication may respond to another.

PAIN CONTROL FOR CANCER AND PALLIATIVE CARE

Pain control for cancer and palliative care is used when pain and symptom control is important for quality of life. An integrated model of care to address the entire patient, body and mind, is the best approach. This may serve as a bridge to hospice care.

What Is Palliative Care

- Palliative care employs an interdisciplinary team to focus on relieving suffering in all stages of disease and is not limited to end-of-life care. This care may occur at the same time as curative or life-prolonging treatments.
- Palliative care is not hospice and doesn't need to have a six-month-terminal-condition prognosis.
- The basic goal of palliative care is symptom management. The care team can typically better manage symptoms of pain, anxiety, shortness of breath, nausea, emesis, constipation, and diarrhea than the busy, multitasking provider.
- Palliative care providers continually strive to clarify the goals of treatment interventions and determine whether they are consistent with the values and decisions of the patient and with the reality of the disease process.
- Palliative care improves quality of life for the patient and their family.
- After serious illnesses, the primary care providers, friends, family members, nursing facilities, specialists, and also hospitalists refer patients to palliative care.
- For patients who have a terminal cancer condition and transition fro, palliative care onto hospice, the goal of treatment for cancer pain is to improve comfort (compared to the goal for treatment of CNCP to improve function). Escalating doses and high MEDs are not unusual in these circumstances. The risk/benefit balance is not the same as it would be in a patient with the expectation of years of productive life. Care must still be taken to ensure that your medication is going to your patient, and not being diverted.

Why Is Palliative Care Important

- Primary care management of pain and symptom relief in the pre-terminal and terminal patients may vary considerably between provider offices.
- PCPs may not have the training or experience to feel comfortable with symptom management, and their offices may not have the dedicated resources for integrated services.
- Palliative care teams are responsive to the questions and needs of the patient and families, and can serve as the eyes and ears for the provider.
- Palliative care can serve as a seamless transition to hospice care during the last six months of life. This benefits everyone.

Palliative Care Approaches

- Non-pharmacologic treatments may include electrical nerve stimulation and TENS units, therapeutic exercise, splints, and nerve blocks.
- Alternative or complementary therapies for pain may include psychological therapies (e.g., guided imagery, cognitive interventions), acupuncture, music therapy, massage, rehabilitation, and physical therapy, along with other mind-body approaches.
- Pharmacologic approaches to pain include the same medications as mentioned above in Pain Control in the Elderly, page 32.
- Novel uses of medications to manage a wide spectrum of symptoms may also be effective.
- Major depression is a treatable condition, even in terminally ill patients.
- Opioids are the mainstay of treatment for pain at the end of life.

OPIOID USE DURING PREGNANCY

There are many factors that make opioid use in pregnancy a unique issue, requiring special understanding and careful treatment.[40] Beyond the obvious—that you are treating two patients, the fetus and the mother—there are other considerations.

- These are by definition young patients whose appropriateness for chronic pain treatment and risk factors for abuse are different from older adults.
- Opioid withdrawal involves a number of possible serious prenatal consequences including preterm labor, abruption, and fetal demise.[41]
- Guilt and shame may create a situation whereby the patient downplays the seriousness of her opioid use. Providers may be misled into believing they are dealing with occasional use, when they are in fact dealing with an opioid-use disorder.[42]
- Metabolic changes may occur during pregnancy that reduce the effect, and thereby the dose, of opioids needed to prevent withdrawal.
- Neonatal abstinence syndrome (NAS) is common after prolonged opioid use, and is best treated when anticipated prior to delivery.[43]
- Buprenorphine and methadone are the drugs of choice for treating opioid-use disorder in pregnancy. Such treatments should be provided by professionals familiar with the special dosing considerations for this population. Methadone has been used successfully for decades, though it has a higher rate of NAS and opioid-related risks. Buprenorphine is safer for the mother and baby and may be the preferred treatment in selected women.

MANAGING PATIENTS IN THE EMERGENCY DEPARTMENT

The Oregon Chapter of the American College of Emergency Physicians has created a set of guidelines regarding the use of opioids in a hospital emergency department (ED). The following is a modified summary of those guidelines. Emergency medical providers (EMPs) should be supported and should not be subject to adverse consequences by any regulating bodies when respectfully adhering to these guidelines.

1. Only one medical professional should provide all opioids to treat a patient's chronic pain, to the extent possible.
2. The administration of intravenous and intramuscular opioids in the ED for the relief of acute exacerbations of chronic pain is discouraged.
3. EMPs should not provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen.
4. EMPs should not provide replacement doses of methadone for patients in a methadone treatment program.
5. Long-acting or controlled-release opioids (e.g., oxycodone, fentanyl patches, and methadone) should not be prescribed by EMPs.
6. EMPs are encouraged to access EDIE (emergency department information exchange) and/or the state PDMP.
7. EMPs should exercise caution when considering prescribing opioids for patients who present to the ED without a government-issued photo ID.
8. Primary care and pain-management physicians should make patient pain agreements accessible to local EDs and work to include a plan for pain treatment in the ED.
9. EDs should coordinate the care of patients who frequently visit the ED, using an ED care coordination program, to the extent possible.
10. The administration of meperidine in the ED is discouraged.
11. ED prescriptions for opioid pain medication for acute injuries should be no more than 10 pills. For more serious injuries (fractured bones), the amount prescribed should be an amount that will last until the patient is reasonably able to receive follow-up care for the injury. In most cases, this should not exceed 20 tablets.
12. EMPs are encouraged to ask patients about past or current substance abuse prior to the EMP prescribing opioid medication for acute pain. Prescribe opiates with great caution in the context of substance abuse.
13. EMPs are required by law to evaluate an ED patient who reports pain to determine whether an emergency medical condition is present. If an emergency medical condition is present, the EMP is required to stabilize the patient's condition. The law allows the EMP to use his or her clinical judgment when treating pain and does not require the use of opioids.

RECOMMENDED OPIOID POLICY FOR DENTISTS

Pain management is routinely required for some dental procedures. Patients must receive respectful care and appropriate management of dental pain. Most often, dental pain management is for acute or episodic situations, requiring short-term prescribing. For many conditions, ibuprofen, acetaminophen, or a combination of the two will suffice for dental pain. In other circumstances, a very small amount of narcotic medications followed by OTCs will provide appropriate pain relief.

1. Prescribe opioids cautiously to those with a substance-abuse history. Be aware that such use can trigger relapse behaviors in susceptible individuals.
2. Ask if patients are getting medications from other doctors, and use the PDMP prior to prescribing opioids whenever possible.
3. Do not prescribe opioids to patients in substance-abuse treatment programs without consulting the program's medical staff.
4. Do not offer prescriptions with refills. Use caution if replacing prescriptions that were lost, destroyed, or stolen.
5. Prescribing over the phone is discouraged, especially with patients you have not met, except in rare cases involving known invasive surgery.
6. The use of non-combination opioids is discouraged.
7. Prescribe opioid pills only in small dosages, which in most cases should not exceed three days or 10 tablets.
8. When prescribing an antibiotic with the opioids, stipulate that the narcotic must be filled with the antibiotics at the pharmacy.
9. Inform patients how to secure medication against diversion and how to dispose of leftover medication.
10. Opioids should not be prescribed more than seven days after the last appointment. In most cases, three days of medication will suffice. It is strongly recommended that the patient be assessed in the clinic prior to providing refills.
11. A second refill (same or different opioid) request should require patient assessment in the dental clinic and only be provided once a supporting diagnosis is established to continue with narcotic pain management.
12. Third refills are strongly discouraged (except in unusual clinical circumstances that are well documented, such as osteonecrosis management); consider the need for chronic pain management by physician.
13. Prolonged pain management (while awaiting specialty care) should be managed by and/or coordinated with the patient's primary care provider.

TAPERING

Opioid Taper/Discontinuation

Opioid therapy should be tapered down or discontinued if any of the following situations occur:

- The medication fails to show significant analgesia despite incremental dose increases.
- The medication fails to show functional improvement over time.
- MED is in excess of 90 mg/d or methadone dose is in excess of 30mg/d.
- Significant physical risk factors are present (sleep apnea, prolonged QT, pulmonary disease, etc.).
- Side effects of medication are interfering with quality of life.
- Patient request.
- Evidence of misuse, abuse, diversion, or other behavioral/psychological dysfunction.
- Other violations of opioid agreement.

Opioids should be weaned, rather than abruptly stopped, after chronic use (30 days or greater). When opioids are being sold, injected, used in a dangerous or clearly illegal fashion, immediate discontinuation should be undertaken for patient safety and compliance with the law. Referral to a medication-assisted treatment program (methadone or buprenorphine) may be a safer and more appropriate treatment consideration under these circumstances.

Some providers have found the following dialogue useful when explaining the process to patients:

"Medical knowledge changes over time, and just as we have discovered that some of our recommendations today concerning the treatment of cancer or heart disease are different from 10 years ago, the same is true of the treatment of chronic pain. We now know that it can be dangerous to take large amounts of opioids every day. We have also learned that pain relief with high doses may not be any better than with lower doses of painkillers."

General considerations

- Some short-term increase in pain is to be expected during the tapering process. This is usually transient, and after achieving a reduced baseline dose, the patient is likely to experience decreased medication-related side effects and a reduced risk of unintentional overdose, without an increase in pain. Many times, opioids may be completely discontinued with no increase in pain, but improved function and quality of life.
- The slower the taper, the less the short-term discomfort. Educating the patient about the risks of their current regimen and what to expect as they taper off the medications is often/can be helpful.
- Some highly motivated patients prefer a rapid taper (weeks versus months). Patient preference needs to be considered in designing a tapering schedule.

- Psychosocial support is an essential component of successful medication withdrawal for patients who have been on long-term opioid therapy. Discussions about weaning are often associated with fear and anxiety about the recurrence or worsening of pain and/or the development of other withdrawal symptoms. Reassure the patient that supportive adjunctive treatment of withdrawal will be provided as needed, and may be quite helpful, but set expectations that this will not include replacement medications such as other opioids or benzodiazepines. Certain medications that treat autonomic responses, medications such as clonidine, loperamide, or hydroxyzine may be useful short-term adjuncts.
- Patient empowerment is key to success. Involve patients in the planning from the beginning. Elicit suggestions from them for healthful activities that can replace reliance on medications.
- Certain therapies, CBT and Living Well With Chronic Illness workshops, for example, can be quite helpful to support patients through the tapering process and beyond.
- The last part of the dosage reduction is the most difficult for the patient. This is a phenomenon that is true for many psychoactive drugs. You and your patient should anticipate this, and engage supports that are meaningful to the patient. In motivated patients, a slow-down of the tapering process may be necessary toward the end. Liquid forms of medication can be helpful for more precise dosing and can be obtained from a compounding pharmacy.
- Ceiling doses of 50, 90, or any number, represent a dose where the risks of the medication are felt to outweigh the benefits. Medication dependence, medication side effects, and other physical and behavioral changes experienced with chronic opioid use, are related to dose, such that, for many individuals quality of life improves as the dose approaches or reaches zero.

Symptoms of Opioid Withdrawal

Early Symptoms	Late Symptoms
› Agitation	› Abdominal cramping
› Anxiety	› Diarrhea
› Muscle aches	› Dilated pupils
› Increased tearing	› Goose bumps
› Insomnia	› Nausea
› Runny nose	› Vomiting
› Sweating	
› Yawning	

Initial steps

1. Calculate the MED, review the ORT (or other risk-screening assessments), and assess the patient progress in treatment, including UDS, PDMP, and any signs of aberrant behavior. Use that review to inform the patient concerning the appropriateness of tapering. Involve the patient in the creation of his or her new care plan.
2. Sometimes, giving the patient some time to assimilate this new information may be appropriate. Starting the taper at the follow-up visit may help to build trust.

3. Patients at risk for aberrant behaviors during the tapering process (suicidality, illicit drug use, loss of impulse control) will need referral to a behavioral health specialist prior to the initiation of the taper. It is helpful to work in parallel with such behavioral specialists during the tapering process for those patients.
4. Document your plan and the reasons for the taper in the chart note, and provide appropriate information to your patient.
5. Medication tapering may be a very stressful experience for patients. Close monitoring for aberrant behaviors is critical during this period to assure patient compliance and safety. Misuse of medications, use of illicit drugs, and "doctor shopping" may necessitate a change in approach, requiring a switch from a tapering strategy to substance-abuse treatment (residential care or medication-assisted treatment, such as buprenorphine).

Slow-taper protocol

1. Long-acting opioids: Decrease total daily dose by 5–10% of initial dose per week.
2. Short-acting opioids: Decrease total daily dose by 5–15% per week.
3. These regimens may need to be slowed toward the end of the tapering process (see General Considerations above). Often, once 25–50% of the total dose is reached, the rate of taper can be slowed to 5% per week.
4. You and your patient should know the signs and symptoms of opioid withdrawal. Some of those symptoms may be present during this process, and can be controlled by support medication, psychosocial supports, or slowing the tapering process.
5. Remain engaged with the patient through the taper and provide psychosocial support as needed. Peer-to-peer, Living Well With Chronic Pain workshops, group visits, CBT, and other counseling modalities may be quite helpful.
6. Consider the following adjuvants as needed:
    - Antidepressants to manage irritability, sleep disturbance (e.g., trazodone)
    - Hydroxyzine for insomnia and anxiety
    - Anti-epileptics for neuropathic pain
    - Clonidine for autonomic withdrawal symptoms such as rhinorrhea, diarrhea, sweating, tachycardia, hypertension
    - NSAIDS for myalgia (e.g., ibuprofen)
    - Anti-diarrheal agents for diarrhea
    - Opioid Withdrawal Attenuation Cocktail (Appendix F)

Special considerations for methadone

Methadone withdrawal symptoms take longer to manifest because of the long and unpredictable metabolism of the drug. Patients may be overconfident early in the tapering process only to experience severe withdrawal over time. The same principles of opioid tapering are true for methadone; although, a more drawn-out taper may be necessary. Understanding the unique metabolic characteristics of methadone will be helpful for you and the patient to achieve a successful dosage reduction.

Opioid Tapering Flow Sheet

START HERE

Consider opioid taper for patients with opioid MED > 90 mg/d or methadone > 30 mg/d, aberrant behaviors, significant behavioral/physical risks, lack of improvement in pain and function.

1. Frame the conversation around tapering as a safety issue.
2. Determine rate of taper based on degree of risk.
3. If multiple drugs involved, taper one at a time (e.g., start with opioids, follow with BZPs).
4. Set a date to begin and set a reasonable date for completion. Provide information to the patient and establish behavioral supports prior to instituting the taper. See OPG guidelines.

OPIOID TAPER

Opioids

Basic principle: For longer-acting drugs and a more stable patient, use slower taper. For shorter-acting drugs, less stable patient, use faster taper.

1. Use an MED calculator to help plan your tapering strategy. Methadone MED calculations increase exponentially as the dose increases, so methadone tapering is generally a slower process.
2. Long-acting opioid: Decrease total daily dose by 5–10% of initial dose per week.

   Short-acting opioids: Decrease total daily dose by 5–15% per week.
3. See patient frequently during process and stress behavioral supports. Consider UDS, pill counts, and PDMP to help determine adherence.
4. After ¼ to ½ of the dose has been reached, with a cooperative patient, you can slow the process down.
5. Consider adjuvant medications: antidepressants, gabapentin, NSAIDs, clonidine, anti-nausea, anti-diarrhea agents.

MED for Selected Opioids

Opioid	Approximate Equianalgesic Dose (oral and ransdermal)
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Methadone Chronic	4mg
Oxycodone	20mg
Oxymorphone	10mg
Tapentodol	75mg
Tramadol	300mg

Morphine Equivalent Dosing (MED) Calculator:
agencymeddirectors.wa.gov/mobile.html

Benzodiazepine Taper/Discontinuation

Benzodiazepines are potentially addictive drugs that may produce physical dependence, amnesia, emotional blunting, psychomotor retardation, and synergistic respiratory depression when combined with opioids. Anxiety, although initially ameliorated by benzodiazepines taken short term, often returns to near baseline levels with chronic use. Patients may be reluctant to taper off of these medications fearing the exacerbation of anxiety that usually accompanies the dose-reduction process.

Unlike opioids, abrupt withdrawal from high doses of benzodiazepines can result in seizures and death. The detoxification resembles alcohol withdrawal in terms of symptomatology and risk. Some patients will need medically supervised residential treatment to successfully discontinue benzodiazepines.

Withdrawal: The longer the treatment, the higher the dosage, the shorter the half-life, or the faster the taper, then the more likely the patient will have withdrawal symptoms. Even small doses of benzodiazepines taken chronically may produce uncomfortable symptoms if discontinued abruptly.

Common Benzodiazepine Withdrawal Symptoms

Difficulty Concentrating	Restlessness	Agitation	Tremor
Increased Acuity to Stimuli	Loss of Appetite	Diaphoresis	Anxiety
Faintness/Dizziness	Fatigue/Lethargy	Tinnitus	Nausea
Muscle Cramps/Twitches	Poor Coordination	Insomnia	Paresthesia
Perceptual Distortions	Depersonalization	Confusion	

General considerations

- Some short-term increase in anxiety is to be expected during the tapering process. This is usually transient, and after achieving a reduced baseline dose, the patient is likely to experience decreased medication-related side effects without an increase in anxiety. Many times, benzodiazepines may be completely discontinued with no increase in symptoms but with improved function and quality of life.
- The slower the taper, the less the short-term discomfort. Educating the patient about the risks of their current regimen and what to expect as they taper off the medications is often/can be helpful.
- Some highly motivated patients prefer a rapid taper (weeks versus months). Patient preference needs to be considered in designing a tapering schedule.
- Psychosocial support is an essential component of successful medication withdrawal for patients who have been on long-term benzodiazepine therapy. Discussions about weaning are often associated with fear and anxiety about the recurrence or worsening of anxiety and/or the development of other withdrawal symptoms. Reassure each patient that supportive adjunctive treatment of withdrawal will be provided as needed, and may be quite helpful, but set expectations that this will not include dangerous replacement medications. Certain non-habit forming medications that treat insomnia specifically (such as trazodone or hydroxyzine) might be useful.
- Patient empowerment is key to success. Involve patients in the planning from the beginning. Elicit suggestions for healthful activities that can replace reliance on medications.

- Certain therapies, CBT and trauma-focused care, for example, can be quite helpful in supporting patients through the tapering process and beyond.
- The last part of the dosage reduction is the most difficult for patients. This is a phenomenon that is true for many psychoactive drugs. You and your patients should anticipate this and use supports that are meaningful to your patients. In motivated patients, a slow-down of the tapering process may be necessary toward the end. Liquid forms of medication can be helpful for more precise dosing and can be obtained from a compounding pharmacy.

Discontinuation strategies

Here are two strategies that can be used to taper off of benzodiazepines:

1. Switching to a long-acting benzodiazepine (or phenobarbital) and slower taper.
2. Simultaneous treatment with an anti-epileptic drug during taper (allows for a more rapid taper).

Special circumstances

Consider inpatient/medical residential treatment in patients with significant substance abuse history, history of benzodiazepine overdose, seizure disorder, or illicit benzodiazepine use. Modified CIWA evaluation or MSSA (withdrawal scoring systems) can be used in such circumstances to determine the total 24-hour dose needed to begin the taper and provide safe medical monitoring of the taper process.

Slow-taper method

1. Calculate the dose equivalence of the current benzodiazepine into clonazepam, diazepam, or phenobarbital long-acting drug: (http://www.benzo.org.uk/bzequiv.htm). Provide behavioral support to the patient during the tapering process above (see General Considerations concerning opioid tapering).
2. Switch the patient from the short-acting drug to the longer-acting drug. Be conservative in estimating the long-acting dose since variation in metabolism may create safety issues. Consider a reduction of 25–50% of the calculated dose for initiation of tapering.
3. See the patient for a return visit a few days after initiating the taper to be sure your dose equivalency is appropriate.
4. Reduce the total dose of the long-acting agent by 5–10% per week in divided doses.
5. Consider slowing the taper to 5% or less per week when the dose has been reduced to 25–50% of the starting dose.
6. Consider adjunctive agents to help with symptoms: trazodone, buspirone, antidepressants, hydroxyzine, clonidine, neuroleptics, and alpha-blocking agents have all been useful.

Benzodiazepine Equivalency Chart

Drug	Action Onset	Peak Onset (hrs)	Half-life (hrs)	Eliminator	Dose Equivalent
Long-Acting					
Chlordiazepoxide (Librium)	Int	2–4	5–30 (parent); 3–100 (metab)	Oxidation	10mg
Diazepam (Valium)	Rapid	1	20–50 (parent); 3–100 (metab)	Oxidation	10mg
Flurazepam (Dalmane)	Rapid	0.5–2	47–100 (metab)	Oxidation	30mg
Phenobarbital (barbiturate)	Slow	0.5–4	53–118 (metab)	Oxidation	30mg
Intermediate-Acting					
Alprazolam (Xanax)	Int	0.7–1.6	6–20 (parent)	Oxidation	0.5mg
Clonazepam (Klonopin)	Int	1–4	18–39 (parent)	Oxidation	0.5mg
Lorazepam (Ativan)	Int	1–1.5	10–20 (parent)	Conjugation	1mg
Oxazepam (Serax)	Slow	2–3	3–21 (parent)	Conjugation	15mg
Temazepam (Restoril)	Slow	0.75–1.5	10–20 (parent)	Conjugation	30mg
Short-Acting					
Triazolam (Halcion)	Int	0.75–2	1.6–5.5 (parent)	Oxidation	0.5mg

Onset of Action

Rapid = within 15 min.
Intermediate = 15–30 min.
Slow = 30–60 min.

Benzodiazepine Tapering Flow Sheet

START HERE

Consider benzodiazepine taper for patients with aberrant behaviors, behavioral risk factors, impairment, or concurrent opioid use.

1. Frame the conversation around tapering as a safety issue.
2. Determine rate of taper based on degree of risk.
3. If multiple drugs are involved, taper one at a time (e.g., start with opioids, follow with BZPs).
4. Set a date to begin and a reasonable date for completion. Provide information to the patient and establish behavioral supports prior to instituting the taper. See OPG guidelines.

BENZODIAZEPINE TAPER

Basic principle: Expect anxiety, insomnia, and resistance. Patient education and support will be critical. Risk of seizures with abrupt withdrawal increases with higher doses. The slower the taper, the better tolerated.

SLOW TAPER

1. Calculate total daily dose. Switch from short-acting agent (alprazolam, lorazepam) to longer-acting agent (diazepam, clonazepam, chlordiazepoxide, or phenobarbital). Upon initiation of taper, reduce the calculated dose by 25–50% to adjust for possible metabolic variance.
2. Schedule first follow-up visit two to four days after initiating taper to determine if adjustment in initial calculated dose is needed.
3. Reduce the total daily dose by 5–10% per week in divided doses.
4. After ¼ to ½ of the dose is reached, you can slow the taper with cooperative patient.
5. With cooperative patients who are having difficulty with this taper regimen, you can extend the total time of reduction to as much as six months.
6. Consider adjunctive agents to help with symptoms: trazodone, hydroxyzine, neuroleptics, anti-depressants, clonidine, and alpha-blocking agents.

RAPID TAPER

1. Pre-medicate two weeks prior to taper with valproate 500mg BID or carbamazepine 200mg every AM and 400mg every HS. Continue this medication for four weeks post-benzodiazepines. Follow the usual safeguards (lab testing and blood levels) when prescribing these medications.
2. Utilize concomitant behavioral supports.
3. Discontinue current benzodiazepine treatment and switch to diazepam 2mg BID for two days, followed by 2mg every day for two days, then stop. For high doses, begin with 5mg BID for two days and then continue as described.
4. Use adjuvant medications as mentioned above for rebound anxiety and other symptoms.

Benzodiazepine Equivalency Chart

Drug	Half-life (hrs)	Dose Equivalent
Chlordiazepoxide (Librium)	5–30 h	25mg
Diazepam (Valium)	20–50 h	10mg
Alprazolam (Xanax)	6–20 h	0.5mg
Clonazepam (Klonopin)	18–39 h	0.5mg
Lorazepam (Ativan)	10–20 h	1mg
Oxazepam (Serax)	3–21 h	15mg
Triazolam (Halcion)	1.6–5.5 h	0.5mg
Phenobarbital (barbituate)	53–118 h	30 mg

OTHER CONSIDERATIONS

Prescription Drug Monitoring Program (PDMP)

The PDMP is an online tool available to all prescribers, pharmacists, and patients in Oregon. Once a prescriber is registered with the program, he or she can learn exactly which prescription medications a patient has taken and is taking. The value of this information cannot be overstated. We strongly encourage its regular use as an assessment and management tool. Without question, a query of the PDMP should be completed for each patient prior to prescribing. Prescribers can now delegate "look-up authority" to their support staff. Go to www.orpdmp.com for details.

Concomitant Benzodiazepine and Opioid Use

Most experts advise against concomitant use of BZPs and opioids because of the synergistic effect of those drugs in combination exacerbating respiratory depression. As many as 50% of opioid overdoses have involved sedative hypnotics. In addition, the anterograde amnesia that is inevitable with benzodiazepines can contribute to inadvertent overdose for predisposed individuals. It is strongly recommended that you check for BZP use by UDS, PDMP query, as well as observing for impairment or sedation. Psychotherapy is often helpful as an adjunct to tapering (see Tapering in this document). Some individuals may require inpatient treatment to successfully discontinue use. Many patients who are dependent on BZPs have a difficult time abstaining from other sedative hypnotic substances (such as alcohol, barbiturates, and carisoprodol), and these drugs have similar risks for overdose when combined with opioids.

Concomitant Marijuana and Opioid Use

Medical and recreational marijuana is legal in Oregon and many other states. It is still illegal, however, under federal law. Marijuana is clearly a mind-altering drug, and though it may provide mild to moderate pain relief, it does have associated risks and side effects, such as altered response times, perceptual changes, and mood changes. In some circumstances, marijuana use may be associated with other illicit or risky drug use.

Some providers do not prescribe chronic opioids when marijuana is used (the patient has to choose which treatment modality to use). Others decide not to include THC in their UDS so as not to create a conflict with their patients. Others believe that marijuana may provide appropriate additional pain relief, particularly CBD (cannabidiol) enhanced varieties.

Disposal

The overprescribing of opioids can lead to the accumulation of unused pills in the medicine cabinet. This is true, especially for acute pain situations, when 30 pills may be prescribed for a time-limited situation and only five pills are taken. Those unneeded medications can pose a risk to children or can inadvertently provide a source of illicit opioids through theft or sharing. The ability to safely dispose of unused medication is an important strategy in the fight to reduce unnecessary opioids in circulation.

Drug take-back programs: The Drug Enforcement Administration promotes national drug-take back day on May 8. Many law enforcement agencies have drug drop boxes in their communities. Some pharmacies may also take unused medications as the laws have been relaxed allowing for medication return in some states. The FDA and DEA have useful hints on their websites for disposal, including how to dispose of unwanted medication safely.

Medication-Assisted Treatment (MAT)

Medication-assisted treatment refers to the use of pharmaceutical agents to treat opioid-use disorder. Generally methadone, buprenorphine, and naltrexone sustained release are used for this purpose. Methadone and buprenorphine have the highest rates of success for opioid-use disorder, an important consideration when weighing the significant risks associated with abuse versus the greater relapse rate associated with non-medication treatment regimens. Remember, those with opioid addiction are living with a potentially fatal chronic disease and deserve prompt and effective treatment.

- Methadone can only be prescribed for addiction treatment in a federally monitored treatment facility. Methadone treatment for chronic pain should be used cautiously, if at all, and only at low doses. Significantly higher daily doses (80–100 mg average) are used when treating opioid-use disorder because the MAT clinic can institute tight medication oversight such as daily nurse monitoring, counseling, UDS, and PDMP query. The use of high-dose methadone in such circumstances does not carry the same degree of risk as it would in a primary-care setting.
- Any physician in an office setting can prescribe buprenorphine, after taking a brief educational course and getting an "X" waiver added to their DEA number.[44] Buprenorphine is safer than methadone and generally more convenient to the patient. It is recommended that if you prescribe opioids for chronic pain, you should either become a buprenorphine prescriber or have ready access to that service.
- Medication-assisted treatment should be accompanied by ongoing behavioral supports, and it is strongly recommended that providers of care utilize such expertise as a part of their treatment plan.
- Recognizing opioid-use disorder in your patient should trigger an immediate referral to an effective treatment program or, if you are X waivered, a switch to buprenorphine treatment.
- Naltrexone-injectable Vivitrol can be another useful tool for the patient motivated enough to begin treatment after total opioid abstinence. It also can be provided in a practitioner's office.

Heroin

There has been a rise in heroin use, heroin overdoses, and heroin treatment admissions in the U.S. over the past decade.[45] Opioid dependency does not differentiate between mu agonists, so individuals who develop a substance-use disorder with prescription opioids will find symptomatic relief with any opioid, including heroin. In many parts of the country, heroin is cheaper than pills and is accessible almost everywhere. Therefore, many individuals who could not stop using pain medicines because of dependency and whose demand exceeded their supply turned to heroin use.

Heroin can be smoked, snorted, or injected. It comes in various forms: black tar, gunpowder, and white powder. The potency of the drug varies both regionally as well as temporally, making dosing decisions on the part of the user difficult and dangerous. Overdoses are common, particularly when an addict has reduced his or her tolerance (jail, prison, sobriety based on residential treatment) and then resumes use. Concomitant use of sedative hypnotics such as alcohol, benzodiazepines, carisoprodol, and sleeping pills increase the risk of overdose.

The most effective treatment for heroin addiction (as well as all opioid substance-use disorder) is medication-assisted treatment (see the MAT section in this document). Any treatment that results in discontinuation of opioids has a risk of relapse, and with relapse at a reduced tolerance comes increased risk of overdose. Risk of relapse and overdose should be an educational component to all opioid treatment.

Bystander naloxone is an essential "downstream" treatment that reduces mortality from opioid overdose. See the Naloxone section (below) in this document.

Individuals with a history of heroin use, past or present, are at high risk of inappropriate use of prescription opioids. Such individuals can safely be treated using buprenorphine or methadone, and primary-care or pain-specialty providers need to be very cautious treating such individuals for pain using opioids.

Naloxone

Naloxone is a pure mu antagonist, and as such, it is an antidote to the effects of opioid intoxication. It reverses respiratory depression that is the cause of death in an opioid overdose. Naloxone has essentially no adverse effects and is remarkably successful in reversing the life-threatening effect of opioids. The incidence of opioid overdose is dose related, but anyone taking opioids is potentially at risk. Therefore, we recommend co-prescribing naloxone for the families and loved ones of all patients prescribed opioids for chronic use.

Naloxone displaces other opioids off the mu receptor sites, but is has a short half-life, having an effect for 30 to 90 minutes. After the drug wears off, the agonists may again reattach to the receptors. Anyone requiring naloxone treatment should be transported to an emergency department for further evaluation since return to the overdose state is possible with the passage of time after the initial naloxone treatment.

Naloxone can be administered parenterally (IV or IM), but it is also effective as a nasal spray. The drug has a very rapid onset of effect when given IV. Its onset of action is more gradual, but still lifesaving, when given via intra-nasal spray. Lay persons can easily be trained to use the intranasal product.

Naloxone is a drug administered by another person to rescue an individual who is overdosing on an opioid. Friends or relatives are often the ones who are present at the time of an overdose and are therefore the individuals who need to receive naloxone training.

Naloxone co-prescribing

Everyone taking opioids on a daily basis should have their friends or loved ones trained in naloxone use. It should be a part of a routine prescribing protocol for prescribers. It communicates your concerns about safety to your patient.

Many states allow lay-person use of naloxone, many insurance companies will pay for the drug, and in Oregon, a simple online training course will suffice to allow dispensing of the drug.

In 2014, 52 people died every day in the United States from prescription-opioid-related overdoses. Cities and states with naloxone distribution programs have seen 37–90% reductions in overdose deaths. Co-prescribing naloxone with medications is an important component of opioid therapy. Patients and their providers commonly underestimate the chance of experiencing an overdose. "Risky drugs, not risky people" is a useful phrase to use when explaining the necessity of naloxone co-prescribing to patients.

Overdose risk factors

As was stated earlier, all individuals taking opioids are at some risk of an overdose. Certain factors will increase that risk:

- Individuals taking sedative-hypnotics (alcohol, benzodiazepines) in addition to opioids are at increased risk. Such individuals may have a partial response to naloxone, since the drug only acts to reverse the opioid component of the overdose.
- Individuals whose opioid tolerance has decreased are at risk. This includes people who leave residential addiction-treatment programs or are released from incarceration.
- Individuals whose dose of opioids is suddenly increased are at risk. A sudden increase in opioid dosing, or a new source of heroin, stronger than what the user was expecting, for example.
- Someone who has previously overdosed is at risk of overdosing again.

Further resources

- Videos demonstrating use of naloxone: http://tinyurl.com/oregonoverdose
- Oregon naloxone law: http://tinyurl.com/oregonODlaw
- Oregon training materials: http://tinyurl.com/naloxonetrainer
- Film and resources for advocates, families and providers: www.reach4me.org
- Prescribing information and guidelines: www.prescribetoprevent.org
- San Francisco Health Department provider guide to prescribing naloxone: http://www.sfhealthnetwork.org/wp-content/uploads/26a-Detailing_Provider_final.pdf
- San Francisco Health Department brochure for patients: http://www.sfhealthnetwork.org/wp-content/uploads/27-Detailing_Patient_final.pdf

MEDICATIONS THAT WARRANT SPECIAL ATTENTION

Sleeping Pills (Z Drugs and Others)

The Z drugs—zolpidem, zaleplon, eszopiclone—are indicated for the short-term treatment of insomnia. These medications are not benzodiazepines, but they do act on the same receptors and yet have a somewhat different risk profile (reduced seizure risk with withdrawal, for example). Many of the adverse effects of BZPs are true for the Z drugs, as well: drowsiness, memory impairment, reduced coordination, depression, and sleep disturbances. Benzodiazepines are also commonly prescribed for insomnia, namely temazepam and lorazepam. As noted, there are many adverse effects associated with use, with little long-term efficacy.

There is an increase in all of these effects with elderly and pediatric patients. Using any of the Z drugs, BZPs, alcohol, or opiates in any combination increases the risks of impairment and overdose. It is easy to become dependent on these medications, and it can be difficult to return to normal, unaided sleep when discontinuing use. There are safer medical alternatives as well as non-pharmacological options that can be explored.

When considering prescribing these medications for insomnia:

- Avoid combinations of Z drugs, BZPs, opioids, or stimulants
- Use the lowest dose possible:
  - Avoid prescribing these for children and adolescents
  - Use cautiously and at the lowest doses in the elderly
- Prescribe for only short intervals (7–10 days)
- Consider alternatives:
  - Trazodone
  - Amitriptyline
  - Melatonin

Tramadol and Tapentadol

These are opiate-like analgesics used to treat moderate to severe pain. In addition to binding to mu opioid receptors, tramadol weakly inhibits norepinephrine and serotonin reuptake and tapentadol inhibits norepinephrine reuptake. Many of the risks associated with opioids are true for tramadol and tapentadol. Tramadol is now a Schedule IV drug and has been shown to increase the risk of precipitating a seizure. Both of these medications can cause physical and psychological dependency.

We recommend that tramadol be treated as other true opioids when evaluating risks and benefits of opioid treatment.

Carisoprodol

Carisoprodol is a muscle relaxant with properties and risks similar to benzodiazepines, with similar habit forming properties. This medication should be used cautiously, *if at all,* especially in combination with opioids. It has been removed from the market in a number of countries worldwide, and the EU recommends it not be used for the treatment of low back pain. In patients experiencing severe pain from spasticity, consider alternatives such as tizanidine or baclofen.

Meperidine

Meperidine is a narcotic analgesic with sedative properties and is not recommended for outpatient treatment of acute or chronic pain. Additionally, meperidine is included in the 2015 AGS Beers Criteria as a potentially inappropriate medication to be avoided in patients 65 years and older because of potentially higher risk for delirium (neurotoxic metabolite), and lack of analgesia when taken orally. Furthermore, the American Pain Society does not recommend its use as an analgesic.

Long-Acting Opioids

Long-acting opiates consist of ER/LA formulations such as oxycodone, morphine ER, fentanyl patches, and methadone, among others.

Long-acting opiates carry the same risks as short-acting formulations. However, the risks of addiction, abuse, misuse, overdose and death are much greater, especially in opiate-naïve patients. For this reason, the use of long-acting opiates should be reserved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative modalities (both pharmacologic and non-pharmacologic) have been maximally tried and subsequently failed.

Methadone

Methadone has unique metabolic properties making it particularly dangerous to prescribe outside of a closely managed methadone clinic. Overdoses are greatly increased with methadone compared to other opioids. Most guidelines recommend dosing at fewer than 30 mg/day or not at all.

You will notice in the table below, as the dose of methadone increases, the potency of the drug in relation to other opioids increases in an exponential fashion. This will assist in making safe medication switches from methadone to other opioids and vice versa.

Morphine Equivalents	Methadone Factor
100 mg	4:1
100 – 300 mg	8:1
300 – 500 mg	12:1
500 – 1000 mg	15:1
1000 – 2000 mg	20:1
> 2000 mg	30:1

Gabapentin

Gabapentin and pregabalin have a role in the treatment of neuropathic pain, but also have potential for misuse and abuse. These agents are perceived on the street as a substitute for most common illicit drugs. Overdoses have been fatal because of CNS depression, especially when combined with opioids, alcohol, or other CNS depressants.

Gabapentin and pregabalin are structurally related to GABA. They reduce the release of excitatory neurotransmitters as well as increase the effects of the dopaminergic reward system. This is responsible for the sedative and dissociative/psychedelic effects that can occur at higher doses. Pregabalin is a Schedule V controlled substance in the U.S. It may have a higher addiction potential than gabapentin resulting from its rapid absorption, faster onset of action, and a greater affinity for binding sites. The bioavailability of pregabalin does not decrease with higher doses, while bioavailability of gabapentin decreases by nearly 50% when the dose is increased from 900 mg/day to 3,600 mg/day. Doses greater than 1,800 mg/day of gabapentin don't appear to provide additional neuropathic pain relief.

Gabapentin may help attenuate withdrawal symptoms from alcohol or opioids, and abusers will often "bridge" with gabapentin until they can obtain a supply of illicit drugs. However, it is important to note that individuals may also experience withdrawal symptoms from gabapentin itself. Consider alternatives such as tricyclics (TCAs) for neuropathic pain as an alternative to high-dose gabapentin.

THE ART OF DIFFICULT CONVERSATIONS

It is common for the provider/healthcare team to experience challenging conversations with patients as safety guidelines in the area of chronic pain and prescription opioids are implemented. Some topics that may elicit fear in patients and therefore potential discord may include:

- Discussing controlled substance client/clinic agreements.
- Discussing community, state, and national guidelines for safe-prescribing practices.
- Informing new patients that opioids or other controlled substances will not be prescribed and/or increased.
- Informing patients that opioids will be discontinued and/or tapered.
- Discussing the dangers and side effects of the medication.

It is understandable and predictable for patients to express strong feelings when they are presented with information such as the need to reduce or eliminate opioids. Pain medications can become a patient's primary coping strategy for dealing with physical, emotional, psychological and post-traumatic pain. Delivering a message about reducing or stopping such medications can be triggering and even terrifying for a patient and the patient's family. In such situations, patient's emotions are commonly first expressed in the form of anger directed toward the prescribing provider and healthcare team. When facing a highly emotional patient, it is helpful to consider what may be underlying the strong emotional expression. Often underneath the heightened emotional response such as anger, there is fear, grief, panic, sadness, and/or a belief that living without prescription opioids is impossible. Being curious and understanding about what may be beneath a highly emotional expression does not mean one should not take action in the service of safety; however, treading lightly and following the recommendations below will make for a more positive outcome.

Value Identification

Prior to engaging in potentially challenging conversations, it is advisable to spend time reflecting on the core values and principles that you are upholding in the difficult conversation. For example, it may be in the service of practicing safe medicine, being in alignment with your colleagues, the medical board and/or community, state, and national safe opioid prescribing guidelines. When you are in alignment with your values and the healthcare team believes that the change is in the patient's best interest, the difficult conversations are often more manageable and rewarding.

Realistic Expectations

When asking a patient to do something they may be afraid to do or that they do not want to do, they may leave the appointment highly distressed, very angry, and/or inconsolably sad. It is common for providers and the healthcare team to feel that if a patient leaves in such a highly agitated way, this indicates that the outcome of the appointment was a failure. Reconsider this belief. When a provider or healthcare team member asks a patient to make a change that is guided by core principles and values and a belief that it is in the patient's best interest to make the change, then the state the patient is leaving in can be considered a natural part of the patient's therapeutic process, and a positive step toward the individual's overall health and well-being.

Willingness to Feel Uncomfortable

Difficult conversations often bring about discomfort for patients, their families, providers, and healthcare team members. When we model our willingness to be uncomfortable to our patients, it helps the process. Consider saying to yourself before engaging in such a conversation, "I am willing to be uncomfortable having this conversation because it is in the service of my value of safety and best-practice medicine." It can be helpful to notice your own sympathetic nervous system activation (e.g., rapid, shallow breathing; clenching fists or jaw), and then engage in an activity to activate your parasympathetic nervous system (e.g., slowing down your exhale and softening your hands or jaw). Just as these situations can be highly triggering for our patients, they can be highly triggering for providers and the healthcare team, as well. These conversations go much more smoothly when providers or healthcare team members can identify which types of patients and situations trigger them the most and develop an intervention strategy to notice the trigger and proceed calmly and effectively with delivering effective patient care.

Relationship as a Resource

It is important not to underestimate the relationship between the patient and the provider or healthcare team as a resource. Most patients genuinely care for their providers and/or healthcare team and want to work collaboratively with them. Often, genuinely communicating with patients that you will stick by their side through the changes can be one of the most powerful tools. Patients often fear their providers or healthcare team will abandon them, ask them to make changes too quickly, not listen to their fears, and or "fire" them from their practice. Proactively quashing such fears and acknowledging that the fear is real to them will go a long way toward reducing those fears.

Belief and Confidence

Expressing the belief in the patient's ability to make the change is one of the most valuable tools for creating positive clinical outcomes such as removing or reducing opioids. You may think the patient knows this; however, it is highly advisable to overtly tell the patient, even over multiple appointments, and even if it feels redundant or if you don't completely believe that your patient will be able to make such changes. Believing the patient can change is critical to the success of the process. Over time, as you see your patient making such changes and actually increasing functioning and quality of life, you will be more confident in your patient's abilities and it will be easier to relay your belief in them.

Resources

Difficult Conversations: Real life examples, Helpful Hints, and Tools - www.oregonpainguidance.org/clinical-tools
Motivational Interviewing Resources - www.motivationalinterviewing.org

TOOLS

There are various tools that can assist you in evaluating and managing your chronic pain patients. The following is a brief overview, while the tools themselves can be found in the Appendices. The following is a brief overview, while the tools themselves can be found in the Appendices. These tools are available online at www.oregonpainguidance.org/clinical-tools.

Assessment Tools

Opioid risk tool (ORT)

The ORT is one of the easiest assessment tools for establishing a patient's susceptibility to misuse of opioids. Other tools are available and are equally appropriate. The ORT is provided in Appendix A. The CDC guidelines suggest that such tools have a low degree of predictability and should be used as only one component of assessment of risk.

SOAPP-R (Screening and Opioid Assessment for Patients with Pain-Revised Screening Test

The SOAPP-R is a brief screening test to help predict possible opioid abuse in adult chronic pain patients. A high score on the SOAPP-R correlates with an increased likelihood of drug abuse. See Appendix B.

Patient health questionnaire for anxiety and depression (PHQ)

The correlation between mental health issues and opioid misuse is well established. The PHQ is a tool to help you identify individuals who are at risk of misusing opioids and benzodiazepines because of mental health issues. Depression and, to a lesser extent, anxiety are well-known risk factors. Bipolar disorder, PTSD, and certain personality disorders are risk factors, as well. Tools like the PHQ are especially useful when used in the context of behavioral health evaluation and/or physical exam. A positive score on the PHQ or other tests, the presence of suicidal ideation, and/or your clinical judgment may indicate that further assessment is warranted. The PHQ-4 is a short questionnaire and can be found in Appendix C.

Screening for post-traumatic stress disorder (PTSD)

PTSD in the form of childhood trauma is a common confounding problem in patients with chronic pain, and in those who become dependent on benzodiazepines. Ensuring you practice trauma-informed care is essential to managing chronic pain patients. See "Primary Care PTSD Screen" in Appendix D.

STOP BANG

STOP BANG helps evaluate the risk of respiratory depression with opioids. Pain often disrupts sleep in chronic pain patients, and the resulting insomnia may increase pain intensity and reduce the pain threshold. Opioids can significantly increase the chance of central sleep apnea, and must be used with caution, especially in those patients identified to have possible obstructive sleep apnea (OSA) prior to the initiation of opioid therapy. Assessment of sleep disturbances is a key metric for evaluating patient risk as well as for monitoring opioid therapy. The STOP BANG assessment is provided in Appendix E.

Chronic pain checklist

This checklist may be useful as a means to ensure compliance with these guidelines with a standardized approach to every pain patient. See Appendix F.

Laboratory Screening

Urinary drug screen (UDS)

UDS helps monitor for unexpected licit and illicit drugs that may be present in your patient's urine. UDSs should be used with every chronic pain patient as a standard part of your office policy. There are two basic types of UDS: POC testing (in office) and confirmatory (laboratory based). See Appendix G for UDS frequently asked questions.

- **Point-of-care (POC)**
  Advantages and limitations: POC tests are inexpensive and easily performed. Testing kits can be configured to your needs. Most common drugs to be included: opiates, benzodiazepines, methadone, amphetamine/ methamphetamine, cocaine, THC, and oxycodone. Other tests commonly included are PCP, barbiturates, and alcohol, but many others are often optional single tests (fentanyl, buprenorphine, for example).

  Remember that these are management tools, not definitive tests to determine deception or illicit use. These tests have a fairly high rate of false negative and false positives. Their interpretation is fraught with difficulties. Understanding of metabolic pathways, cutoff levels, drug-drug interactions, and what drugs are and are not picked up on a particular test are essential to the interpretation of POC testing. Some examples:

  - Hydrocodone often is not detected on the POC opioid strip.
  - Hydrocodone can metabolize to hydromorphone and be detected as Dilaudid, when in fact none was prescribed.
  - Diazepam metabolizes to oxazepam and can present as a drug not prescribed.
  - Clonazepam and lorazepam are sometimes not detected on the benzodiazepine screen.
  - Amphetamines appear as a false positive result with some frequency.

- **Confirmatory lab-based tests**
  Advantages: These tests, GC-MS and LC/MS-MS, can be highly accurate, depending on the type used. For instance, LC/MS-MS testing allows for extremely low opiate cutoffs.

  Limitations: Many lab-based tests are quite expensive. Some clinics use them for verification purposes. One approach is to use POC testing first and, if results are unexpected, following up with a laboratory test.

Metabolism data for common medications

This is a table of useful information regarding the metabolism of common opioids and other medications. The time limits of detection, tests to order, and "expected results" are listed in Appendix H.

Patient-Provider Communication

Patient treatment agreements

Many providers wish to have conditions of treatment clearly stated in a written document prior to prescribing. Samples patient agreements are provided in Appendix I.

Material risk notice

The Oregon Medical Board states that a material risk notice needs to be signed by the patient whenever opioids are prescribed chronically. A Material Risk Notice is provided in Appendix J.

Medical risks of long-term opioid use

Many patients are not familiar with the wide range of medical risks of long-term opioid use. When they understand the risks involved, they are more likely to be receptive to reducing or discontinuing opioid use. We recommend that you print out this one-page document, give it to your patient and go over with them the many risks and side effects of using opioids long term. This patient education handout is provided in Appendix K.

Assessing Progress

Graded pain and function scale

The goal of opioid treatment is to improve function, both physical and emotional. Activities of daily living (ADLs) are critical to evaluate at each visit, as are other quality-of-life indicators. This is a very simple tool to track function and pain over time. The graded pain and function scale is provided in Appendix L.

Oswestry low-back pain disability questionnaire

This is a comprehensive functional assessment tool for following a patient's "functional progress" over time. The form is provided in Appendix M.

PEG-3 Pain Screening Tool

This three-question tool helps the provider determine the impact that pain is having on a patient's activity level and quality of life. The PEG-3 is a useful assessment tool that can be used routinely at follow-up visits for chronic pain patients. See Appendix N.

Other Tools

Additional assessment tools

A description of many of the commonly used screening tools for substance-abuse history, mental health history (including suicidal ideation or attempts), activities of daily living (ADLs), and a patient's own disability perception. This list is provided in Appendix P.

Behavioral health risks screening tool for pregnant women and women of child-bearing age

Women and their children's health can be affected by emotional problems, alcohol, tobacco, other drug use and violence. This screening tool can help guide referrals to tobacco cessation programs, addictions and recovery programs, domestic violence prevention and mental health programs. See Appendix Q.

Opioid withdrawal attenuation cocktail

This is a list of medications that can be used to help manage "withdrawal symptoms" in patients who are being tapered down or off of their opioids. See Appendix R.

Patient and community resources

This is a local southern Oregon resource guide, including addiction and residential services, populations served, as well as insurances accepted. This listing is located in Appendix S.

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APPENDICES

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OPIOID RISK TOOL (ORT)

			Mark each box that applies	Item score if FEMALE	Item score if MALE
1	Family history of substance abuse	Alcohol	☐	1	3
		Illegal drugs	☐	2	3
		Prescription drugs	☐	4	4
2	Personal history of substance abuse	Alcohol	☐	3	3
		Illegal drugs	☐	4	4
		Prescription drugs	☐	5	5
3	Age (mark box if 16–45)		☐	1	1
4	History of preadolescent sexual abuse		☐	3	0
5	Psychological disease	Attention deficit disorder	☐	2	2
		Obsessive compulsive disorder	☐	2	2
		Bipolar	☐	2	2
		Schizophrenia	☐	2	2
		Depression	☐	1	1
			TOTAL	_____	_____

Total Score Risk Category

0–3 = low risk

4–7 = moderate risk

≥8 = high risk

Reference: Webster LR. Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the opioid risk tool. *Pain Medicine.* 2005;6(6):432-442. Used with permission.

The ORT and other tools are available online at www.oregonpainguidance.org/clinical-tools.

SCREEN AND OPIOID ASSESSMENT FOR PATIENTS WITH PAIN—REVISED (SOAPP®-R)

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.	Never 0	Seldom 1	Sometimes 2	Often 3	Very Often 4
1. How often do you have mood swings?					
2. How often have you felt a need for higher doses of medication to treat your pain?					
3. How often have you felt impatient with your doctors?					
4. How often have you felt that things are just too overwhelming that you can't handle them?					
5. How often is there tension in the home?					
6. How often have you counted pain pills to see how many are remaining?					
7. How often have you been concerned that people will judge you for taking pain medication?					
8. How often do you feel bored?					
9. How often have you taken more pain medication than you were supposed to?					
10. How often have you worried about being left alone?					
11. How often have you felt a craving for medication?					
12. How often have others expressed concern over your use of medication?					
13. How often have any of your close friends had a problem with alcohol or drugs?					
14. How often have others told you that you had a bad temper?					
15. How often have you felt consumed by the need to get pain medication?					
16. How often have you run out of pain medication early?					
17. How often have others kept you from getting what you deserve?					
18. How often, in your lifetime, have you had legal problems or been arrested?					
19. How often have you attended an AA or NA meeting?					
20. How often have you been in an argument that was so out of control that someone got hurt?					
21. How often have you been sexually abused?					
22. How often have others suggested that you have a drug or alcohol problem?					
23. How often have you had to borrow pain medications from your family or friends?					
24. How often have you been treated for an alcohol or drug problem?					

Please include any additional information you wish about the above answers.

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PHQ-4: THE FOUR-ITEM PATIENT HEALTH QUESTIONNAIRE FOR ANXIETY AND DEPRESSION

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3
TOTALS				

Total score is determined by adding together the scores of each of the 4 items.
Scores are rated as normal (0-2), mild (3-5), moderate (6-8), and severe (9-12).
Total score ≥3 for first 2 questions suggests anxiety.
Total score ≥3 for last 2 questions suggests depression.

Reprinted with permission from Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics. 2009;50(6):613-21. From Principles of Neuropathic Pain Assessment and Management, November 2011.

The PHQ-4 and other tools are available online at www.oregonpainguidance.org/clinical-tools.

PRIMARY CARE PTSD SCREEN

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, **in the past month**, that you*		
1. Have had nightmares about it or thought about it when you did not want to?	☐ YES	☐ NO
2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	☐ YES	☐ NO
3. Were constantly on guard, watchful, or easily startled?	☐ YES	☐ NO
4. Felt numb or detached from others, activities, or your surroundings?	☐ YES	☐ NO

Current research suggests that the results of the PC-PTSD should be considered "positive" if a patient answers "yes" to any three items.

A positive response to the screen does not necessarily indicate that a patient has Posttraumatic Stress Disorder. However, a positive response does indicate that a patient may have PTSD or trauma-related problems and further investigation of trauma symptoms by a mental-health professional may be warranted.

If the PC-PTSD screening instrument is utilized, clarify responses to determine:

a. Whether the patient has had a traumatic experience

"I notice from your answers to our questionnaire that you experience some symptoms of stress. At some point in their lives, many people have experienced extremely distressing events such as combat, physical or sexual assault, or a bad accident, and sometimes those events lead to the kinds of symptoms you have. Have you ever had any experiences like that?"

b. Whether endorsed screen items are really trauma-related symptoms

"I see that you have said you have nightmares about or have thought about an upsetting experience when you did not want to. Can you give me an example of a nightmare or thinking about an upsetting experience when you didn't want to?"

If a patient gives an example of a symptom that does not appear to be in response to a traumatic event (e.g., a response to a divorce rather than to a traumatic event), it may be that he or she is ruminating about a negative life event rather experiencing intrusive thoughts about a traumatic stressor.

c. Whether endorsed screen items are disruptive to the patient's life

"How have these thoughts, memories, or feelings affected your life? Have they interfered with your relationships? Your work? How about with recreation or your enjoyment of activities?"

Positive responses to these questions in addition to endorsement of trauma symptom items on the PCPTSD Screen indicate an increased likelihood that the patient has PTSD and needs further evaluation.

Discern whether traumatic events are ongoing in a patient's life

If ongoing traumatic events are a part of the patient's life, it is critical that the primary care practitioner discern whether the patient needs an immediate referral for social work or mental-health services. The practitioner might ask:

"Are any of these dangerous or life-threatening experiences still continuing in your life now?"

If ongoing family violence is suspected, it is imperative that the patient be told the limits of confidentiality for medical professionals, who are mandated to report suspected ongoing abuse of children and dependent adults. Discussion of possible abuse should take place in the absence of the suspected perpetrator; if the abuser is present, victims may deny abuse for fear of retaliation.

If ongoing threats to safety are present:

- Acknowledge the difficulty in seeking help when the trauma has not stopped.
- Determine if reporting is legally mandated. If it is, develop a plan with the patient to file the report in a way that increases rather than decreases the safety of the patient and his or her loved ones.

If reporting is not appropriate, provide written information (or oral if written might stimulate violent behavior in the perpetrator) about local resources that might help the situation. Establish a plan that the patient will agree to in order to move toward increased safety. The National Domestic Violence Hotline is available to guide callers to local resources: 1-800-799-SAFE or TTY: 1-800-787-3224.

Source: http://www.ptsd.va.gov

The PC-PTSD screen and other tools are available online at www.oregonpainguidance.org/clinical-tools.

STOP BANG

Screening for Obstructive Sleep Apnea

Ask your patient to answer the following questions to determine if he or she is at risk of obstructive sleep apnea.

S (snore)	Have you been told that you snore?	YES	NO
T (tired)	Are you often tired during the day?	YES	NO
O (obstruction)	Do you know if you stop breathing, or has anyone witnessed you stop breathing while you are asleep?	YES	NO
P (pressure)	Do you have high blood pressure, or are you on medication to control high blood pressure?	YES	NO

If the patient answered yes to two or more questions on the STOP portion, he or she is at risk of obstructive sleep apnea.

To find out if the patient is at moderate to severe risk of obstructive sleep apnea, he or she should complete the BANG questions below.

B (BMI)	Is your body mass index greater than 28?	YES	NO
A (age)	Are you 50 years old or older?	YES	NO
N (neck)	Are you a male with a neck circumference greater than 17 inches, or a female with a neck circumference greater than 16 inches.	YES	NO
G (gender)	Are you a male?	YES	NO

The more questions the patient answers yes to, the greater his or her risk of having moderate to severe obstructive sleep apnea.

OSA **Low** Risk: Yes on 0–2 questions

OSA **Intermediate** Risk: Yes on 3–4 questions

OSA **High** Risk: Yes on 5–8 questions

Reference: Modified from Chung F et al J Clin Sleep Med Sept 2014.

STOP BANG and other tools are available online at www.oregonpainguidance.org/clinical-tools.

CHRONIC PAIN TREATMENT CHECKLIST

This checklist may be useful as a means to ensure compliance with these guidelines.

- [ ] Hx and Px with assessment of baseline function and pain.
- [ ] Review all relevant prior records.
- [ ] Has there been a prior unsuccessful attempt to treat with non-opioid modalities?
- [ ] Is the diagnosis appropriate for opioid treatment?
- [ ] Psychosocial and risk assessment: risk of medication abuse (ORT), psychiatric co-morbidity PHQ-4 or other validated tools, evidence of existing abuse (PDMP).
- [ ] Are there co-prescribed drug interaction risks? Benzodiazepines are generally contraindicated.
- [ ] Sleep risk assessment (S T O P B A N G or equivalent).
- [ ] UDS: Any unexpected results?
- [ ] Have you checked the PDMP for prescriptions of which you were unaware?
- [ ] Create a treatment plan that emphasizes patient self-management.
- [ ] Are there appropriate referrals?
- [ ] Have you explored all reasonable non-opioid treatment options: medical, behavioral, physiotherapy, and lifestyle changes?
- [ ] Have you considered partnering with a substance abuse treatment program?
- [ ] Check women of child-bearing age for pregnancy.

If prescribing opioids, proceed with caution:

- [ ] Obtain a signed Material Risk Notice.
- [ ] Establish treatment goals with periodic review of goals over time.
- [ ] Monitor compliance (UDSs, pill counts, PDMP, call-backs).
- [ ] Monitor improvement in pain and function, including overall well-being.
- [ ] Obtain consultation as needed: mental health, substance abuse, pain management, specialty care, pregnant women.
- [ ] Have you considered partnering with a behavioral health specialist (CBT counselor, peer-to-peer coordinator, Living Well with Chronic Disease facilitator, substance abuse counselor)?

URINE DRUG SCREENINGS (UDS) FAQ

Using UDS to Monitor Opioid Therapy for Complex Chronic Non-Cancer Pain

The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse, and to verify compliance with treatment. If a decision has been made to prescribe opioids for chronic non-cancer pain, the prescriber should get a baseline UDS prior to prescribing and periodically thereafter. The frequency of such testing can be determined by risk stratification based upon screening tools already mentioned in this document (page 11) and Appendix A). Risk determination may change over time as you get to know the patient better, so clinical judgment is critical in determining an appropriate testing schedule. Often explaining the need for routine UDS can lead to a beneficial discussion between provider and patient concerning risky concomitant substance use.

Prior to drug testing, the prescriber should inform the patient of the reason for testing, frequency of testing and consequences of unexpected results. This gives the patient an opportunity to disclose drug use and allows the prescriber to modify the drug screen for the individual circumstances and more accurately interpret the results.

Q Drug screening implies that I don't trust my patients. How do I get around this?

A A self-report of drug use has limited validity, and monitoring behavior alone can fail to detect problems revealed by UDSs. Creating a UDS policy in advance and applying it consistently to all patients on opioids may help de-stigmatize the testing. Inform patients that drug testing is a routine procedure for all patients starting or maintained on opioid therapy and it is an important tool for monitoring the safety of opioid therapy. Possible language for explaining to patient includes:

- "Ensures my capacity to provide treatment for your pain while balancing the need for safety."
- "Provides critical information needed to assess the success of your therapy."
- "Prescription medications are a common form of treatment for chronic pain. However, each person reacts differently to them. UDS enables us to identify individual risks related to your medications and avoid problems."
- "Our clinic uses 'universal precautions' in opioid prescribing, which includes UDS. This is the same as wearing gloves on all patients when drawing blood."

Q Can I tell whether my patient has taken the dose of opioid(s) I prescribed?

A No. It is very difficult to correlate urine drug concentration with a patient's dose. UDS can detect the parent drug and/or its metabolite(s) and demonstrate recent use of prescribed drugs and illegal substances. However, it *cannot* determine the amount of drug used and when the last dose was taken, nor can it identify the source of the drug.

Q My patient says he is a "high metabolizer" and that is why the expected drug is not found in the urine. Is this possible?

A A small percentage of persons are ultrarapid metabolizers. They metabolize specific drugs more rapidly than typical patients. It would be rare to take an opioid as prescribed and have a totally negative UDS. It is important that you use testing that is specific to the medication of interest and with cutoff thresholds that are extremely low.

Q How do I deal with marijuana?

A This is a complex issue. Marijuana is currently classified as a Schedule I drug by the DEA. For that reason, many providers will not prescribe opioids to patients using cannabis. Other providers reference State "Medical Marijuana" laws (http://apps.leg.wa.gov/RCW/default.aspx?cite=69.51A&full=true) and feel comfortable prescribing opioids to cannabis users. Some providers adopt a "don't ask, don't tell" policy, and request the lab to remove marijuana from the UDS so that positive results are not seen. Do your homework and create an office policy. Then disclose this policy to your patients.

Q Would short-acting opioids show up in UDS?

A Urine testing typically has a 1- to 3-day window of detection for most drugs depending on dose and individual differences in drug metabolism. Short-acting opioids can be detected if the lab removes the cutoff concentration so that the presence of lower concentrations is detected. If the laboratory uses LC/MS/MS, then it will have a lower limit of detection (LOD) with less interference.

Q Why confirm results?

A Immunoassays used in drug screening can cross-react with other drugs and vary in sensitivity and specificity. Thus, confirmation with a more accurate method may be required for clinical decision making. Confirmatory drug testing (GC/MS or LC/MS/MS) of the original specimen is recommended for unexpected results, or in cases where patients are known to be high risk. However, on occasion, even confirmatory testing requires expert assistance for interpretation. Consider consultation with the lab before discussing/confronting the patient with unexpected test results and discontinuing opioid therapy.

Q Should I use temperature and adulteration strips?

A It depends. Drug testing for clinical compliance, unlike employment testing, does not require a strict "chain-of-custody." However, if tampering is a concern, the specimen should be monitored for temperature and/or adulterants. Normal human urine should have a temperature between 90°F–100°F, pH between 4.5–8.5 and creatinine >20 mg/dL. Be aware that there are multiple websites and devices devoted to getting a "clean" urine drug screen.

Q Should I perform a drug screen on every visit for patients using opioids for chronic pain?

A No. Random screening based on the frequency recommended in the guideline should suffice for most patients. Those patients who you feel require drug screening on every visit, are perhaps not candidates for chronic opioid therapy.

Risk Category	UDS Frequency	Recommended Drug Panel to Test
LOW RISK by ORT (1 or more/year)	Periodic (e.g. up to 1/year)	Drug you are prescribing if not listed Amphetamines Opiates Cocaine Benzodiazepines Alcohol Barbiturates Oxycodone Methadone Fentanyl Marijuana *Testing for all drug classes may not be necessary, depending on clinical situation.*
MODERATE RISK by ORT (2 or more/year)	Regular (e.g. up to 2/year)	
HIGH RISK by ORT (3 or more/year) or opioid doses >120 mg MED/d	Frequent (e.g. up to 2+/year)	
Aberrant Behavior (lost prescriptions, multiple requests for early refills, opioids from multiple providers, unauthorized dose escalation, apparent intoxication, etc.)	At time of visit (Address aberrant behaviors in person, not by telephone)	

Consideration

Typically, the initial (screening) drug test uses an immunoassay method to identify the presence of a drug (presumptive positive). Because of cross reactivity and different sensitivity and specificity between immunoassays, a second confirmatory test is required unless result is expected or the patient has disclosed drug use. Confirmatory drug tests use gas chromatography/mass spectrometry or liquid chromatography/tandem mass spectrometry (GC/MS or LC/MS) to verify a presumptive positive result.

Contact the laboratory director, toxicologist or a certified Medical Review Officer (MRO) in your area for questions about drug testing or result.

If a point of care (POC) test is used, contact technical support from the manufacturer for questions.

UDS Results

Interpreting UDS results can be challenging, especially when the parent drug can be metabolized to other commonly prescribed drugs. The table in Appendix H may aid prescribers when interpreting UDS results. The following UDS results should be viewed as a "red flag," requiring confirmation and intervention:

- Negative for opioid(s) you prescribed
- Positive for drug (benzodiazepines, opioids, etc) you did NOT prescribe or have knowledge of
- Positive for amphetamine or methamphetamine
- Positive for alcohol
- Positive for cocaine or metabolites

If a confirmatory drug test substantiates a "red flag" result AND is positive for prescribed opioid(s):

- Prescriber should consider a controlled taper and a referral to an addiction specialist or drug treatment program depending on the circumstances.
- Prescriber should consider extraneous circumstance such as duration of action of the drug and timing of last dose. Consultation with your laboratory's pharmacologist may be useful. Discontinue prescribing opioid(s) and consider a referral to an addiction specialist or drug treatment program depending on the circumstances.

References

Heltsley R, Zichterman A, Black DL, et al. Urine drug screening of chronic pain patients. II. Prevalence patterns of prescription opiates and metabolites. Journal of Analytical Toxicology. 2010;34(1):32-38.

Moeller KE, Lee KC, Kissack JC. Urine drug screening: practical guide for clinicians. Mayo Clinic Proceedings. 2008;83(1):66-76. doi: 10.4065/83.1.66.

Standridge JB, Adams SM, Zotos AP. Urine drug screening: a valuable office procedure. American Family Physician. 2010;81(5):635-40.

UDS FAQs and other tools are available online at www.oregonpainguidance.org/clinical-tools.

METABOLISM DATA FOR COMMON MEDICATIONS

Drugs or Drug Classes	Detection Time in Urine*	Urine Drug Screening to Order	Expected Results	Consideration
Opioids or "opiates" – Natural (from opium)				
Codeine (Tylenol #2/3/4)	1–3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS – codeine, possibly morphine and hydrocodone	Immunoassays for "opiates" are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.
Morphine (Avinza, Embeda, MS Contin, Kadian)	1–3 days		Opiates Immunoassay – positive GC/MS or LC/MS/MS – morphine, possibly hydromorphone	
Opioids – Semisynthetic (derived from opium				
Hydrocodone (Lorcet, Lortab, Norco, Vicodin)	1–3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS – hydrocodone, possibly hydromorphone	"Opiates" immunoassays may also detect semisynthetic opioids depending on their cross-reactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS/MS) is required to verify compliance with the prescribed semisynthetic opioid(s). Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.
Hydromorphone (Dilaudid, Exalgo)	1–3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS/MS – hydromorphone	
Oxycodone (Roxicet, OxyContin)	1–3 days	Oxycodone Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS/MS – oxycodone possibly oxymorphone	
Oxymorphone (Opana)	1–3 days	Opiates or Oxycodone Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates or Oxycodone Immunoassay – positive GC/MS or LC/MS/MS – oxymorphone	
Opioids – Synthetic (man-made) – *continued on next page*				
Fentanyl	1–3 days	GC/MS or LC/MS/MS Fentanyl	GC/MS or LC/MS/MS – fentanyl & norfentanyl	Current "opiates" immunoassays do not detect synthetic opioids. Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.
Meperidine (Demerol)	1–3 days	GC/MS or LC/MS/MS Meperidine	GC/MS or LC/MS/MS – normeperidine, possibly meperidine	

Drugs or Drug Classes	Detection Time in Urine*	Urine Drug Screening to Order	Expected Results	Consideration
Opioids – Synthetic (man-made) – *continued*				
Methadone (Methadose)	3–7 days	Methadone Immunoassay + GC/MS or LC/MS/MS Methadone	Methadone Immunoassay – positive GC/MS or LC/MS/MS – methadone & EDDP	
Propoxyphene (Darvon, Darvocet)	1–3 days	Propoxyphene Immunoassay + GC/MS or LC/MS/MS Propoxyphene	Propoxyphene Immunoassay – positive GC/MS or LC/MS/MS – propoxyphene & norpropoxyphene	
Others				
Alcohol	Up to 8 hours	Alcohol	Alcohol – see Consideration	Additional testing for alcohol metabolites, ethyl glucuronide (EtG) or ethyl sulfate.
Amphetamines	2–3 days	Amphetamines, Methamphetamines or MDMA Immunoassay + GC/MS or LC/MS/MS Amphetamines	Amphetamines, methamphetamines or MDMA Immunoassay – see Consideration GC/MS or LC/MS/MS – amphetamine, methamphetamine or MDMA	Amphetamines immunoassays are highly cross-reactive so results should be interpreted cautiously, and may require consultation with the lab. They may detect other sympathomimetic amines, such as ephedrine, pseudoephedrine or selegiline. Confirmatory testing can identify which amphetamine is present.
Barbiturates	1–3 days w/ short-acting; up to 30 days w/ long acting	Barbiturates Immunoassay	Barbiturates Immunoassay – see Consideration	The clearance half-life of intermediate-acting barbiturates averages 24 hours. It takes about 5 to 7 half-lives to clear 98% of a drug dose. Thus, the presence of anintermediated-acting barbiturate indicates exposure within 5–7 days.
Benzodiazepines	1–3 days w/ short-acting; up to 30 days w/ long acting	Benzodiazepines Immunoassay	Benzodiazepines Immunoassay – see Consideration GC/MS or LC/MS/MS – alprazolam, diazepam, clonazepam, lorazepam, etc.	Immunoassays for benzodiazepines have a 28% overall false negative rate and vary in cross-reactivity. Certain benzodiazepines (clonazepam and alprazolam) have limited detectability by most available immunoassays. Confirmatory testing is needed when use is expected or suspected.
Cocaine or benzoylecgonine	2–4 days	Cocaine Metabolites Immunoassay	Cocaine Metabolites Immunoassay – see Consideration	Cocaine immunoassays do not cross-react with other topical anesthetics that end in "caine" (e.g. lidocaine) and are highly specific for cocaine use.
Marijuana	2–4 days; up to 30 days w/ chronic heavy use	Cannabinoids (THC) Immunoassay	Cannabinoids Immunoassay – see Consideration GC/MS or LC/MS/MS – THC	THC may be an indicator of the patient's risk category. Prescribers should have an office policy, discuss with the patients reason for use and adjust monitoring plan accordingly.

*Agency Medical Directors Group, Interagency guideline on Opioid dosing for Chronic Non-cancer Pain, 2010.

PATIENT TREATMENT AGREEMENTS

Sample 1. Controlled Substance Agreement

Why an agreement? The medication we are prescribing has the potential to provide much benefit, but it also can do harm to you or others. Misuse of pain medications is becoming a large problem in our community. We are doing our part to ensure that our prescriptions are taken as directed. We also want to protect you and inform you concerning the uses and abuses of this medication.

What are the benefits of opiate treatment? Opiates, also called opioids, provide relief from pain and a sense of well-being. They can allow you to perform activities that you might otherwise find limited due to pain.

What are the risks of opioid treatment? Opioids produce physical dependency with prolonged use. That means that you may experience discomfort if you discontinue these medications abruptly after taking them for over a few weeks. Some individuals have a hard time remaining medication free after being on long term opioids for that reason.

Opioids may decrease your ability to breathe deeply. This is especially true when they are combined with other sedating drugs like alcohol and some tranquilizers. This can lead to accidental overdose deaths.

Less serious side effects may include: constipation, decrease in sexual interest and performance, weight gain, sleepiness, urination difficulties, and itchiness. As with any medication, there is the rare possibility of a severe allergic reaction.

Some people are at risk of abusing these medications and may feel compelled to take them for their pleasurable effect. Therefore we are obliged to provide safeguards to protect you from these potential risks.

What are those safeguards? Our clinic has the following regulations for all patients taking long-term opioids; we will not prescribe these medications for chronic use without first:

- Obtaining all pertinent medical records
- Obtaining a urine drug screening (UDS)
- Reviewing your medical condition and past history
- Having a signed agreement between a clinician and yourself outlining the expectations of both parties.

What can I expect from the clinic? Our clinic agrees to provide you with appropriate doses of medication in a timely fashion and on an ongoing basis as long as there are no contraindications. You will be treated respectfully and professionally.

What does the clinic expect from me? The clinic expects all patients will agree to the following:

- Agree to have only one prescriber of opioids and use only one pharmacy.
- Bring their pill bottles to every clinic visit.
- Have a valid phone number available to our staff, and to respond within 24 hours to the clinic if asked.
- Agree to random urine drug screenings and random pill counts.
- Agree to a chemical dependency or other specialist consultation should your provider feel that would be appropriate.
- Allow open communication between this clinic and other providers concerning the use of these medications.
- Advise other treatment providers of the medication you are taking and to inform this clinic of any health care emergencies requiring pain or anxiety treatment.
- Agree to treat our staff respectfully and courteously.

Suggestions for safely handling your prescription: These medications can be dangerous if combined with other sedating substances. These medications are sought after by drug abusers. Therefore we ask that you follow these suggestions to provide safety for you and your medications:

- Keep all medicines in a safe, preferably locked container, out of sight and out of the reach of children.
- Never share these medicines with others. Never take other people's pain medications.
- Avoid drinking alcohol while taking these medicines.
- Never combine these medications with other opioids or benzodiazepines (tranquilizers like lorazepam/Ativan, alprazolam/Xanax, diazepam/Valium, clonazepam/Klonopin) unless advised to by your provider.
- Never use illicit drugs while using these medications.
- Be aware that opioids may affect your judgment and driving skills, particularly when your dose is increasing.

How will I obtain my refills? The clinic's policy on refills is:

- Refill prescriptions will only be written at a clinic visit. Therefore refills will not take place over the phone, through the mail, or by calling the pharmacist.
- All dosage changes will occur at the next clinic visit.
- Lost or stolen medications may not be refilled until the next scheduled visit.

Will this medication relieve my pain? It is unrealistic to expect opioids to relieve all discomfort. We hope to reduce your pain so that you can regain function; that is to allow you to enjoy activities that you participated in prior to the onset of your pain. We will continue to ask that you participate in activities that improve your ability to perform daily activities. We may, in the course of your treatment, ask you to exercise, attend classes, or see a specialist of our choosing.

What are the consequences of not following these agreements? Your clinician has agreed to provide you with these medications as long as necessary, but also has the obligation to protect you and the community from abuse of these substances. In the event of suspected misuse, your provider may insist on a referral to a specialist in the assessment and treatment of drug dependency, or may immediately discontinue prescribing. Lack of improvement in function or to achieve adequate pain control may also necessitate the discontinuing of opioid medications.

I will receive my prescriptions at the following pharmacy only:

Name and phone: _____

I agree to allow the following health care facilities to share information (including any pertinent mental health, drug or alcohol history or conditions) with my provider, and to allow my health care provider to freely share pertinent health care information with these facilities for the purpose of coordinating my medical care.

Facility: _____

Facility: _____

Facility: _____

Facility: _____

By signing below I am agreeing to abide by the conditions of this agreement.

Patient's signature: _____ **Date** _____

Person obtaining the consent: _____ **Date** _____

Sample 2. Patient/Clinic Agreement for the use of Controlled Substances

Your provider has prescribed _____ for _____ (diagnosis).

To continue receiving this medication from your provider, you are expected to follow the policies below. If you do not follow them, your provider may decide to stop prescribing the medication for you.

1. You are expected to take the medication as directed by your clinician, and to make your medication last until the next scheduled appointment. We expect our patients to be responsible for their prescriptions. You should never give any of your medications to someone else. We will not fill requests for lost or stolen prescriptions or medications.
2. Refills for controlled substances will only be done by appointment at the clinic. **We will not fill requests for controlled substances by phone, after hours, or on weekends.** We expect our patients to plan ahead to upcoming vacations, weekends and holidays and make a timely appointment if a prescription will need to be filled early.
3. By signing below you agree to submit urine or blood as requested by your provider for random drug screens. You also agree to have a working phone number where clinic staff can reach you within 24 hours. That number is _____. You agree to update the clinic anytime you move or change your phone number.
4. You agree to bring your pill bottles to each regular visit.
5. Any patient who receives controlled substances from our clinic on an ongoing basis is expected to receive these prescriptions only from our organization. If you receive additional medicines for an unanticipated injury or condition, and these are not prescribed by a our clinic provider, you are required to call the clinic the next business day, advise us of the situation and release records of the encounter to our clinic.
6. While taking narcotics or other controlled substances you are expected to refrain from misusing or abusing other drugs which could alter consciousness, impair judgment, or cause addiction, including, alcohol, marijuana, methamphetamine, or other illegal drugs. If you in any way use these medications to harm yourself, you will no longer receive them at this clinic.
7. You may be required to seek treatments or consultations you have to pay for yourself.
8. In addition to taking pain relief medication, you are expected to comply with your clinician's other recommendations for improving your pain relief, or ability to function.
9. We require you to use only one pharmacy for your refills. Your pharmacy is _____. If you decide to change pharmacies you must advise us immediately.
10. You authorize, by your signature below, any employee of our clinic to call any other health care provider, including Emergency Department staff and pharmacies, to obtain information regarding the prescription of any substance.

Your signature acknowledges you have received a copy of this agreement.

Patient Signature _____ Date _____

Print Name _____ Medical Record Number _____

The use of narcotics poses risks to patients. By prescribing _____ to you, we expect the following improvements:

_____ Increased ability to exercise

_____ Increased ability to participate in family activities

_____ Increased ability to do housework

_____ Lose weight

_____ Able to go shopping

_____ Able to return to work

OR _____

Alternatives to taking _____ include: _____

In addition to taking _____ to reduce your chronic pain, you are expected to:

_____

Your allergies are: _____

The following is not necessarily a complete list of the side effects of pain medicines, but common side effects include: _____

BRAIN	Sleepiness, difficulty thinking, confusion, slow reflexes. It is possible to be convicted of driving under the influence (DUI) if you drive while using prescribed medication.
LUNG	Difficulty breathing or slowed breath rate to the point you stop breathing.
STOMACH	Nausea, vomiting. Constipation can be severe.
SKIN	Itching, rash.
GENITO-URINARY	Difficulty urinating. These drugs reduce interest in and ability to perform sexual activities.
ALLERGY	Potential for allergic reaction.
TOLERANCE	With long term use, an increasing amount of the same drug may be needed to achieve the same effect.

PHYSICAL DEPENDENCE/WITHDRAWAL: Physical dependence develops within 3-4 weeks when taking these drugs. If they are stopped abruptly, symptoms of withdrawal may occur. Withdrawal can be extremely difficult and last a long time. Use of all controlled substances needs to be slowly tapered off under the direction of your prescriber.

ADDICTION: This refers to the abnormal behavior directed toward acquiring or using drugs in a non-medically necessary manner. People with a history of alcohol or drug abuse are at increased risk.

Avoid medications or substances which increase drowsiness or limit the ability to think clearly, react quickly, or which decrease your rate of breathing. Talk to your provider before taking any of these medications, even if you can buy them over the counter.

I understand these risks and agree to accept them. I will let my prescriber know of any problems or side effects I am having with this medication.

Name (print) _____

Signature _____ Date _____

Sample patient treatment agreements are available online at www.oregonpainguidance.org/clinical-tools.

Sample 3. Patient Treatment Agreement

I, _____ (patient receiving chronic pain medications), agree to correctly use pain medications prescribed for me as part of my treatment for chronic pain. I understand that these medications may not get rid of my pain but may decrease the pain and increase the level of activity that I am able to do each day. I understand that the Pain Management Clinic will deal with my chronic pain and will not deal with any of my other medical conditions.

I understand that (name) will be my pain management provider and the only provider who will be ordering medications for my chronic pain.

I understand that I have the following responsibilities (initial each item you agree to):

_____ I will only take medications at the amount and frequency prescribed.

_____ I will not increase or change how I take my medications without the approval of my pain management provider.

_____ I will not ask for refills earlier than agreed. I will arrange for refills ONLY during regular office hours. I will make the necessary arrangements before holidays and weekends.

_____ I will get all pain medications only at one pharmacy. I will let my pain management provider know if I change pharmacies. **Pharmacy** _____ **Phone Number** _____

_____ I will allow my pain management provider to provide a copy of this agreement to my pharmacy.

_____ I will not ask for any pain medications or controlled substances from other providers and will let my pain management provider know of all medications I am taking, including non-legal drugs.

_____ I understand that other physicians should not change doses of my pain medications made by another provider.

_____ I will notify the Pain Management Clinic of any changes to my pain medications made by another provider.

_____ I will let my other health care providers know that I am taking these pain medications and that I have a pain management agreement.

_____ In event of an emergency, I will give this same information to emergency department providers.

_____ I will allow my pain management provider to discuss all my medical conditions and treatment details with pharmacists, physicians, or other health care providers who provide my health care for purposes of care coordination.

_____ I will inform my pain management provider of any new medications or medical conditions.

_____ I will protect my prescriptions and medications. I understand that lost or misplaced prescriptions will not be replaced.

_____ I will keep medications only for my own use and will not share them with others. I will keep all medications away from children.

In addition, I will do the following (initial each box):

_____ I must make an appointment with a drug and alcohol counselor and bring proof of following my treatment plan.

_____ I must take a drug test test _____ (frequency).

_____ I agree to pill counts to prove I am using my medications correctly.

_____ If I fail a drug test, I will take the drug test _____ (frequency).

_____ If I fail a drug test, I will be referred to Medicaid's Patient Review and Coordination Program that restricts me to certain providers, such as a primary doctor.

_____ If I sell my narcotics, my name will be referred to the DSHS fraud unit.

_____ If I fail all of the above, I will be discharged from your care with no notice.

Should any of the above not show good faith efforts and my providers feel they can no longer prescribe my pain medications in a safe and effective way, I may be notified and discharged from their care.

I agree to use only the following providers. I will notify my physician of any changes in my health care and/or changes in my providers.

Provider _____ **Clinic** _____ **Phone** _____

Provider _____ **Clinic** _____ **Phone** _____

Patient Signature _____ **Provider Signature** _____

Source: Group Health, Chronic Opioid Therapy for Chronic Non-Cancer Pain Guideline, 2010.

MATERIAL RISK NOTICE

This will confirm that you, _____, have been diagnosed with the following condition(s) causing you chronic intractable pain: _____.

I have recommended treating your condition with the following controlled substances: _____.

In addition to significant reduction in your pain, your personal goals from therapy are: _____.

Alternatives to this therapy are: _____.

Additional therapies that may be necessary to assist you in reaching your goals are: _____.

Notice of Risk: The use of controlled substances may be associated with certain risks such as, but not limited to:

Central Nervous System: Sleepiness, decreased mental ability, and confusion. Avoid alcohol while taking these medications and use care when driving and operating machinery. Your ability to make decisions may be impaired.

Cardiovascular: Irregular heart rhythm from mild to severe.

Respiratory: Depression (slowing) of respiration and the possibility of inducing bronchospasm (wheezing) causing difficulty in catching your breath or shortness of breath in susceptible individuals.

Gastrointestinal: Constipation is common and may be severe. Nausea and vomiting may occur as well.

Dermatological: Itching and rash. Endocrine: Decreased testosterone (male) and other sex hormones (females); dysfunctional sexual activity.

Urinary: Urinary retention (difficulty urinating).

Pregnancy: Newborn may be dependent on opioids and suffer withdrawal symptoms after birth.

Drug Interactions: With or altering the effect of other medications cannot be reliably predicted.

Tolerance: Increasing doses of drug may be needed over time to achieve the same (pain relieving) effect. Physical dependence and withdrawal: Physical dependence develops within 3-4 weeks in most patients receiving daily doses of these drugs. If your medications are abruptly stopped, symptoms of withdrawal may occur. These include nausea, vomiting, sweating, generalized malaise (flu-like symptoms), abdominal cramps, palpitations (abnormal heartbeats). All controlled substances (narcotics) need to be slowly weaned (tapered off) under the direction of your physician.

Addiction (Abuse): This refers to abnormal behavior directed towards acquiring or using drugs in a non-medically supervised manner. Patients with a history of alcohol and/or drug abuse are at increased risk for developing addiction.

Allergic reactions: Are possible with any medication. This usually occurs early after initiation of the medication. Most side effects are transient and can be controlled by continued therapy or the use of other medications.

This confirms that we discussed and you understand the above. I asked you if you wanted a more detailed explanation of the proposed treatment, the alternatives and the material risks, and you (Initial one):

_____ was satisfied with that explanation and desired no further information.

_____ requested and received, in substantial detail, further explanation of the treatment, alternatives and material risks.

_____ DATE _____

PATIENT SIGNATURE

Explained by me and signed in my presence.

_____ DATE _____

PHYSICIAN SIGNATURE

MEDICAL RISKS OF LONG-TERM OPIOID USE

Medical risk	How common?	Description and information
Respiratory depression		
Opioid overdose	< 1% per year but increases with dose	Caused by severely slowed breathing, which you may not notice Severe cases are treated in the hospital Can cause death
Breathing problems during sleep	Not known	Opioids may cause or worsen sleep apnea You may not notice breathing problems
Injuries		
Falls and fractures	Not known	
Motor vehicle crashes	Not known	
Gastrointestinal problems		
Constipation	30 - 40%	It helps to use stool-softeners or drugs that stimulate bowel movements
Serious intestinal blockage	<1% per year	Caused by severe constipation Severe cases are treated in the hospital
Hormonal effects		
Hypogonadism, impotence, infertility, osteoporosis	25% - 75%	Hypogonadism = lowered sex hormones, which can worsen sexual function Osteoporosis can make you more likely to fracture or break a bone
Cognitive and neurophysiologic effects		
Sedation	15%	Can cause difficulty driving or thinking clearly
Disruption of sleep	Not known	
Hyperalgesia	Not known	Hyperalgesia = being more sensitive to pain
Psychosocial		
Depression, anxiety, de-activation, apathy	Not known	Depression can worsen pain, while pain can worsen depression. Opioids can cause loss of interest in usual activities, which can increase depression.
Addiction, misuse, and diversion	5 - 30%	Common signs of prescription opioid addiction are preoccupation with opioid use or craving, unsuccessful attempts to discontinue use or cut down, cutting down or giving up activities due to opioid use, and using more medication than prescribed.
Oral Health		
Dry mouth that may sometimes cause tooth decay	Dry mouth is common	Brush your teeth and rinse your mouth often Chew sugarless gum and drink water or sugar-free, non-carbonated fluids
Myoclonus	Not Known	Myoclonus = muscle twitching

Reference: Group Health, Chronic Opioid Therapy for Chronic Non-Cancer Pain Guideline, 2010.

GRADED PAIN AND FUNCTION SCALE

Pain Intensity and Interference

In the last month, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? (That is, your usual pain at times you were in pain.)

No Pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	**10**

In the last month, how much has paininterfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No Interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	**10**

The Graded Pain and Funtion Scale and other tools are available online at www.oregonpainguidance.org/clinical-tools.

OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the "gold standard" of low back functional outcome tools.

Scoring instructions

For each section the total possible score is 5: If the first statement is marked, the section score = 0; if the last statement is marked, the score = 5. If all 10 sections are completed, the score is calculated as follows:

Example: 16 (total scored)
50 (total possible score) x 100 = 32%

If one section is missed or not applicable, the score is calculated:
16 (total scored)
45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (Change of less than this may be attributable to error in the measurement.)

Interpretation of scores

0% to 20%: minimal disability	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting, sitting and exercise.
21%-40%: moderate disability	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult, and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected, and the patient can usually be managed by conservative means.
41%-60%: severe disability	Pain remains the main problem in this group, but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%	These patients are either bed-bound or exaggerating their symptoms.

Instructions

The following questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realize you may consider that two or more statements in any one section apply, but please check only the box that indicates the statement which most clearly describes your problem.

Reference: Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52; discussion 52.

The Oswestry Disability Index and other tools are available online at www.oregonpainguidance.org/clinical-tools.

Section 1—Pain intensity

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2—Personal care (washing, dressing, etc.)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally but it causes extra pain.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of self-care.
- ☐ I do not get dressed, I wash with difficulty and stay in bed.

Section 3—Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed, eg. on a table.
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4—Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me from walking more than 1 mile.
- ☐ Pain prevents me from walking more than ½ mile.
- ☐ Pain prevents me from walking more than 100 yards.
- ☐ I can only walk using a stick or crutches I am in bed most of the time.

Section 5—Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me sitting more than one hour.
- ☐ Pain prevents me from sitting more than 30 minutes.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6—Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than 3 minutes.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7—Sleeping

- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain I have less than 6 hours sleep.
- ☐ Because of pain I have less than 4 hours sleep.
- ☐ Because of pain I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8—Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9—Social life

- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests (e.g., sports).
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 10—Travelling

- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere but it gives me extra pain.
- ☐ Pain is bad but I manage journeys over two hours.
- ☐ Pain restricts me to journeys of less than one hour.
- ☐ Pain restricts me to short necessary journeys under 30 minutes.
- ☐ Pain prevents me from travelling except to receive treatment.

PEG-3: PAIN SCREENING TOOL

What number best describes your pain on average in the past week?

No Pain										Pain as bad as you can imagine
0	1	2	3	4	5	6	7	8	9	**10**

What number best describes how, during the past week, pain has interfered with your enjoyment of life?

Does not interfere										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	**10**

What number best describes how, during the past week, pain has interfered with your general activity?

Does not interfere										Completely interferes
0	1	2	3	4	5	6	7	8	9	**10**

To compute the PEG score, add the three responses to the questions above, then divide by three to get a final score out of 10.

Final Score

The final PEG score can mean very different things to different patients. The PEG score, like most other screening instruments, is most useful in tracking changes over time. The PEG score should decrease over time after therapy has begun.

Reference: Krebs, E.E., Lorenz, K.A., Blair, M.J., et al. (2009). Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. Journal of General Internal Medicine, 24: 733-738.

The PEG-3 and other tools are available online at www.oregonpainguidance.org/clinical-tools.

ADDITIONAL ASSESSMENT TOOLS

Specific Psychosocial Assessment	Tools to Evaluate
Substance abuse history	ORT, CAGE, Audit, Dast. SOAPP-R
Psychiatric/Mental health history	PHQ, PMQ, DIRE, GAD-7, PCL-C
ADLs/self-care	Oswestry, SF-36 or 12, pain log/diary, ACPS QOL
Self-perception of disability	DIRE, COMM, SF-36 or 12
SI/SA history	Roland-Morris Low-Back Pain and Disability Questionnaire

ORT Opioid Risk Tool. Very simple, evidence-based and widely used.

CAGE Four-item self-test for identifying usage patterns that may reflect problems with alcohol.

PHQ Patient Health Questionnaire, a 2-, 4-, or 9-item depression scale; tool for assisting in diagnosing depression.

DIRE Diagnosis, intractability, risk, efficacy tool that assesses the risk of opioid abuse and the suitability of candidates for long-term opioid therapy.

COMM Current Opioid Misuse Measure. A 17-item self-assessment to identify patients with chronic pain who are taking opioids and have indicators of current aberrant drug-related behaviors.

SBIRT Screening, brief intervention, and referral to treatment. An effective, evidence-based method to intervene in alcohol and drug misuse.

OSWESTRY The Oswestry Low-Back Pain Disability Questionnaire, a tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the gold standard of low back functional outcome tools.

SOAPP-R The Screener and Opioid Assessment for Patients with Pain-Revised. Predicts possible opioid abuse in chronic pain.

This information and other tools are available online at www.oregonpainguidance.org/clinical-tools.

BEHAVIORAL HEALTH RISKS SCREENING TOOL

SOUTHERN OREGON Perinatal Task Force

For Pregnant Women and Women of Childbearing Age

Patient/Client Name _____ Date _____

Screener Name _____ Date _____

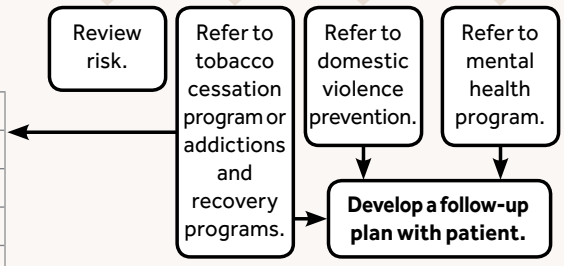
Reviewed by Qualified Provider _____ Date _____

Women and their children's health can be affected by emotional problems, alcohol, tobacco, other drug use and violence. Women and their children's health are also affected when these same problems are present in people who are close to them. Alcohol includes beer, wine, wine coolers, liquor and spirits. Tobacco products include cigarettes, cigars, snuff and chewing tobacco.

1. Have you smoked any cigarettes or used any tobacco products in the past three months?	**TOBACCO**	☐ YES	☐ NO
2. Did any of your parents have a problem with alcohol or other drug use?	**PARENTS**	☐ YES	☐ NO
3. Do any of your friends have a problem with alcohol or other drug use?	**PEERS**	☐ YES	☐ NO
4. Does your partner have a problem with alcohol or other drug use?	**PARTNER**	☐ YES	☐ NO
5. In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?	**PAST**	☐ YES	☐ NO
6. Check YES if she agrees with any of these statements. – In the past month, have you drunk any alcohol or used other drugs? – How many days per month do you drink? _____ – How many drinks on any given day? _____ – How often did you have 4 or more drinks per day in the last month? _____	**PRESENT**	☐ YES	☐ NO
7. Over the last few weeks, has worry, anxiety, depression, or sadness made it difficult for you to do your work, get along with other people, or take care of things at home?	**EMOTIONAL HEALTH**	☐ YES	☐ NO
8. Are you feeling at all unsafe in any way in your relationship with your current partner?	**VIOLENCE**	☐ YES	☐ NO

PROVIDER USE ONLY

Brief Intervention/Brief Treatment	**Y**	**N**	**NA**
Did you **State** your medical concern?	☐	☐	☐
Did you **Advise** to abstain or reduce use?	☐	☐	☐
Did you **Check** patient's reaction?	☐	☐	☐
Did you **Refer** for further assessment?	☐	☐	☐
Did you **Provide** written information?	☐	☐	☐



Moderate drinking for non-pregnant women is one drink per day. Women who are pregnant or planning to become pregnant should not use alcohol, tobacco, illicit drugs or prescription medication other than as prescribed.

Developed by the Institute for Health and Recovery (IHR), Massachusetts, February, 2007. Adapted by the Southern Oregon Perinatal Task Force in partnership with AllCare Health, Oregon, May 2013.

OPIOID WITHDRAWAL ATTENUATION COCKTAIL

Acute Withdrawal

Clonidine 0.1mg QID x anticipated length of withdrawal. (Check BP and watch for hypotension.)

Diarrhea: Loperamide 4mg then 2mg QID. May have opioid effects at high doses. Alternatively, consider Hycosamine 0.125mg q 4-6 hrs PRN

Myalgias: Ibuprofen 400mg po QID or Acetaminophen 325mg po Q6hrs

Anxiety: Hydroxyzine 25mg po TID

Insomnia: Trazodone 50-100mg po QHS

Nausea: Ondansetron 8mg po BID x anticipated length of withdrawal. (Check QTc)

Anticipated Withdrawal as a Part of a Planned Taper

Anxiety: Gabapentin Escalating Dose to 1200mg/day. Start loading one month prior to planned taper.

Clonidine 0.1mg QID x anticipated length of withdrawal. (Check BP and watch for hypotension.)

Diarrhea: Loperamide 4mg then 2mg QID

Myalgias: Ibuprofen 400mg po QID or Acetaminophen 325mg po Q6hrs

Anxiety: Hydroxyzine 25mg po TID

Insomnia: Trazodone 50-100mg po QHS

Nausea: Ondansetron 8mg po BID x anticipated length of withdrawal. (Check EKG for QTc interval)

This information and other tools are available online at www.oregonpainguidance.org/clinical-tools.

PATIENT AND COMMUNITY RESOURCES

	Inpatient care, residential	Populations served	Chronic pain services	Sliding scale	Payment options
Adapt Josephine County-Recovery Services					
418 NW 6th St., Grants Pass, OR 97526 541-474-1033 Fax: 541-474-0770 www.adaptoregon.org		Adults and adolescents	✓	✓	OHP, commercial insurance
The Addictions Recovery Center					
111 Genesee St., Medford, OR 97504 541-779-1282 Fax: 541-779-2081 www.addictionsrecovery.org	✓	Adults		✓	OHP, commercial insurance
Allied Health-Recovery Services					
777 Murphy Road, Medford, OR 97504 541-772-2763 Fax: 541-734-3164		Adults	✓ (for those with addiction only – Methadone and Suboxone)	✓	OHP, commercial insurance
Choices Josephine County-Recovery Services					
109 Manzanita Ave., Grants Pass, OR 97526 541-479-8847 Fax: 541-471-2679		Adults and adolescents	✓ (for those with addiction only)		OHP, commercial insurance
Jackson County Mental Health					
1005 E Main St., Medford, OR 97503 541-774-8201 www.co.jackson.or.us	✓	Adults and families	✓ (for those with addiction only)	✓	OHP
Kolpia-Recovery Services *(offices in Medford and Talent)*					
607 Siskiyou Blvd., Ashland, OR 97520 541-482-1718 Fax: 541-482-0964 www.kolpiacounseling.com		Adults and adolescents		✓	OHP, commercial insurance
On Track-Recovery Services *(offices in Medford, Grants Pass, White City, and Ashland)*					
221 W Main St., Medford, OR 97501 541-772-1777 Fax: 541-734-2410 www.ontrackrecovery.org	✓	Adults and children	✓	✓	OHP, commercial insurance
Options for Southern Oregon, Inc.					
1215 SW G St., Grants Pass, OR 97526 541-476-2373 Fax 541-476-1526 www.optionsonline.org	✓	Adults and families		✓	OHP
Phoenix Counseling Center-Recovery Services					
153 S Main St., Phoenix, OR 97520 541-535-4133 Fax: 541-535-5458 www.phoenixcounseling.org		Adults and adolescents	✓	✓	OHP, commercial insurance

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GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

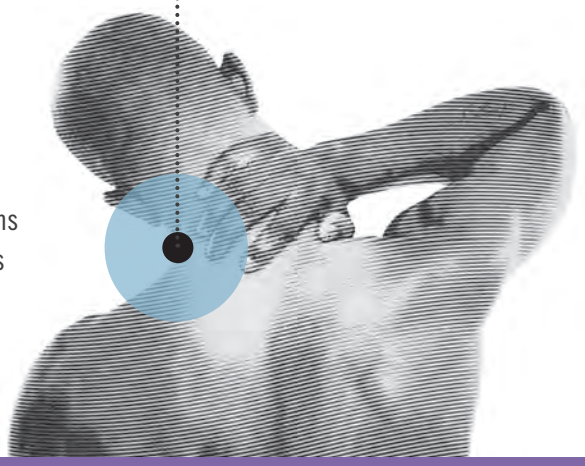
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**
- **Discuss benefits and risks and availability of nonopioid therapies with patient**



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- **Use immediate-release opioids when starting**
- **Start low and go slow**
- **When opioids are needed for acute pain, prescribe no more than needed**
- **Do not prescribe ER/LA opioids for acute pain**
- **Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed**

4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7 Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- **Evaluate risk factors for opioid-related harms**
- **Check PDMP for high dosages and prescriptions from other providers**
- **Use urine drug testing to identify prescribed substances and undisclosed use**
- **Avoid concurrent benzodiazepine and opioid prescribing**
- **Arrange treatment for opioid use disorder if needed**

NEWSLETTERS & ARTICLES OF INTEREST

OREGON ORAL HEALTH COALITION

Improving general health through oral health for all Oregonians

(971) 224-1038 OrOHC.org Firsttooth@ocdc.net

IN THIS ISSUE...

Maternity:
Teeth for Two Webinar
April 28th
9:00-10:00 AM

Register now!
Room for 100
in our live session.

Save the Date!

OrOHC's 11th Annual
Fall Conference

The New Face of Dentistry

Who might be looking in your mouth?

Keynote Speaker:
MarkoVujicic
American Dental Association

November 18th
Portland

Local Oral Health Coalition and First Tooth workshops will be held on November 17th.

Free School Dental Sealant Program Training!

The Oregon Health Authority's (OHA) Oral Health Program is offering **two more certification trainings this spring** for local school dental sealant programs.

One will be held on April 29th at OrOHC (in Wilsonville) and the other on June 3rd in Grants Pass.

As a reminder, this training is a requirement for certification. A representative responsible for coordinating and implementing a local school dental sealant program must attend a one-time certification training provided by OHA.

Register for one of the trainings online at
http://www.healthoregon.org/sealantcert.

Rinehart Clinic Tooth Fairy Visits Nehalem Elementary

The Rinehart Clinic has long known that it needed to offer more dental services for the rural community of North Tillamook County. When the opportunity came to join a pilot for Oral Health Integration with Oregon Primary Care Association (OPCA), the Rinehart Clinic jumped at it! The first step was a recent First Tooth training focused on oral health integration into primary care.

During one of the planning sessions for Oral Health Integration, staff members discussed organizing a kickoff event. "We wanted to celebrate our devotion to oral health in primary care while educating our community on the services we had to offer. Our Outreach Coordinator, Alice, contacted the schools to discuss our new endeavor, and the idea of a school assembly featuring a Tooth Fairy was born," reports Keri Scott, Rinehart's Director of Quality.

After the First Tooth training, the outreach team started planning the assembly and practicing their skills on family and friends. The team included the RN Care Coordinator, the Clinic Staff Supervisor (playing the evil Plaque Fairy), and the Outreach Coordinator (who partnered as the Plaque Monster). The Director of Quality played the Tooth Fairy.

"We put together a 10-minute skit that focused on healthy eating habits, good oral health, and fluoride varnish protection. It was a prime opportunity to partner with the local grocery store and we invited the Apple mascot from Manzanita Grocery and Deli to join us," says Keri.

On the day of the kick-off event the motley crew of fairies, apple, nurse, and plaque monster enthralled the kids of Nehalem Elementary with the joys good of oral health. Each kid went home with a packet containing a clinic brochure, coloring pages, a monthly brushing chart, PlakSmackers, fluoride toothpaste, a sparkly toothbrush, and education materials for the parents. The feedback was fast and furious. The kids were excited, the parents were interested, and the principal was ecstatic!

"I was very impressed with your assembly! Sometimes people come in and aren't sure how to talk to kids, but your group did GREAT! Thanks for the packets to send home! I'll post a little diddy about the assembly on our NKN Facebook page sometime today!"

-Christy Woika, Nehalem Elementary Principal

The event was so successful that the Outreach team has booked another assembly at Garibaldi elementary.

See the **Rinehart Clinic Facebook page**
and check out the **skit**!

Greetings from Oregonians at the 2016 National Oral Health Conference!

Pictured are 20 of about 30 oral health professionals participating In the National Oral Health Conference in Cincinnati this week. Many of Oregon's team are presenting at the conference this year on a variety of topics, including OrOHC's Oral Health for Senior's Pilot Project.

Like OrOHC on Facebook!

Samantha Ulrich and Karen Hall at NOHC 2016

Katie Kuspis Joins OrOHC

Katie Kuspis will be joining the OrOHC team in May to assist in our work of integrating oral health into primary care and supporting that work through strengthening our Local Oral Health Coalition network.

Katie, an AmeriCorps VISTA, is a 2015 graduate of the University of Arizona and has a Bachelor's of Science in Anthropology with a minor in Public Health. During her studies Katie focused on Medical Anthropology and connections between diseases and human evolution. Her honors thesis was centered on Post Traumatic Stress Disorder, its treatments, and barriers to care.

Katie initially got interested in public health though her medical anthropology studies. Her fascination grew as she studied how structural inequalities, culture, and diseases as they interacted in public health at the community level solutions. Her primary interests are in epidemiology of contagious diseases and public policy. "Public health is how I personally can effect change in a way that is meaningful", says Katie.

After gaining some more public health at OrOHC, Katie would like to pursue her Masters in Public Health in epidemiology, global health, or policy.

Welcome, Katie!

Summer Internship Filled by Kaylynn Walls

Kaylynn Walls, an Oregon State University public health student, will be completing her degree with a summer internship with OrOHC. Her work will revolve around the development OrOHC's new oral health and diabetes curriculum.

"I'm interested in the prevention of oral health diseases because they are connected to major health problems in the United States, which is often overlooked," says Kaylynn. She will be pursuing a career as a dental hygienist so she can treat and promote healthy hygiene and reduce the burden of oral health diseases in the community.

Kaylynn also has a minor in Spanish. During her time at OSU, Kaylynn worked at the College of Education advising office as an Administrative Student Worker.

Her love of travel, learning about new cultures, and desire to immerse herself in the Spanish language inspired her to study abroad at the Universidad del Bio-Bio in Chile.

One of Kaylynn's favorite things to do is travel. "I think it's the best way to understand the world and various perspectives on life", she says. So far Kaylynn has traveled to Chile, Peru, the Bahamas, and will travel to Honduras in June 2016.

Teledentistry Project Underway

The Capitol Dental Care teledentistry program has been up and running since September 2015. The program "keeps me on my toes and is always interesting," says Meagan Kintz, the dental hygienist providing services for this program.

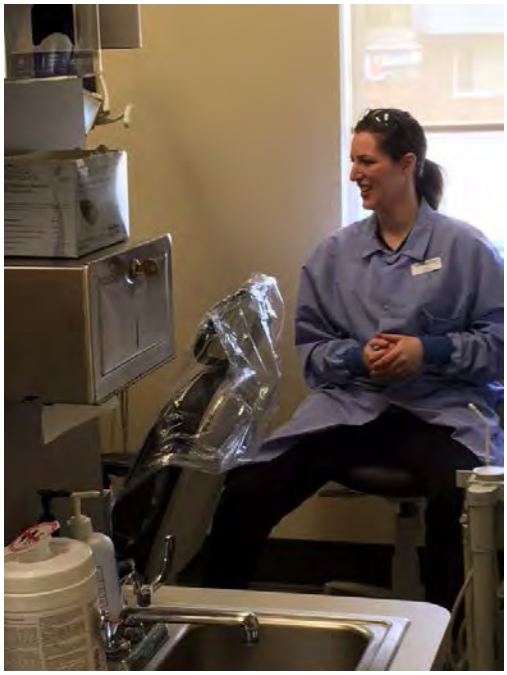
As an expanded practice dental hygienist for Capitol Dental Care, Meagan is no stranger to inspecting smiles. With the teledentistry program, however, Meagan explains, "I have the opportunity to provide services (with the help of a dental navigator) to elementary school aged children in the Central School District, specifically kindergartners through second graders," while they are at school. One goal of the program is to eliminate barriers to dental care such as transportation, wait time for an appointment, missing school, and cost of care. "By starting in kindergarten, we hope to see a reduction in tooth decay by the time the child enters second grade due to services, education, and early intervention." By serving students at school, dental appointments can also be freed up for patients in need of advanced care.

"Utilizing my expanded practice permit, I am able to perform every service a child would have completed at a regular preventive dental appointment, with the exception of seeing a dentist face to face. Each child's appointment looks a little different based on their age and needs but typically, I do an initial disease or dental assessment, take intraoral photographs, radiographs with a portable x-ray unit, cleanings, sealants as needed and fluoride varnish. After collecting data, I build an electronic chart for each child seen," says Meagan. By uploading the charts to a cloud-based server, a partnering dentist can review the information in 24-28 hours to decide if the child can stick with preventive care visits or needs to be seen by a dentist.

This program is a great fit for Meagan, whose interest in public health was inspired by volunteering to conduct dental screenings in rural communities. "I saw the need for not only preventive services but education and knew there had to be more to hygiene than a bricks and mortar clinical job. I love performing hygiene services in a nontraditional setting." Creating access to care is very important to her, and she also enjoys the variety that comes with her job. "Every day is something new. You never know what you're going to get with kids. One of the most rewarding parts of my job is taking an apprehensive child and getting them to love their dental appointments, knowing that will stay with them for life!"

Independence Has More Smiles with Katie Clanton's Assistance

Thanks to help from Katie Clanton, a Capitol Dental Care Expanded Practice Dental Hygienist, the Independence School Based Health Center and Salem-Keizer sealant program have been successes in the 2015-2016 school year.



With goals to serve Capitol patients' dental needs, provide access to care, and screen and seal students' teeth free of charge, Katie's efforts have a large impact on the oral health of her community. "I am responsible for regular dental hygiene services such as cleaning teeth, taking x-rays, and doing disease assessments to help determine if a patient needs to be seen by a dentist or not," she says.

With the Salem-Keizer sealant program, Katie places sealants and screens for possible treatment needs. These programs serve primarily underserved populations and those with a lower socio-economic students.

The best parts of Katie's jobs are "making things fun" and providing kids with a positive dental experience.

"I used to work for a migrant Head Start and saw many preschoolers with a mouthful of decay," says Katie. "I wanted to gain knowledge about the cause of caries and be able to help kids so fewer would have to suffer dental problems."

Pilot Project Evaluation

The Dental Pilot Project Program at the Oregon Health Authority (OHA) is accepting applications for the Pilot Project Evaluation Committee. The committee will track and evaluate the two approved pilot projects: Oregon Tribes Dental Health Aide Therapist Pilot Project #100 and Training Dental Hygienists to Place Interim Therapeutic Restorations, #200.

The Evaluation Committee is an interdisciplinary team composed of representatives of the dental board, professional organizations, other state regulatory bodies. It will also include interested parties who have applied to participate in evaluating a Dental Pilot Project. The applicant must not be involved in the specified project in any way in order to be a member of the Evaluation Committee.

Evaluation Committee Members are tasked with reviewing progress reports and conducting site visits. Evaluation Committee members are non-paid. Eligible travel expenses will be reimbursed according to State of Oregon guidelines.

Evaluation Committee Responsibilities & Rules:

- Participation and Attendance in Evaluation Committee Annual Meetings
- Advisement on the efficacies of training, competencies and the collection of data
- Review and advisement of project protocols related to the ongoing assurance of patient safety
- Participation and attendance in Site Visits; members are requested to attend at least one Site Visit during each year of the pilot project
- Advisement on the evaluation of project progress reports as needed
- Advisement on project issues, should they arise

Learn more and apply today

Upcoming Oral Health Events

- **Toothtastic Jab-a-Palooza** - April 27, Yamhill
- **DentaQuest's Western Regional Convening** - May 11-13, San Diego
- **CCO Oregon's Fall Conference** - Sept. 27, Salem
- **Oregon Rural Health Conference** - Sept. 28-30, Portland
- **ODA House of Delegates** - Oct. 6-7, Portland
- **American Dental Association Convention** - Oct. 20-25, Denver
- **DentaQuest Oral Health 2020 National Network Gathering** - October 25-28, Phoenix
- **National Network for Oral Health Access** - Nov. 6-9, Denver
- **ODHA Dental Hygiene Conference** - Nov. 11-12, Portland
- **OrOHC's 11th Annual Fall Conference** - Nov. 18, Portland

Local Oral Health Coalition Now Serving Oregon's South Coast

Local stakeholders are working together in the formation of a new coalition to help the oral health of community members in Coos and Curry Counties. The South Coast Oral Health Coalition is one of the eight Local Oral Health Coalitions working to identify and solve oral health issues such as disparity of care and lack of timely access in communities across Oregon.

The group aims to help all community members, especially those currently undeserved, achieve optimal oral health. They have identified coordination, collaboration, communication, and community engagement as key strategies to achieve their goals.

The coalition also determined the need for an updated needs assessment. A needs assessment provides better knowledge of the people they serve and where there are gaps in care or coverage. Most importantly, the needs assessment usually pinpoints others in the community who are working in isolation on some of the same issues. Through collaboration, these community members strengthen the opportunity for sustainable, local solutions.

The South Coast Coalition meets on the first Tuesday of every month and alternates meetings between Coos and Curry Counties. The group is working on getting their charter finalized, identifying priority areas, and creating common oral health messaging for community members as well as medical and dental providers.

Oregon Oral Health Coalition, 9140 SW Pioneer Ct, Suite E, Wilsonville, OR 97070

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Tribal pilot program may point to dental-care future for all Oregonians (OPINION)

A girl receives a dental examination in 2012 at the Multnomah County Health Clinic in Southeast Portland. *(Benjamin Brink/Staff)*

By **Guest Columnist**

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on April 19, 2016 at 10:13 AM

By Sen. Laurie Monnes Anderson

Oregon, already nationally recognized as a leader in health care innovation, is now making similar strides to address the barriers to oral health care that many face. Last month, the Oregon Health Authority took a common sense step to improve dental health access by approving a dental pilot project that will help dentists in tribal communities see more patients. As a co-author of recent legislation that strengthened Oregon's pilot law, it is rewarding to see the initial pilots gain approval, providing a pathway to modernize Oregon's oral health care system in some of the communities that need it the most.

Under this first pilot, two tribes in southwest Oregon—the Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians and the Coquille Indian Tribe, working with the Northwest Portland Area Indian Health Board—have announced plans to hire highly trained midlevel professionals to work as part of their dentists' teams. Similar to physician assistants on a medical team, these providers—called dental therapists—will help dentists deliver routine care such as filling cavities, placing temporary crowns and extracting badly diseased or loose teeth.

American Indians face alarming oral health disparities, with rates of decay in children triple that of any population in the United States. This pilot is an important step forward in addressing the oral health issues afflicting Native communities and potentially other **Oregonians facing barriers to care**. More than one quarter of our population live in areas with a shortage of dentists, and one in five of our children ages 6 to 9 had untreated tooth decay in 2012.

I have seen first-hand the devastating effects of poor oral health and lack of access to care. As a public health nurse, I worked with many families in poverty who struggled to find or get to a dentist. Mothers would have to take their children to the emergency room when the child developed mouth pain and infection.

Fortunately, allowing dentists to hire dental therapists has provided a way to address these and other problems elsewhere in the country. These providers have been practicing successfully as part of the dental team in **Alaska's tribal communities** for more than a decade. With bipartisan support, Minnesota and Maine passed laws enabling dentists to hire dental therapists in 2009 and 2014 respectively.

Oregon has always been a leader, and we look forward to exploring how this and other innovations can improve access to dental care for those most in need in our state.

Democrat Laurie Monnes Anderson, of Gresham, represents Senate District 25 in the Oregon Legislature.

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Oregon Health Authority
Dental Pilot Project Program

Dental Pilot Project: Application #100

Abstract
Oregon Tribes Dental Health Aide Therapist Pilot Project
February 8, 2016

Applicant/Sponsor:	Northwest Portland Area Indian Health Board 2121 SW Broadway, Portland, Oregon 97201
Project Director:	Christina Peters, Northwest Portland Area Indian Health Board
Training Supervisor:	Mary Williard, DDS

Sponsor Type:	Community Hospital or Clinic

Northwest Portland Area Indian Health Board is a non-profit tribal organization established under the Indian Self-Determination and Education Assistance Act (P.L. 93-638) and serves all forty-three federally recognized tribes of Oregon, Washington, and Idaho. NPAIHB represents individual tribes which have local community health clinics serving their tribal populations. There are currently 9 tribes operating clinics and/or providing direct medical and/or dental services in the State of Oregon.

Purpose:	• Develops new categories of dental health care personnel. • Teach new oral health care roles to previously untrained individuals

Approved Project Period:	6/1/2016-5/31/2021

Proposed Number of Sites:	**2**

Site Locations:	
Training/Didactic Phase:	Alaska Native Tribal Health Consortium Dental Health Aide Training Program Anchorage, Alaska: Year One Bethel, Alaska: Year Two
Utilization Phase:	• Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians: CTCLUSI Dental Clinic • Coquille Indian Tribe: Coquille Indian Tribal Community Health Center (CITCHC)

Proposed Number of Trainees:	**5-7**
Proposed Number of Supervisors:	**2**
Number of Collaborating Dentists:	**9**
Proposed Number of Sites:	**2**

Application Chronology:

Application Submitted:	October 6, 2015
Application Approved for Completeness:	October 19, 2015
Application Received by Technical Review Board:	October 19, 2015
TRB Application Review Comments Due:	November 20, 2015
TRB Board Meeting:	December 10, 2015
Addendum to Application Received by Dental Pilot Project Program:	January 7, 2016
Addendum Received by Technical Review Board:	January 7, 2016
Applicants Notified of Intent to Approve Application:	January 8, 2016
Application Under 10 Day Period of Public Comment:	January 11, 2016 – January 22, 2016
MOA Received: Project Site Coquille	February 5, 2016
Project Approved by Director	February 8, 2016
Oregon Board of Dentistry Notified of Approval Status	February 8, 2016

Estimated Cost and Funding Source(s):

Estimated Cost:	$544,600 (First Two Years)
Funding Source(s) Committed:	• W.K.Kellogg Foundation • Pew Charitable Trusts • Northwest Portland Area Indian Health Board • Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians • Coquille Indian Tribe
Total Committed:	$2,509,460

Background and History of the Project:
Selected Passages from the DPP #100 Application

Need for the Project:
Native communities are struggling under the weight of devastating oral health disparities and are searching for innovative solutions to address the unique barriers that keep oral health care out of reach for many of their members. Data presented in the Oral Health of AI/AN Preschool Children 2014 IHS Survey includes: • Prevalence of tooth decay in AI/AN children ages 2 to 5 is nearly three times that of white children in the U.S. • By the age of 5, 75% of AI/AN children have a history of tooth decay. • More than 40% of AI/AN children ages 3-5 have untreated tooth decay compared to 14% in the general population.
Description of patients:
Patients at the first two pilot sites will be primarily American Indian/Alaska Natives (AI/AN) but also includes spouses and employees of those tribes. Patients may include a limited number of general public patients. A large majority of patients are low-income and many have no insurance at all. For most of these patients, the tribal dental clinic is the only access they have to oral health care.

Purpose of the Project:
The purpose of the Tribal Dental Health Aide Therapist Project (TDHATP) is to develop a new category of dental personnel in Oregon and teach new oral health care roles to previously untrained individuals. NPAIHB will be utilizing the very successful Alaska Dental Health Aide Therapist (DHAT) program that has been providing services in Alaska for the last 11 years. The Alaska DHAT program is modeled off the international model of dental nurses that have been providing oral health services in nearly 100 countries around the world. This modernization of the dental team has put DHATs on the frontlines in Alaska, wiping out decay and improving overall oral health in previously underserved tribal communities. We believe that those outcomes can be replicated in Oregon with the addition of a DHAT to the dental team at our pilot sites.

Project Description:
Select tribal communities in Oregon will send trainees to the DHAT program in Alaska to train as Dental Health Aide Therapists (DHAT). While these trainees are receiving their education (2 years), the tribal health directors and tribal leaders will work closely NPAIHB to create the necessary regulatory structure, train dentists to be DHAT supervisors, and do education and outreach to the community about the new provider. The DHAT program is an existing decade-old program in Alaska that provides an evidence based and competency based curriculum. Skills are based on those required to be certified as a Dental Health Aide Therapist under the Alaska CHAP standards and procedures 2.30.200. One year prior to the graduation of the trainees, an experienced DHAT will come to the pilot site to begin offering services alongside the supervising dentist. When the DHAT trainee returns to his or her tribe to complete a minimum 400-hour preceptorship with the supervising dentist, the experienced DHAT will continue to serve the community and work as part of the dental team. After the trainee has completed the preceptorship, the experienced DHAT, the supervising dentist, and the newly trained DHAT will work together for at least one year. We intend in the first 3 years of the pilot project to educate a total of 5-7 DHAT trainees in up to 4 pilot sites and to have experienced DHATs working in each site during the training period of the DHAT trainees. As part of our yearly evaluation of the program, in year 3 we will evaluate the program with our pilot sites and make decisions at that point about whether or not we will add additional sites and trainees.

Project Objectives:

Short-Term Objectives:	• Increase the efficiency of the dental clinic and dental team; • Increase the ability of tribal health programs to meet unmet need; • Increase provider job satisfaction and patient satisfaction. • Increase the number of Native providers serving Native communities; • Increase patient education at the community level;
Long-Term Objectives:	• Increase treatment of decay and decrease decay rates in pilot populations; • Improve overall understanding of oral health in relation to overall health, and: • Improve oral care behaviors in pilot communities.

Laws and Regulations Pertinent to the Proposed Project:	Current dental practice laws in Oregon do not allow our trainees to provide the oral health services that are within the scope of the DHAT as utilized in Alaska. The category for this provider does not exist and there is no existing state licensing structure in Oregon to allow for DHATs to practice outside of the Dental Pilot Project as authorized by SB 738. • Chapter 679 o 679.010 – Definitions – DHAT category doesn't exist + Definition of Dentistry o 679.020 (1)- practice of dentistry o 679.025 (1) – License required to practice dentistry

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Oregon Health Authority
Dental Pilot Project Program

Dental Pilot Project: Application #200

Abstract
Training Dental Hygienists to Place Interim Therapeutic Restorations
February 19, 2016

Applicant/Sponsor:	Oregon Health & Science University, School of Dentistry, 3181 SW Sam Jackson Park Road, Portland, OR 97239
Project Director:	Eli Schwarz, DDS, MPH, PhD Department of Community Dentistry, Oregon Health & Science University 3030 SW Moody Ave, Suite 135B Portland, OR 97201
Training Supervisor(s):	Eli Schwarz, DDS, MPH, PhD & Richie Kohli, BDS, MS

Sponsor Type:	Non-Profit Educational Institution

Oregon Health & Science University is a nationally prominent research university and Oregon's only public academic health center. It educates health professionals and scientists and provides leading-edge patient care, community service and biomedical research.

The OHSU School of Dentistry shares the mission of the Oregon Health & Science University to provide educational programs, basic and clinical research, and high quality care and community programs. We strive to foster an environment of mutual respect where the free exchange of ideas can flourish. The dental school prepares graduates in general dentistry and the dental specialties to deliver compassionate and ethical oro-facial health care.

The mission of the Department of Community Dentistry is to promote critical analysis of social, behavioral, and policy-influenced factors that affect oral health outcomes in both individual patients and the entire population. These goals are achieved through a comprehensive didactic and experiential learning curriculum that begins in year one of the pre-doctoral program and culminates with the DS4 clinical rotations in community based dental clinics. We strive to develop curricula that lay the foundation for the student's life-time professional

development, commitment to service and community collaboration, and ensure awareness and cultural competency of the comprehensive and complex nature of health care for vulnerable populations.

Purpose:	• Teaches new skills to existing categories of dental health care personnel.
	• To train Expanded Practice Dental Hygienists (EPDHs) and demonstrate that EPDHs can successfully place "Interim Therapeutic Restorations" (ITRs) when directed to do so by a collaborating dentist. The ITR is an interim restoration designed to stop the progression of dental caries until the patient can receive treatment for that tooth by a dentist.

Proposed Project Period:	11/1/2015 – 9/1/2020

Proposed Number of Sites:	Polk County**:** Central School District School: 5 School Sites

Site Locations:	
Training/Didactic Phase:	• Didactic training will be held via online management system called Sakai, webinars, and in-person meetings in the conference rooms at Capitol Dental Care. • Didactic resources are available through University of the Pacific (UoP). • Laboratory and clinical training will take place at Capitol Dental Care which has fully equipped dental clinics.
Utilization Phase:	• **Ash Creek Elementary**, Independence OR. 492 total student enrollment, 243 K-2nd grade students. 64% free and reduced lunch population • **Independence Elementary**, Independence, OR. 421 total student enrollment, 200 K-2nd grade students. 77.7% free and reduced lunch population • **Monmouth Elementary**, Monmouth OR. 547 total student enrollment. 266 K-2nd grade students. 55.9% free and reduced lunch population. • **Falls City Elementary**, Falls City, OR. 97 total school enrollment. 31 K-2nd grade students. 70.1% free and reduced lunch population.

	• **Community Action Head Start**-Independence Site. 40 children, age 3-5. OCDC Head Start-Independence Site. • In addition, we have also been meeting regularly with a Steering Group of those likely to participate in the pilot project, now and at a future time. These include representatives from: • Capitol Dental Care • Virginia Garcia Memorial Health Center • Advantage Dental • Kemple Memorial Children's Dental Clinic

Proposed Number of Trainees:	**10-12**
Proposed Number of Supervisors:	**4**
Number of Collaborating Dentists:	**4**
Proposed Number of Sites:	**5**

Application Chronology:

Application Submitted:	November 2, 2015
Application Approved for Completeness:	November 30, 2015
Application Received by Technical Review Board:	December 11, 2015
TRB Application Review Comments Due:	January 28, 2016
MOA Received by Program:	February 5, 2016
Applicants Notified of Intent to Approve:	February 19, 2016
Application Under 10 Day Period of Public Comment:	February 22, 2016 – March 4, 2016

Estimated Cost and Funding Source(s):

Estimated Cost:	$111,797.01
Funding Source(s) Committed:	Three sources of funding have been identified: 1) Oregon Health Plan (OHP) covers dental care for Medicaid members through capitated payments to the Dental Care Organization (DCO) to which the CCO has assigned the members; 2) The training, technical assistance, and evaluation will be funded in the initial year through a telehealth grant from the Oregon Health Authority through September 2016; 3) A group of funders of Oregon Oral Health Funders Collaborative that has supported the planning grant to develop the present application has expressed an interest to fund ongoing support of the evaluation and

	testing of the pilot project.
Total Committed:	$111,797.01 for first 18 months

Background and History of the Project:
Selected Passages from the DPP #200 Application

Need for the Project:

Numerous reports within the last ten years have addressed workforce shortages in the dental field, lack of access to oral health care among low-income, rural, and other disadvantaged population groups, and the resulting profound oral health disparities experienced by these groups. Recent reports document that very slow progress is being made in improving the access to oral health care for these population groups. The health transformation process underway in Oregon has recently expanded access to the Oregon Health Plan for around 250,000 additional members. However, since the workforce situation has not been addressed, the existing dental workforce is under additional pressure and overall, access to dental care may further deteriorate. According to an Oregon Healthcare Workforce Institute analysis, the number of dentists practicing in Oregon decreased by 8% from 2010 to 2012 which may indicate a continuous trend. The traditional dental care delivery model of stationary dental offices or community health centers with dental practitioners and auxiliaries needs to be expanded to test alternative and sustainable models.

Studies in other states have shown that a remotely located dentist, working with an Expanded Practice Dentist Hygienist (EPDH), who is seeing a patient at a different location, can collaboratively deliver quality dental care. Led by an EPDH, Capitol Dental Care will implement telehealth-connected oral health teams to reach children who have not been receiving dental care on a regular basis and to provide community-based dental diagnostic, prevention and early intervention services, including ITR placement when indicated by the dentist.

Description of patients:

Demographic Data about Availability of Health Care Services
Polk County continues to show an increase in diversity, especially within the Hispanic population. 11.2% of the population considers themselves Hispanic compared to 10% in 2007. The Caucasian population has grown from 86% to 87.9% while the American Indian/Alaskan Native population has remained consistent at 1.9%. There were slight increases in the African American population from .4% to .5% and in the Asian/Pacific Islander population from 1.6% to 1.9% in 2009. According to the 2005-2009 US Census Bureau data, 11.4% of Polk County residents speak a language other than English in their home compared to 14% of Oregon residents and 19.6% of US residents.

Oral Health needs assessment suggested that 34.3% of the Polk County residents had no dental visit in the last 12 months. Currently, only about 20% of Oregon dentists accept Oregon Health Plan (OHP) members. In Marion and Polk Counties, there are 122 OHP enrolled dentists. This is approximately 1 dentist for every 550 members of the Willamette Valley Community Health (WVCH) Coordinated Care Organization. Although this may be considered an acceptable ratio issues remain of provider timely availability, appointment timing, and insurance coverage; thus, there are still barriers for OHP members' access.

Oregon 2012 Smile Survey: This statewide survey gauges the health of the Oregon dental system by looking at the oral health, access, and overall quality of dental care for school children, aged 6 to 9. The survey examines the percentage of children who need urgent dental care, have any tooth decay, have rampant tooth decay (7 or more cavities), and have received dental sealants. The survey showed those with lower incomes, non-English speaking, and Hispanic background generally have worse dental health outcomes than those who have higher incomes, speak only English, and are white.

Purpose of the Project:

To train Expanded Practice Dental Hygienists (EPDHs) and demonstrate that EPDHs can successfully place “Interim Therapeutic Restorations” (ITRs) when directed to do so by a collaborating dentist. The ITR is an interim restoration designed to stop the progression of dental caries until the patient can receive treatment for that tooth by a dentist.

Oregon is in the midst of a dental health care crisis with more than 91 areas in the state designated as dental care health professional shortage areas (Kaiser Family Foundation study, April 28, 2014). This level of “deficiency” translates to more than 61% of Oregon residents not having their dental care needs met. One county where the need is particularly great is Polk County, and it is within this county - and the Polk County School District that a collaborative consisting of OHSU School of Dentistry, University of the Pacific Center for Special Care, and Capitol Dental Care (CDC) will implement its pilot project to train Expanded Dental Hygienists to place interim therapeutic restorations (ITR) within the context of a telehealth connected dental team.

This OHSU project has been planned and developed in collaboration with the University of the Pacific, Arthur A. Dugoni School of Dentistry (UoP) and Capitol Dental Care (CDC).

Project Description:

Under the dental pilot project program [Capitol Dental Care] CDC will build upon existing community outreach programs in Polk County by adding the telehealth model to existing preventive services, which include assessment, radiographs, intra-oral photographs, cleanings, sealants, fluorides, oral health instruction, and ITR if indicated. CDC’s telehealth connected dental team of Expanded Practice Dental Hygienists, dental assistants, and supervising dentist, will visit three schools within the District, serving approximately 10 children per day~75 per month with a total expected population of 1200-1500 measurable encounters over the life of the 15-month project.

Those children with advanced disease in need of additional care will be referred for care either through CDC’s mobile van operatory, or directed to a dental clinic for restorative care, as needed.

This Dental Workforce Pilot Project (DWPP) will add one new duty to those currently permitted for Expanded Practice Dental Hygienists (EPDHs) that are part of a community-based telehealth connected team system of care already under way.

The Oregon Health and Science University will train Expanded Practice Dental Hygienists

(EPDH) to perform a new duty in community settings to improve the oral health of underserved populations and demonstrate their ability to carry out this duty.

Project Objectives:

Short-Term Objectives:	• Train EPDHs and evaluate their competence to place ITRs.
Long-Term Objectives:	• Through the performance of these duties to allow EPDHs working in community settings with underserved populations to facilitate collaboration with a dentist and to develop an appropriate plan of care for the patient. The placement of ITRs when directed to do so by a collaborating dentist will allow EPDHs to stabilize patients' oral health from further deterioration until they can be seen by a dentist in an appropriate setting. • To facilitate the development of new models of care designed to improve the oral health status of underserved populations.

Laws and Regulations Pertinent to the Proposed Project:	The Dental Practice Act governs the scope of practice for both dentists and dental hygienists operating in the state of Oregon. The key provisions can be found at Oregon Revised Statutes, Chapter 680 (680.010 – 680.210 and 680.990 (Dental Hygienists). Currently, an Expanded Practice Dental Hygienist (EPDH) may only perform the placement and finishing of direct alloy and direct composite restorations after the supervising dentist has prepared the tooth (teeth) for restorations (ORS 818-035-0072).

Message from the President—Dr. Nathaniel Tippit

Dr. Nathaniel Tippit

Welcome to the 2016 examination season! I want to welcome our new examiners and briefly touch on recent improvements to the WREB exams.

Our CTP examination component is now fully implemented. Great thanks to the myriad of examiners who have flown into Phoenix for en masse grading. We really appreciate your dedication and effort.

The Provisional Acceptance of radiographs has been well received and is a great convenience to candidates. The first full year of immediate hygiene retakes has been very successful as well. WREB is certainly headed in the right direction.

I would like to take a moment and change the tone to say goodbye to Dr. Charles Broadbent. Charlie has been a blessing to WREB; he is in the class of David Lowe for contributions made to our organization. I will miss his guidance and judgment. Goodbye, Charlie. Thanks for an incredible job and good luck. You will be missed.

2016 WREB Board of Directors

WREB is proud to introduce the 2016 Board of Directors.

From left to right: Dr. James Ence, DERB Chair; Dr. Arne Pihl, At-Large Member; Mary Davidson, HERB Chair; Dr. Dale Chamberlain, At-Large Member; Dr. Nathaniel Tippit, President; Dr. Jeff Lunday, At-Large Member; Dr. Bruce Horn, Director of Dental Exam Administration; Beth Cole, WREB CEO; Diane Klemann, RDH, At-Large Member; Janet Ingrao, RDH, Co-Director of Dental Hygiene Exam Development & Administration; Dr. James Sparks, At-Large Member; Dr. Gregory Waite, Treasurer; Kelly Reich, RDH, Co-Director of Dental Hygiene Exam Development & Administration; Dr. Norm Magnuson, President-Elect

Dr. Paul Stubbs Receives the David S. Low Service Award

The David S. Low Service Award, created in 2006, is awarded annually by the Board of Directors to those who give truly noteworthy and extraordinary service to WREB. It is intended to memorialize the 26 years of exceptional leadership that Dr. Low gave to WREB.

This award, WREB's highest commendation, recognizes the invaluable contributions that outstanding WREB team members render to the examining community. Recipients must demonstrate the highest level of commitment, dedication and innovation. In addition, they must possess a genuine compassion for candidates, patients, fellow examiners, and staff.

WREB is pleased to announce that Dr. Paul Stubbs has been selected as the recipient of this year's David S. Low Service Award. Dr. Stubbs received a plaque at February's Leadership Meeting to memorialize his award. In addition, his name will be added to the recipient plaque in the Board Room at the WREB office.

When presented with the award, Paul was very appreciative and humbled.

Congratulations Dr. Stubbs! And thank you for your many years of service to WREB!

New faces at the WREB Office

Meet Shelly Clifton, Accounting Clerk. Shelly will be taking over the Expensewire, payroll, and accounts payable responsibilities, and will report directly to the Office Manager, Stacy Tomko.

Shelly Clifton lives with her husband Rob, two children Morgan and Mallory, and two dogs in N. Phoenix. She is originally from Omaha, NE, but has lived in the valley for over 20 years and loves it. Her work background consists of both Accounting and Media Sales for 19 years.

She enjoys doing any outdoor sports and activities such as boating at Bartlett Lake, hiking the Grand Canyon, and trail biking. She loves to travel abroad as well as discovering new places in the United States. She also likes to cook and barbeque because it's a great way to spend time with family and friends. Shelly is happy to be the newest member of the WREB family and looks forward to meeting everyone.

New faces at the WREB Office *continued*

Victoria Melendez is now WREB's new Dental Hygiene Supervisor. Victoria, also known as Toria by her friends and family, is a proud native of Arizona. She grew up in Phoenix where she resides with her fiancé, Tom and their three dogs.

Victoria loves the outdoors and enjoys hiking, camping, and gardening. Before she studied English and Creative Writing at Arizona State University, she also studied photography. For the past seventeen years, she has been photographing a wide variety of subjects. One of the most exhilarating experiences in her photography career was filling in for a colleague for an aerial photo shoot from a helicopter.

One of Victoria's life-long passions is writing. She has written three children's books and is currently working on two more. She hopes to be published someday. She also loves to travel and is planning to take her first trip to Europe this year with her fiancé, where they will explore London, Paris, and the Northwest region of Spain.

Victoria's work background consists mostly of working in the media industry, and includes managing traffic departments at local radio and television stations in the valley. After over 15 years of working in the media industry, she decided to pursue more fulfilling opportunities. Before she came to WREB, she was a Staff Development Coordinator for a national rehab agency, where she handled the on boarding and training of newly hired physical, occupational, and speech therapists. She is thrilled to be a part of such a great organization such as WREB and is looking forward to a long working relationship.

Emily Stallings, Dental Hygiene Coordinator is WREB's newest member of the Dental Hygiene Department. Emily grew up in Houston, Texas with her parents and two sisters, one older and one younger. She considers herself the "well adjusted middle child."

Emily attended Texas A&M University and graduated with a Bachelor's degree in Sociology. She has two children, a son Justin, 22 and a daughter Sydney, 17. Emily would be remiss if she didn't mention their newest member of the family, Mollie. Mollie is a Great Dane/Pointer mix that Emily rescued from the Great Dane Rescue of Arizona.

Emily moved to Phoenix about thirteen years ago and now resides in Anthem. She worked for an advertising agency for the last twelve and a half years but was given notice at the end of November that the company was closing its door at the end of December. At the time, this news was shocking to her, but now she says it was a blessing in disguise to end up at WREB.

In her free time, Emily volunteers a couple times a year with the Hopi Tewa Indians up in Northern Arizona and on the weekends at Healing Hearts Animal Refuge in New River where she helps to nurse back to health and adopt out horses and the occasional donkey or burro.

Staffing Update

Robin Yeager has been promoted to Director of Dental Hygiene Operations. Robin has 10 years of service with WREB.

Denise Diaz is now Director of Dental Operations. Denise has 9 years of Service with WREB.

In our last newsletter, we introduced **Edna Ontiveros** as a new Dental Hygiene Coordinator for dental hygiene department. In January, however, she joined the WREB Dental Department as the new Dental Supervisor. Edna has been with WREB since December of 2014.

Nic Cronin has been promoted to IT Manager and has been with WREB for 7 years.

AnneMette Lavery is now Project Manager. AnneMette has been with WREB since October of 2013.

Provisional Acceptance off to a Great Start

WREB constantly strives to improve the exam experience for Candidates. The 2016 Dental exam season introduced the new provisional acceptance process. This process allows Candidates at participating sites to have patients radiographically accepted by Grading Examiners prior to the exam. 19 of the 26 Dental exam sites chose to participate in the process for 2016. As of the writing of this article, 63% of Operative Candidates in sites whose submission windows had passed participated in the process. Feedback from those who participated has been exceedingly positive. Candidates appreciate the peace of mind that comes from knowing in advance that their patients qualify radiographically. There are also benefits at the clinical exam. Patient waiting lines tend to be shorter because Candidates treating provisionally accepted patients no longer have to submit them to the grading area. This helps alleviate the morning and mid-day patient lines usually correlated with acceptance.

Examiner participation has also gone well. Examiners are given the dates of their approval window in advance and have about seven days to complete the online calibration then process their assigned submissions. It is a simple and quick process. School personnel are also essential. Designated persons at each site are responsible for uploading radiographs submitted by Candidates, ensuring that files are formatted correctly and helping Candidates ensure all information is accurate. While it is an uncomplicated process, there is additional work involved but it is well worth the effort to achieve the benefit for Candidates.

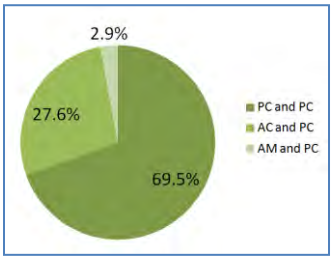
As with any new process, a great deal has and will continue to be learned during the first season. Improvements are already in the works for the 2017 version of provisional acceptance. Comments and feedback from Candidates, Examiners, and schools are always welcome. All will be reviewed and considered.

Revised Dental Requirements Met with Enthusiasm

2016 Dental Candidates are now required to perform one Posterior Composite restoration and have the option to perform a second Posterior Composite restoration in order to meet the Operative section requirements. Previously, Candidates were only allowed to perform one Posterior Composite, then had to choose a different option for their second restoration. The change to require one and allow a second Posterior Composite is in line with the findings of WREB's Practice Analysis committee. Data gathered by the committee in 2015 showed that Posterior Composites are one of the most frequently performed procedures in practice. This has been strongly supported by Candidate behavior. The majority of Candidates are taking advantage of the new option. After the first nine exams of the 2016 exam season, 69.5% of Candidates performed two Posterior Composite restorations for their Operative procedure requirements. 27.6% of Candidates performed an Anterior Composite for their second procedure, and only 2.9% performed an Amalgam as their second procedure.

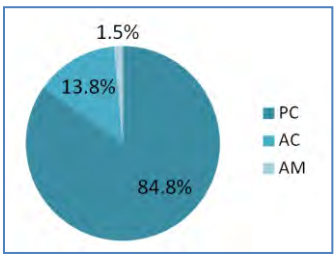
Procedure Combinations

Early 2016 (after 9 exams)



Individual Procedures

Early 2016 (after 9 exams)



Dental Hygiene On-site Retakes: First Year Psychometric Review

Many Dental Hygiene Candidates pass their Hygiene examination on their first attempt. The passing percentage for first attempt has been between about 89% and 91% for the past several years. Of those Candidates who are not successful on their first attempt, many do pass upon their second attempt, with about 77% to 80% passing upon second attempt. The passing percentage continues to drop upon third attempt, at which point remediation is required prior to challenging the examination again.

2015 was the first year Dental Hygiene Candidates who were unsuccessful at their first or second examination attempt had the option to participate in one retake at the same examination site. Retake attempts were conducted on the last day of the examination or the next morning following the last session, for those who were not required to remediate after their failure onsite. Over 150 Candidates (about 73% of eligible candidates) chose to participate in an on-site retake in 2015.

As with any new examination feature, the on-site retake process was developed and reviewed before implementation with attention to possible threats to examination validity in the areas of administration, scoring, content, and technical quality. After all of the simulations, field testing and statistical estimation, we began to collect empirical evidence of validity upon implementation. One of the most important issues to investigate is whether the option to retake on site confers any systematic advantage or disadvantage to Candidates over conventional retakes at another examination site. So - the questions I have been asking over the past year include: "Is the retake success rate comparable between on-site and conventional retakes? Is the retake success rate comparable between 2015 and the previous year? What does performance look like for the subset of candidates that have an unsuccessful attempt in a morning examination session and then opt to retake at the afternoon session of the same day?"

On-site Retakes and Conventional Retakes: 62% of all Dental Hygiene examination retakes in 2015 were on-site retakes. The percentage of successful on-site retakes was consistent with conventional retakes during the 2015 season, with 79.2% passing for on-site retakes and 77.7% passing for conventional retakes. The difference between the percentages is not statistically significant.

2014 (before on-site retakes were implemented) and 2015 (with On-site Retakes): The percentage of successful retakes was consistent between 2014 and 2015, with a 2014 retake percent passing of 78.8% and a 2015 retake percentage passing of 78.6%. Again, the difference between the percentages is not statistically significant.

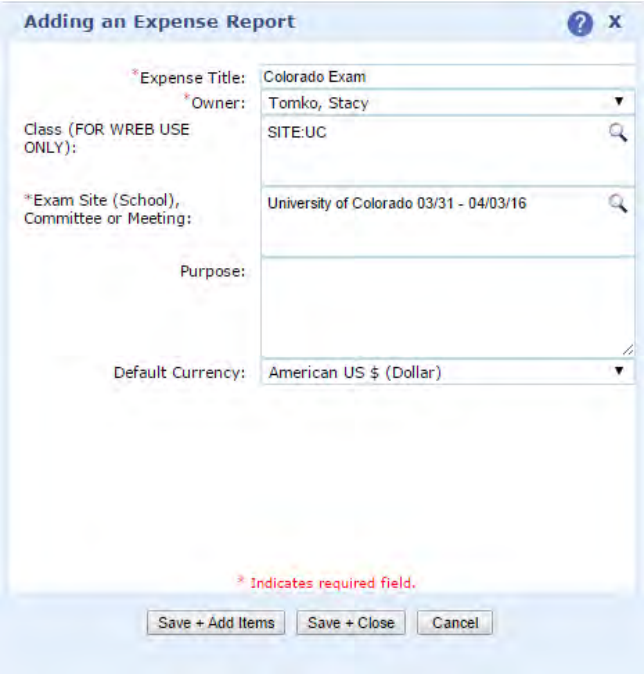
Same day Retake and Next day or longer time between attempts: Dental Hygiene Candidates are randomly assigned to an examination day and session (morning or afternoon). Depending on the size of the site and number of candidates, the additional retake session for an examination may be held on the same day as the last regular session. About 15% of on-site retakes occurred at an afternoon session on the same day as an initial unsuccessful attempt, that morning. The percentage passing for this same-day group was actually 87.0%, compared to 77.9% for other on-site retakes. While it may appear that the Same-day group may have actually performed better, the difference is not statistically significant due to the small number of candidates in this group (that is, only one or two different outcomes can change the percentage dramatically within a small number).

Summary

No statistically significant difference in Pass/Fail outcome between different types of retakes has been found since the implementation of optional on-site retakes, which provides us with important evidence that the option to retake on site does not confer any systematic advantage or disadvantage to Candidates over conventional retakes. We will continue to assess the quality of onsite retakes during the 2016 season. Feel free to contact Sharon Osborn Popp at the WREB office if you have any questions about the details of our analyses, so far.

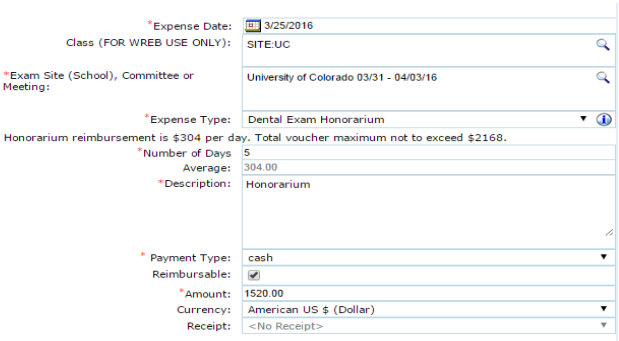
Improvements to Expensewire

By now, most Expensewire users should have been able to experience the new and improved process for submitting expenses. For those of you that have not seen or been able to test out some of the new features, it's great practice and you are encouraged to do so. One of the changes that most users will notice is that there are less options to choose from when you are creating your expense report.



There are only 2 areas that need your attention when creating your expense report. The Title needs to be entered and the Exam Site needs to be selected by clicking on the magnifying glass and then the gray "search" box. This will give you the list of available exams and meetings to select from. All other fields will auto populate based on your selection.

Do not tab into the Class field. This field will auto-populate based on your Exam site, committee or meeting selection and will also default into each of your line items (see example below). This was a huge improvement made.



ExpenseWire Tips

Exam season is upon us again! If you are examining this year or attending a meeting for WREB, you'll be submitting your expenses through ExpenseWire (www.expensewire.com). Below are a few reminders to help you get those expenses to WREB as easily and quickly as possible.

- Send your receipts to your personal ExpenseWire receipts email address *before* you start your expense report. This email address can be found in your "profile" in ExpenseWire. Send one receipt per email, and remember to describe the receipt you are sending in the subject line of your email. This will make attaching receipts to line items *much* easier.
    - Your expensewire receipts email address looks something like this: firstname.lastname####@receipts.expensewire.com
    - Be sure to add your personal receipts email address to your contacts in your cell phone to make emailing your receipts even easier.

- You are welcome to combine like-items in a single picture and add only one line in your expense report for the total amount of the like-items. For example, if you have three taxi receipts, take one picture of all three receipts and send it to your ExpenseWire receipts email address. When adding a line item for "Taxi/Shuttle", add up all three receipts and put the total in the Amount field. Attach your receipts as you normally do. This method can be used for other expenses like "Baggage" and "Gas" to make submitting easier.

- If you are asked to choose a size for the picture you are sending, please select **medium** or larger so your receipt can be viewed clearly upon approval.

- If you forward an email to your personal ExpenseWire receipts email address, remember that the email *must* include an **attachment** that ExpenseWire can interpret (PDF, GIF, JPEG or PNG formats). ExpenseWire *cannot* read the text of an email to create a receipt.

- Please submit your expenses in a timely manner (30 days or less) so WREB can close out exams as soon as possible.

- For questions regarding Expensewire, please contact **Stacy Tomko** at **623-209-5401**.

Ideas for the next newsletter? Feedback on this newsletter? We'd love to hear from you! Email Stacy Tomko at stomko@wreb.org.

2016 WREB Calendar of Events	
Dental AC/SC Training, Phoenix, AZ	Jan 16
Board of Directors Meeting—Phoenix, AZ	Jan 22
WREB Leadership Training – Tempe, AZ	Feb 4 – 6
DERB Meeting – Phoenix, AZ	Feb 12
CTP Committee Meeting – Phoenix, AZ	Feb 26 - 27
HERB Meeting – Phoenix, AZ	Mar 11
Anesthesia Committee Teleconference, Phoenix, AZ	Apr 5
Board of Directors Meeting—Chicago, IL	Apr 9
AADB Meeting – Chicago, IL	Apr 10
Operative Committee Meeting	Apr 15 - 16
HERC Meeting – Austin, TX	Jun 22
HERB Meeting – Austin, TX	Jun 23
DERB Meeting – Austin, TX	Jun 24
Board of Directors Meeting—Austin, TX	Jun 25
DERC Meeting – Austin, TX	Jun 26
CTP Committee Meeting – Phoenix, AZ	Sep 16 – 17
Dental Hygiene Committee Meeting – Phoenix, AZ	Sep 22 – 24
Restorative Committee Meeting – Phoenix, AZ	Sep 30 – Oct 2
Perio Committee Meeting – Phoenix, AZ	Oct 7
Endo Committee Meeting – Phoenix, AZ	TBD
Anesthesia Committee Meeting – Phoenix, AZ	Oct 15 – 16
Board of Directors Meeting—Denver, CO	Oct 20
ADA Annual Meeting – Denver, CO	Oct 20 – 23

2016 Dental Exam Schedule

Exam Location	Exam Dates	App Dead-line	Final Dead-line	Exam Fee	Registration Opens
Midwestern University*, Glendale, AZ	Mar 3 - 6	9/1/2015	2/11/2016	$2,040	8/3/15 10:00 AM
Roseman University, South Jordan, UT	Mar 3 - 6	9/1/2015	2/11/2016	$2,540	8/3/15 11:00 AM
Tufts University*, Boston, MA	Mar 4 - 7	9/1/2015	2/12/2016	$2,040	8/3/15 1:00 PM
Case Western Reserve University, Cleveland, OH	Mar 11 - 14	9/1/2015	2/19/2016	$2,340	8/3/15 3:00 PM
University of Nevada Las Vegas, Las Vegas, NV	Mar 12 - 15	9/1/2015	2/22/2016	$2,465	8/5/15 10:00 AM
New York University*, New York, NY	Mar 17 - 20	9/1/2015	2/25/2016	$2,490	8/5/15 11:00 AM
University of California - Los Angeles, Los Angeles, CA	Mar 18 - 21	9/1/2015	2/29/2016	$2,700	8/5/15 1:00 PM
Loma Linda University, Loma Linda, CA	Mar 18 - 22	9/1/2015	2/26/2016	$2,540	8/5/15 3:00 PM
University of Washington, Seattle, WA	Mar 23 - 26	9/1/2015	3/02/2016	$2,490	8/6/15 10:00 AM
University of Missouri - Kansas City*, Kansas City, MO	Mar 31 – Apr 3	9/1/2015	3/10/2016	$2,040	8/6/15 11:00 AM
University of Colorado, Aurora, CO	Mar 31 – Apr 3	9/1/2015	3/10/2016	$2,640	8/6/15 1:00 PM
Western Univ. of Health Sciences, Pomona, CA	Mar 31 – Apr 3	9/1/2015	3/10/2016	$2,540	8/6/15 3:00 PM
Boston University*, Boston, MA	Apr 1 - 4	9/1/2015	3/14/2016	$2,040	8/10/15 10:00 AM
Temple University, Philadelphia, PA	Apr 13 - 16	9/29/2015	3/23/2016	$2,465	8/10/15 11:00 AM
University of Southern California, Los Angeles, CA	Apr 15 - 18	9/29/2015	3/25/2016	$2,640	8/10/15 1:00 PM
Creighton University, Omaha, NE	Apr 21 - 24	9/29/2015	3/31/2016	$2,490	8/10/15 3:00 PM
Baylor College of Dentistry, Dallas, TX	Apr 22 - 25	9/29/2015	4/1/2016	$2,540	8/12/15 10:00 AM
Arizona School of Dental & Oral Health, Mesa AZ	Apr 28 – May 1	9/29/2015	4/7/2016	$2,440	8/12/15 11:00 AM
Oregon Health and Science University, Portland, OR	Apr 29 – May 2	9/29/2015	4/11/2016	$2,540	8/12/15 1:00 PM
University of Texas - San Antonio, San Antonio, TX	Apr 29 – May 2	9/29/2015	4/8/2016	$2,540	8/12/15 3:00 PM
University of Oklahoma, Oklahoma City, OK	May 6 - 9	9/29/2015	4/15/2016	$2,590	8/13/15 10:00 AM
University of Texas - Houston, Houston, TX	May 11 - 14	9/29/2015	4/20/2016	$2,540	8/13/15 11:00 AM
University of California - San Francisco, San Francisco, CA	May 13 - 16	10/27/2015	4/25/2016	$2,700	8/13/15 1:00 PM
University of Louisville, Louisville, KY	May 19 - 22	10/27/2015	4/28/2016	$2,590	8/13/15 3:00 PM
University of the Pacific, San Francisco, CA	May 20 - 23	10/27/2015	5/2/2016	$2,540	8/17/15 10:00 AM
University of the Pacific, San Francisco, CA	Jun 3 - 6	10/27/2015	5/23/2016	$2,540	8/17/15 11:00 AM
Tufts University*, Boston, MA	Jun 3 - 6	10/27/2015	5/20/2016	$2,040	8/17/15 1:00 PM
Loma Linda University, Loma Linda, CA	Jun 10 - 14	10/27/2015	5/27/2016	$2,540	8/18/15 10:00 AM
University of Southern California, Los Angeles, CA	Jun 17 - 20	10/27/2015	6/3/2016	$2,640	8/18/15 11:00 AM
University of Southern California, Los Angeles, CA	Aug 12 - 15	6/30/2016	7/22/2016	$2,640	2/1/16 10:00 AM
University of Utah, Salt Lake City, UT	Nov 3 – 6	9/1/2016	10/13/2016	$2,540	6/1/16 8:00 AM

*Site charges an additional fee to candidates.

LICENSE RATIFICATION

16 . RATIFICATION OF LICENSES

As authorized by the Board, licenses to practice dentistry and dental hygiene were issued to applicants who fulfilled all routine licensure requirements. It is recommended the Board ratify issuance of the following licenses. Complete application files will be available for review during the Board meeting.

DENTAL HYGIENISTS

H7160	MEGAN ANN RUNYON, R.D.H.	4/14/2016
H7161	PATTI GOLDEN, R.D.H.	4/14/2016
H7162	CHELSEA DAWN NASTIUK, R.D.H.	4/14/2016
H7163	RACHEL ANN ZERWIG, R.D.H.	4/14/2016
H7164	CHELSIE A YOUNG, R.D.H.	4/20/2016
H7165	CANDICE LEWIS KIDD, R.D.H.	4/20/2016
H7166	GINA MARIE DURANDO, R.D.H.	5/5/2016
H7167	ASHLEY D WALDEN, R.D.H.	5/5/2016
H7168	SIENA MARIE WEIRICH, R.D.H.	5/5/2016
H7169	AMY M GAINER, R.D.H.	5/5/2016
H7170	CLAUDIA F GROVER, R.D.H.	5/5/2016
H7171	ELISA JOY KING, R.D.H.	5/5/2016
H7172	LAURA LYNN GEELAN, R.D.H.	5/6/2016
H7173	SARAH ELIZABETH MC GRAW, R.D.H.	5/9/2016
H7174	AMANDA C GATES, R.D.H.	5/9/2016
H7175	CARA LEE FERY, R.D.H.	5/9/2016
H7176	PETRA TOPETE-MARTINEZ, R.D.H.	5/9/2016
H7177	JENNIFER LYNN NOE, R.D.H.	5/9/2016
H7178	BRITTANIY K BUCKINGHAM, R.D.H.	5/9/2016
H7179	MARIELA QUEVEDO RAMOS, R.D.H.	5/9/2016
H7180	KIMBERLY A PERLOT, R.D.H.	5/9/2016
H7181	KASSANDRA L COLEMAN, R.D.H.	5/12/2016
H7182	THAO PHU NGUYEN, R.D.H.	5/19/2016
H7183	WHITNEY J HULL-PITCHER, R.D.H.	5/19/2016
H7184	TIANA L SELLARS, R.D.H.	5/19/2016
H7185	MARY E MATZEN, R.D.H.	5/19/2016
H7186	AMANDA JOANN LEWIS, R.D.H.	5/19/2016
H7187	ANDREA D STUTZMAN, R.D.H.	5/20/2016
H7188	ISRAEL JOSUÉ RIVAS, R.D.H.	5/20/2016
H7189	JESSICA JEAN MILLER, R.D.H.	5/20/2016
H7190	EVDAKAYA SNEGIREFF, R.D.H.	5/20/2016
H7191	CARRIE ELIZABETH MCHILL, R.D.H.	5/20/2016
H7192	HAILEY F TOTORICA, R.D.H.	5/24/2016
H7193	MALLORY MC KAY KAUS, R.D.H.	5/25/2016
H7194	BRITTANY MARIE ANDERSON, R.D.H.	5/25/2016
H7195	KJERSTIN M WELKER, R.D.H.	5/25/2016
H7196	WENDY L RIGGI, R.D.H.	5/25/2016
H7197	OWEN NEIL FAIRCHILD, R.D.H.	5/27/2016
H7198	EMMA LEEANNE CAREY, R.D.H.	5/27/2016
H7199	KAREN JOY GAUNT, R.D.H.	5/27/2016
H7200	HEATHER A GRIFFITH, R.D.H.	5/27/2016

DENTISTS

D10414	ASHLEY NICOLE BENNETT, D.D.S.	4/14/2016
D10415	BARRY F MORRIS, D.D.S.	4/20/2016
D10416	JAMES ALLEN KATANCIK, D.D.S.	4/20/2016

D10417	REBECCA LOUISE GUILD, D.M.D.	4/20/2016
D10418	ALEXANDER DAVID SNYDER, D.M.D.	4/20/2016
D10419	KRISTA LEAH MATTSON, D.D.S.	4/20/2016
D10420	HUJATULLAH BAYAT, D.D.S.	4/20/2016
D10421	JONATHAN MICHAEL BROWN PETERSEN, D.M.D.	5/5/2016
D10422	LORI A CARDELLINO, D.M.D.	5/5/2016
D10423	JOHN H HASTINGS, D.D.S.	5/5/2016
D10424	MARC S SHRYER, D.D.S.	5/5/2016
D10425	GEOFFREY A SKINNER, D.D.S.	5/5/2016
D10426	SHRUTI M JADEJA, D.D.S.	5/5/2016
D10427	CHERYL PEZZOTTI HANSEN, D.D.S.	5/5/2016
D10428	FERNANDO VELASQUEZ, D.M.D.	5/9/2016
D10429	SUHER BAKER, D.M.D.	5/9/2016
D10430	BENJAMIN R BRYAN, D.M.D.	5/9/2016
D10431	JARED R ADAMS, D.D.S.	5/12/2016
D10432	JORDAN WILLIAM ENDRES, D.D.S.	5/19/2016
D10433	ERUM HUSSAIN, D.M.D.	5/19/2016
D10434	CHELSEA ELESE ZAMUDIO, D.D.S.	5/19/2016
D10435	FRANCES E GOLLY, D.D.S.	5/19/2016
D10436	JEFFREY MICHAEL CLAWSON, D.M.D.	5/20/2016
D10437	DAVID MICHAEL KELLY, D.D.S.	5/24/2016
D10438	SARA ELISABETH DAY, D.M.D.	5/26/2016
D10439	EMILY CATHERINE WINELAND, D.D.S.	5/26/2016
D10440	TED ROTHSTEIN, D.D.S.	5/26/2016
D10441	MICHAEL JOHN NEISH, D.M.D.	5/27/2016
D10442	JESSICA M ROSS, D.M.D.	5/27/2016
D10443	BRAD T ANDERSEN, D.M.D.	5/27/2016
D10444	ROBIN RENEE PIATT, D.M.D.	5/27/2016
D10445	AIXA YARI DEVARIE MORALES, D.M.D.	5/27/2016
D10446	MELISSALYNN LAURON DIXON, D.M.D.	5/31/2016
D10447	JORDAN RUSSELL SINGER, D.M.D.	5/31/2016
D10448	JUSTIN D POULSON, D.D.S.	5/31/2016

LICENSE, PERMIT & CERTIFICATION

Nothing to report under this tab