CENTER FOR PREVENTION AND HEALTH PROMOTION
Oral Health Program
Kate Brown, Governor

Oregon Health Authority

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AGENDA

Dental Pilot Project #100 "Oregon Tribes Dental Health Aide Therapist Pilot Project"
Quarterly Dental Pilot Project Program Advisory Committee Meeting DPP #100
December 3, 2018, 10:00am – 12:30pm

Location: Portland State Office Building, 800 NE Oregon Street, Room 1E, Portland **Conference Line: Dial-In Number: 1-888-273-3658 Participant Code: 76 64 09**		
10:00-10:10	Official Introductions, Agenda Review	Bruce Austin, DMD Sarah Kowalski, RDH, MS
10:10-11:10	Presentation; Patient Harm, Adverse Events – Terminology Discussion	Karla Kent, MA, PhD Rose McPharlin, DDS
11:10-11:30	Facilitated Discussion with Advisory Committee Members and Invited Guests	Bruce Austin, DMD
11:30-11:40	Project Data Update	Kelly Hansen
11:40-11:50	Dental Pilot Project Program Update; Revised Oregon Administrative Rules	Sarah Kowalski, RDH, MS
11:50-11:55	Review Advisory Committee Charter	Bruce Austin, DMD
11:55-12:10	Nitrous Oxide Modification Request; Introduction to Northwest Portland Area Indian Health Board Internal Advisory Committee	Rachel Hogan, DDS Gita Yitta, DMD
12:10-12:20	Facilitated Discussion with Advisory Committee Members and Invited Guests	Bruce Austin, DMD
12:20-12:25	Follow Up Items, Future Meeting Dates, Closing	Sarah Kowalski, RDH, MS
12:25-12:30	Public Comment Period	Public comments are limited to 2 minutes per individual

Next Meeting: Monday, Monday, March 4, 2019, Portland State Office Building 800 NE Oregon Street Portland, Oregon, Room 1A, 10:00am – 12:00pm

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Quarterly Dental Pilot Project Meeting: DPP 100 Meeting Minutes

Date: Monday, December 3, 2018
Time: 10:00 AM – 12:30 PM
Location: OHA Public Health Division
800 NE Oregon Street
Portland, OR 97232
Conference Room 1E – First Floor

Committee Members Present:
Len Barozzini, Paula Hendrix, Linda Mann, Connor McNulty, Carolyn Muckerheide, Karen Shimada, Brandon Schwindt,

Committee Members Present Phone:
Jennifer Clemens, Kyle Johnstone, Jill Jones

Committee Members Absent:
Leon Assael, Richie Kohli, Kenneth Wright

OHA Staff:
Bruce Austin, Danna Drum, Fred King, Kelly Hansen, John Putz, Amy Umphlett

Oregon Board of Dentistry Staff:
Daniel Blickenstaff

Public Attendees:
Azma Ahmed, Jennifer Lewis-Goff, Rachel Hogan, Pam Johnson, Karla Kent, Allyson Lecatsas, Rose McPharlin, Christina Peters, Eli Schwarz, Gita Yitta, Cara Kao-Young

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Meetings was recorded and transcribed. *** indicate portions of the meeting that were not audible in the recording.**

Meeting began at 10:04am. Committee Members and OHA Staff introduced themselves.

Other Speaker: Good morning everybody. Um, I'm Bruce Austin. We'll get started, uh, now. We're having a little bit of a disruptive start. It's five minutes after, I apologize. Uh, Sara's, Sara Kowalski's out today. She won't be able to be here. She's sends her regards that it was very unavoidable. Um, we also had to change rooms at the last minute so obviously, all of us got to work, but there are a few stragglers because of that. And you can also see, for those of you that have been here before, we have this new microphone system, um, and apparently the red light means my mic is live and you can see the little speaking voice and the little muted mic down here. So I've heard it's important, uh, that we have all but a mic or two turned on. So, when you're done speaking, just turn the mic off. So the little, the little voice

emanating symbol is on and the **** is off. And, and we are recording this ****. So, let's **** the meeting. Um, so let's go around the room first with introductions and we'll introduce those on the phone. Um, the people at the table are, are invitees to this meeting so they're able to speak and share other members on the – and well, some, some invited members may be on the phone, too, but if, if you're here as a member of the public, we'll have a public –

Next Speaker: You have to **** close to your mouth. It's, uh, voice activated.

Next Speaker: Oh, okay. Thanks, ****. So, we, we will have a period of public comment at the end. It's on the agenda. And we also have a pretty tight agenda today, so Kelly and I will work to keep us on task with that. And with that, let's start with introductions. Um, so, I'm Bruce Austin. I'm the **** double director. And let's start with you, John, and go around this way.

Next Speaker: Okay. I'm, uh, I'm John **** and the, um, surveillance ****.

Next Speaker: Kate Wilcox, material and child health manager.

Next Speaker: Kelly Gibson, um, oral health research analyst.

Next Speaker: Paula Hendricks, I'm the academic coordinator at health sciences at Chemeketa Community College and I'm also a hygienist.

Next Speaker: ****.

Next Speaker: Uh, Brandon ****, uh, pediatric dentist, uh, ****.

Next Speaker: **** Oregon Dental Association.

Next Speaker: Jenna ***** Oregon Dental Association and I'm here ****.

Next Speaker: Eli Schwartz. I'm a chair of community dentistry at **** and I'm the project director for pilot project 200.

Next Speaker: Kyle Johnstone, expanded practice, dental hygienist **** through **** Garcia Memorial Center.

Next Speaker: Rose McFarland, general dentist, I'm here from OHSU and presenting on ****.

Next Speaker: I am Carla Kent. I am also from OHSU and along with Dr. Woodcock ****, um, we're here to talk about adverse events in dentistry.

Next Speaker: Good morning, I'm Karen Chevon. I'm with the Board of **** Rural Health Coalition, member of the advisory committee.

Next Speaker: Hi, Len Barizini, dental director, ****.

Next Speaker: The one with, uh –

Next Speaker: ****.

Next Speaker: Kara Kow Yung, dental hygiene instructor, Portland Community College.

Next Speaker: ****.

Next Speaker: Yeah, it should be that one.

Next Speaker: ****.

Next Speaker: I don't think **** –

Next Speaker: **** Kelly –

Next Speaker: Try the next one.

Next Speaker: – it's a –

Next Speaker: Oh, all of –

Next Speaker: It's malfunction, yeah.

Next Speaker: Everybody cross your, press the, the speaker button ****.

Next Speaker: The face or the –

Next Speaker: The face, cross the face. **** oh, that's fun. It's only that side of the room.

Next Speaker: Okay.

Next Speaker: **** broke it for you ****.

Next Speaker: Yeah.

Next Speaker: I **** on this.

Next Speaker: Yeah –

Next Speaker: Well **** she should ****.

Next Speaker: Which button is it?

Next Speaker: ****.

Next Speaker: I'm, I unplugged, I unplugged mine and I'm putting it back in **** turn it off. ****.

Next Speaker: Talk loudly.

Next Speaker: Yeah, talk loudly for now. We'll figure it out.

Next Speaker: Okay.

Next Speaker: ****.

Next Speaker: Oh. Try that one again.

Next Speaker: ****.

Next Speaker: No ****.

Next Speaker: Okay. I'm Daniel Blickenstaff. I'm the interim dental director for the Board of Dentistry.

Next Speaker: I'm Jennifer Clemmons from Capital Dental Care.

Next Speaker: Fred King, maternal and child health, research analyst.

Next Speaker: **** um, **** pilot project 100.

Next Speaker: And I'm Rachel Hogan. I'm a dentist and I'm the dental director at **** and tribal community. And I am here to speak about ****.

Next Speaker: ****. All right ****.

Next Speaker: Okay. Sure, we can do that, because we did invite – we have some invited guests today to sit at the table and also **** so, that's not a bad idea. Raise your hand if you are part of the project 100 advisory committee. So, Dr. **** Barizini, um, Kyle, Dr. Schwartz, **** I can see the hand. Connor, Connor, Paula and me. All right, uh, thank you. Um, so now to the phone. Uh, who's, who's here on the phone? Uh, go ahead and try to sort it out.

Next Speaker: You're gonna have to wait 'till tech people get here.

Next Speaker: ****.

Next Speaker: Um –

Next Speaker: Jill, Jill Jones, Lane Community College Dental Hygiene.

Next Speaker: Thanks, Jill.

Next Speaker: Linda Mann, Capital Dental.

Next Speaker: Shannon English, **** Dental, as a member of the public.

Next Speaker: Okay, three people on the phone. Anyone else? Jill, Linda and Shannon. Okay. Well, with that, let's get going. Um, like I said, we have a tight **** schedule, so let me review the schedule quickly before we dive into it. Uh, and since Sara's not here, Kelly and I are trying to fill in and, and try to realize what her intent for the day was and that gaps that, that she was gonna do. Um, we have a, a summary list here that I, that I'd like to go through to introduce the agenda first. And just as a reminder of what the role of OHA and our advisory, advisory committee is, um, we conduct site visits, um, to make sure that the projects complying with their **** application and that part involves ****, um. The, the new rules have been finalized. We'll cover that later in the agenda. Um, but the new rules state the use of patient records to monitor for patient safety and training compet, competency, quality of care, ****

standard of care and compliance with the ****. So that's, that's a new addition there a little bit. Thanks. Okay, thanks, ****. Um, so, so now with the new rules we're tasked with, with looking at more than just patient safety which we **** in the past again, that's what, what I just read to you and that's in the new rules. We'll, we'll talk to that a little bit later. So the, the over **** goals of the, of the presentation today, you'll see the second on the agenda is our presentation from Dr. McFarland and Dr. Kent. Um, this was **** uh, they were invited because of, of their published work and I'll introduce that, but that came about because of the questions that arisen in the last few months and at the, uh, the last advisory committee meeting. So, and then, you know, remember we sent out for those, the only committee we sent out as a survey, uh, after that to get input on, on what the members thought the definition of patient harm was. So the point of the, the presentation today should, uh, be perfect timing for that and give us some definition on, uh, patient harm, adverse events, standard of care and quality of care. Uh, that will be the, the presentation by Dr. McFarland and Dr. Kent next on the agenda. Um, and then, the, following that, we've got time on the agenda for a conversation based on that presentation, but Dr. McFarland when you start, let's **** so, if you're okay with conversation as we go along or if you'd like to hold questions until the end, whatever your preference is. But we should have plenty of time for that. Um, as a reminder for all the attendees, this is a public meeting. Uh, like I said, it'll be recorded and everything, um, here today will be part of public record. Um, and like I said, we have advisory committee members here from both committees. That's why the table's bigger this time. And then this afternoon a group of, a smaller group obviously, of the dentists that review charts for this project will get together to go through the new, uh, chart evaluation process we have and, uh, um, a standardization calibration type exercise. So, so that's an overview of how the day looks and with that, let's get into Dr. McFarland and Dr. Kent and I'll let you introduce yourselves and your roles ****.

Next Speaker: Would you prefer to stay there or **** –

Next Speaker: Yes –

Next Speaker: – **** there.

Next Speaker: Okay.

Next Speaker: There's the pointer.

Next Speaker: It's well established in medical literature that healthcare is one of the least safe industries in the world. Medical adverse events have gained prominent attention in academia, healthcare, government institutions and organizations. However in dentistry the study of adverse events is still in its **** and its infancy while our medical counterparts are quite advanced in their documentation of adverse events. Um, we all acknowledge that we can find in the literature instances of reported injuries whether they be lacerations, um, extrusion, sodium hypochlorite, um, **** from hand piece laceration, death from over sedation. Published dental adverse events highlight the harms that can occur in the dental office and although we admit to their occurrence, they are difficult to detect. In response to several calls to action in our profession, a team of faculty from four US dental schools participated in collaboration of research on dental adverse events. Those, um, schools were Harvard School of Dental Medicine, the University of Texas, Houston, UC San Francisco and OHSU. Um, the Institute for Healthcare Improvement which is based in Cambridge, Massachusetts, has developed a strategy for employing political trigger tools so that we could find notations of adverse events in the electronic record. Dr. Carla Kent and I are from OHSU. Carla is a professor in the Department of Integrated Biosciences and she's the chief safety officer, um, and the director of quality improvement. I am a practicing general dentist in the Department of

Restorative Dentistry and an executive board member of the faculty dental practice. Carla first joined the research team in 2015 and then I joined it in 2016. So thank you for inviting us to present our research and in doing so we will hope to meet these objectives.

Next Speaker: So, I wanted to just, um, kind of acknowledge and explain that throughout this, um, research project we had an advisory board, um, that consisted of patient safety experts from medicine, um, as well as, um, experts in public health and in bio ****. Um, a number of dentists, um, uh, who have affiliations or associations with, um, uh, research or, or boards or foundations that, um, were concerned with patient safety. And so we really relied a lot upon the advice from this advisory board. We met with them every year and we brought to them questions that we had and they were really, um, important and instrumental in helping us define, um, harm and adverse events and, um, guiding us particularly from their expertise. Um, one of the, um, board members was Lucien **** and he was, um, one of the authors of the Seminole publication called, uh, To Err is Human. Um, that really kind of brought to light all of the, um, errors in medicine and advocated for, um, um, the, the medical community to really take action and, um, to, to, uh, deal with, um, the, the consequences of these errors and to try and prevent them. So, um, we really felt fortunate to have these experts guiding us and, um, in the end, um, uh, we often didn't agree on what an adverse event was. And, um, we, we did go to them and, and have them, uh, help us and, uh, sometimes they didn't agree either. So, it's not a simple, um, decision, um, most of the time. So our objectives today really are to, um, describe what we did, how we defined and identified and classified adverse events from the **** charts that we were able to trigger. Um, to give you some examples of the adverse events that we identified by our consensus process to discuss examples of quality of care events that we, um, found as we were reviewing charts, but determined that, uh, they were not adverse events. They were, um, possibly precursors to an adverse event, but not an adverse event. Um, and then, um, we'll talk about some of the challenges that we faced as we went along.

Next Speaker: Excuse me, Dr. Kent, um, would you two be okay with conversation as we go along or –

Next Speaker: Sure.

Next Speaker: – you rather hold **** –

Next Speaker: Absolutely.

Next Speaker: Okay.

Next Speaker: Please, please do, interrupt, yes.

Next Speaker: All right, thanks. We have 'till 11:30 then for this portion.

Next Speaker: So, as our guiding principle it is, above all do no harm and yet at the same time, even though it may be our intent to do best inevitably, because we are human and because we work in, you know, ****, uh, accidents or adverse events do happen. Um, so as we had mentioned, in dentistry there is not a lot of literature and that is the main thing which we are trying to contribute. Um, all of this data comes from different, um, institutions and even the data that will come out of your study, your pilot, will add to that. Dental schools are, fall under the Commission on Dental Accreditation and they outline that each school must conduct and maintain a formal system of measurable criteria for continuous quality improvement. **** certain that government agencies also do have their systems for maintaining quality improvement however, there's not a standardized list of criteria, forms or specific protocols for

capturing these events. Um, I'm sure that that's part of what the problem is in getting your pilot project going is trying to determine what, what is, what calibrated and what are these events.

Next Speaker: So, um, we wanted to first just define some of the terms that we're going to be, uh, using, um. One of the databases that we initially, um, searched to find examples of adverse events in dentistry was the, um, FDA database, the MOD database, um, which is the manufacturer and user facility device experience. Um, not only do manufacturers submit to, um, that database adverse events, um, but also, um, uh, practitioners can submit to that database and so, um, we, our, um, colleagues initially extracted from that database examples of adverse events and that was one of the first tools that we used to try to help us categorize and, um, get some specific examples. Um, Dr. McFarland already mentioned the, um, IHI Institute for Healthcare Improvement, um, that developed the strategy for employing, um, trigger tools and then, um, when we use the word trigger, what we mean is, um, ****, um, an opportunity or a clue that allows us to identify, um, an a, an adverse event in a patient record. So the trigger itself, um, is not the adverse event, but it's just something that allows us to, um, enrich our sample of patient records so that we can find more, uh, adverse events in those records. So, um, a number of organizations and institutions have different definitions of adverse events, but they're mostly similar. Um, Institute of Medicine, um, defines it an adverse event as an injury resulting from a medical intervention. Um, so it's not something that's due to the underlying, um, condition of the patient. The, um, 8HRQ, uh, which is, um, involved in healthcare research and quality, um, defines it as injury caused by medical care. The IHI as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization or if it results in death. And the FDA, um, describes it as undesirable experience associated with use of a medical product in a patient. So we started off by looking at all of the different definitions of adverse event that we could find and ultimately, um, working with our advisory board and with each other, **** we've narrowed it down to come up with our definition. But we started with the definitions that we found in medicine. Um, we also learned that some of the things that we might have originally thought were adverse events, **** were not considered adverse events. But often they were things that like caused or lead to an adverse event and these would include errors. So not all medical errors or dental errors, um, lead to an adverse event, particularly if they're caught before the, there's a consequence. Um, near misses, um, aren't adverse events, but they're good to identify because it can help, um, prevent an adverse event from happening in the future. Um, and then poor or unacceptable quality of care. That's kind of a hot topic and, um, it, again, it all depends upon whether that leads to the adverse event. So there may be something that's considered poor quality, um, may not be aesthetically pleasing, but, um, it hasn't actually harmed a patient. And then, of course, the natural course of disease is not considered an adverse event. So if a patient comes in, um, with a particular symptom, that's not the adverse event, that's just the disease that the patient is arriving with. And sometime there may even be treatment, um, and the patient may go home and experience something, um, that one might consider an adverse event or an unpleasant experience, but it may just be the natural course of the disease and not something that was caused by treatment. Yes?

Next Speaker: So, maybe you'll, maybe you'll cover this, but where does pain enter into this, um? And when is pain part of the course of treatment and when it's a, an adverse event?

Next Speaker: Right. Right, yeah. So we will talk about pain, uh, in particular. We will talk, we will talk about pain as we, as we go along. Um, we did not initially think about pain as an adverse event, but, um, we were finding a lot of examples of pain in our reviews and so we did determine in the end that pain was going to be one of the adverse events. And we spent a lot of time on it towards the end of the project.

Next Speaker: With, with the, uh, continuous quality improvement you mentioned with various organizations, do they typically just track the adverse events or are those three things, the errors, near misses and **** quality usually part of that, uh, measurement as well?

Next Speaker: Uh, are you asking about medicine or –

Next Speaker: Med - I guess **** for now, yeah.

Next Speaker: Um, yeah, there are more, um, examples I guess, of quality of care, um, being tracked in medicine than in dentistry. I mean, dentistry's still really in its infancy there, too. And that's something that we decided in the course of our research that may be a next step for, for that research, uh, because there really, um, aren't good definitions, um, in dentistry at this point. Um, there are lots of different, um, organizations that do focus on quality and sometimes quality refers to other sorts of measures, not necessarily something that happens during treatment or is related necessarily to treatment, but it may be some other kind of outcomes that show that you're, you know, seeing a certain number of patients who need certain kind of care and things like that. So, different kinds of quality ****. Um, but we will talk about some examples, um, that we did find in our, um, reviews that, um, we did consider quality of care issues and not adverse events.

Next Speaker: ****.

Next Speaker: Pain, incidentally, was one of the largest categories, um, that we had to search and it, it is a gray area, um, because we all know that in this profession there is a certain amount of pain that we sort of accept as part of the procedure. We looked at adverse events, pain adverse events, when there was protracted pain long beyond the time that we would expect, um, under like the natural course of the disease. That would include things like very deep caries which ended with ****. So a lot of those types of things were things that generated a lot of discussion.

Next Speaker: So, um, in the very beginning, some of the, um, colleagues searched the **** database that I mentioned and what they found, um, was that between, uh, 1996 and 2011, there were, um, 28,046 examples of, um, adverse events involving dental devices and that boiled down to about 1.4 percent of all the reports. Um, there were also reviews of case reports and literature, um, during that same time frame and, um, some of the examples of adverse events that were extracted included aspiration, edema due to sodium **** type chloride extrusion, sublingual thrombose vein due to a laceration from a hand piece and, um, also death. Um, so after reviewing those case reports and the MOD database, um, we determined that there really was a need to identify other adverse events that occurred in the dental setting, um, and nothing really had formally been, um, published before on the various categories, um, the severity or even, you know, um, other types of adverse events that, that might of heard that hadn't been reported probably because they weren't as severe as the ones that ultimately were reported in these case reports were reported to the, uh, FDA.

Next Speaker: So, for the purposes of our research, we had defined an adverse event as harm under the treatment within a certain time frame that's relevant to the clinical scenario. And so that's something that you will need to keep in mind for, um, defining harm or adverse events within your, uh, pilot study.

Next Speaker: So, um, after we reviewed, um, the examples of adverse events in the MOD database and in the literature, um, we needed to come up with, um, our own definition, uh, in order to proceed further with identifying adverse events in patient charts and so, um, we

worked with the advisory board and, um, just in doing some initial reviews of patient charts and pilot studies to, um, come with, come up with, um, a, a definition. And then we used these guidelines as we moved along to kind of help us remember what our definition was. I mean it's easy to forget and get distracted and, um, start identifying other things as adverse events such as causes or hazards or, um, um, errors that didn't lead to, um, an adverse event. So these are some of the guidelines that we came up with and, um, some of them, um, sound very informal but they really helped us, um, work with our, our charts and, and identify the adverse events. So, um, hazards or potential harms we decided are not adverse events. Um, errors, negligence, blame, accusations or malpractice are not adverse events. And we did not include omissions. So our, um, definition included commissions but not omissions. So, um, neglecting to provide treatment was not considered an adverse event. Um, quality of care issues in the absence of harm are not adverse events. And we determined that harm could be temporary or permanent, um, and that we would include moderate to severe harm as what we called it, level two, minimal to mild temporary or permanent harm as a level one. Um, and we'll talk about the severity, um, uh, ranking in just a minute. Um, we also **** that anything we called, um, a level two adverse event had to be totally defensible, um, with a group of our peers. And so, um, the term we kind of used over and over again was rock solid. Um, it meant that everybody would agree that this was an adverse event. Um, that, um, there wouldn't be any, um, dissent about, um, something that maybe happened so often in dentistry, but it's really considered, um, a part of, of dental treatment, um, and that might be a quality of care issue or it might be something that's just expected in terms of a level of pain. Um, and so anything that, um, kind of fell below that rock solid, totally defensible level two, um, might have been classified as a level one, sort of a, um, a milder version. Um, and we decided that it didn't matter if the adverse event or the treatment that caused the adverse event occurred in the dental office or if it had occurred at another dental office beforehand. And so, um, we basically said that if we found an adverse event in one of our patient charts, um, that was caused by treatment done at a, at another office, that we kind of inherited it and it became our adverse event. Um, repeated treatment attempts with poor prognosis we called heroic dentistry and determined that that was not an adverse event if there wasn't any harm caused by it. Um, so for example, if you repeatedly attempt to restore a tooth because the patient really, really wants to keep that tooth, um, and in the end the, the tooth has to be extracted, we did not consider that harm to the patient. Um, temporary loss of function in the absence of harm, um, was not considered an adverse event. Um, and that might be, um, loss of a, of a denture and, um, a patient can't, um, uh, chew or smile until that's replaced. Um, severely debilitated teeth from decay, restoration, um, root canal therapy that may fracture or fail, um, are not considered adverse events unless directly related to the treatment and, um, any kind of disease progression of a tooth, um, we decided, or determined, that that would not be considered an adverse event. So we used all of these guidelines. Um, each time we, we had discussions about adverse events and sometimes when we disagreed we'd come back to these guidelines and say, ah hah, you know, that's what this guideline is telling us and we have to stick to this and so we, we're not gonna consider this particular thing an adverse event because we think it's a hazard and not an adverse event, that sort of thing.

Next Speaker: So, we needed to define the types and the severity and what you see there are the 11 or 12 most commonly found, um, adverse events. And then we would read the chart and determine, um, which category it went into and then the severity of it and then you all were provided the severity tree which I believe is the next slide. So, of course, the initial question is, was there harm to the patient? And was that harm to be considered permanent or temporary? Um, for most procedures the harm is temporary, what, what people are commonly complaining about or what we see. Um, and so then in our severity tree, if it was mild, mild pain or mild temporary duration it would be, at level E1. Permanent harm fell into the category, or we classified it as G1 or G2 and those would be things like, um, damage

to hard tissue ****. Is then, it's hard to recover that bone loss. Those are the things, um, nerve injury that did not resolve. Those were all the things that fell into the permanent category. And then very few, thank goodness, were things that fell into the category of needing an emergency room or intervention to sustain life.

Next Speaker: So, we also had some guidelines that we used, um, when we were trying to, um, rank, um, severity, um, and so we used, um, an intensity scale from zero to 10. This is particularly, particularly useful when we're talking about pain. Um, duration, time period of harm, um, whether it's acute or chronic, whether it lasts, um, hours, days, or, or longer. Um, and then how often, um, this, um, harm occurred, um, over the time period. So if it was rare, sometimes, often, always, um, and, um, like I said, this, this was particularly u, useful in, um, determining the level of, of pain in many cases. So –

Next Speaker: Yeah, so, if you're curious how these are triggers, um, we searched the database for actual words in the chart. So, for example, um, under the diagnosis, if it said burn or cut or laceration or bleeding, those were all words that were searchable. We also used CBT codes, um, and that's how we found our implant problems because things had to be **** out or there was an ex-plant. We even used words like mucal peri, parasitis to catch the inflammation, um, so once you have a way or a list of terms, it is easier to take the charts, read them and find out whether or not something has occurred and then we would come to consensus when we would discuss this case. Was there actually a problem?

Next Speaker: Question.

Next Speaker: Yes.

Next Speaker: So earlier you said that, uh, omissions weren't part of this or was not adherence to proper technique.

Next Speaker: That's correct.

Next Speaker: Is that accurate? So – yeah. And so, for instance, if someone did not, who admitted that they place the rubber dam before they did endo, and then this aspiration occurred. That would not capture, that would not capture this in your chart review?

Next Speaker: Aspiration would be a positive. So it's not because of the rubber dam, it's the aspiration occurred.

Next Speaker: That would trigger it?

Next Speaker: Yes. Yes.

Next Speaker: Okay.

Next Speaker: Correct.

Next Speaker: Okay, so the event that triggers it, not the act of omission triggers it?

Next Speaker: Correct.

Next Speaker: Thank you.

Next Speaker: But that's not to say that you couldn't use, um, failure to use a rubber dam as a trigger if that was something that helped you, um, sort of enhance the number of charts that you could then review, uh, and then you would look for whether or not there was an aspiration that resulted because of that. Um, but the goal of the triggers really was to kind of enhance the number that, uh, were found in, um, in the database, um, really enrich it for the number that would have adverse events. So we were search, searching through hundreds and hundreds and hundreds of charts ****.

Next Speaker: To narrow it. Gotcha. ****.

Next Speaker: Now we started off with some additional triggers and over time we found that some just didn't perform very well. Very large number of charts that would be triggered without many adverse events in them and so sometimes we excluded those triggers or we might of combined some triggers together because they were **** the same kinds of charts over and over again.

Next Speaker: I think that in your question about the rubber dam, might fall more like in the quality of care. Um, so in ours, we were actually looking at where harm had already occurred. But it seems to me that, um, in doing like a study might be interested in what is the quality and so then you might elect to say, in how many instances is a rubber dam employed?

Next Speaker: So, I think **** clarify that. So, um, so what you're describing is a technique that you guys used with these other schools to help define this. But this is a moveable ****, a moveable target based on the, on the charts or the treatment you're looking at. Is that right?

Next Speaker: So, you could, you could define your triggers, you know, according to what you're looking for, for sure. I mean like you said, these – the triggers themselves aren't adverse events, but they were meant to really enrich the number of charts that we found, um, so that we were, we were looking for, um, we were finding more adverse events than having to search through all of the charts and just, or just doing a random chart, um, selection. So, um, some of the – one of the triggers that we ultimately excluded was multiple visits because we thought that, you know, if a patient had to come in for multiple visits that might indicate that there was a problem. Um, in the dental schools patients always come in for multiple visits. We try to get them in every week and so that turned out not to be a very good trigger for us.

Next Speaker: So, this isn't so much for you – oh – to look at that adverse counts. This, this slide here is so that you could sort of just see what the categories are, um, in terms of what had happened.

Next Speaker: Yeah, and, um, there are also some examples there, um, so, um, pain, um, obviously is, um, one of the categories that we, um, we found in a large number of adverse events. Um, and, um, infections, um, hard tissue damage, um, and then fewer and fewer in the subsequent categories. So nerve injury and then soft tissue injury, other orofacial complications which, um, could include something like a sinus perforation, um, or facial pain, um, and then allergy toxicity or foreign body response, um, common, uh, examples there would be something like a reaction to a medication or drug. Um, aspiration, ingestion of foreign bodies, um, those actually, um, in our, in our pilot, and that's what this chart is showing, the numbers that we found in our, our initial pilot study, um, that weren't really very high. I think in, um, a lot of, um, at least in dental schools, this would be something that one would get a report on anyway. Um, so we have unusual occurrence reports in school of dentistry and so when somebody aspirates or swallows something, we get a report on that and so, um, the

trigger didn't really help us find those. Um, we already knew about them anyway, but, um, it's there to help, uh, perhaps find some, some other examples that might not have been reported like maybe, um, a patient might of aspirated some impression material and coughed it out. And that might not of been necessarily reported to us. Um, some other, um, systemic complications, um, an example would be, um, vomiting, um, because of, uh, anesthesia. Um, wrong site, wrong procedure, wrong patient errors, um, we didn't find any in our, our pilot, but we did find some of those, um, uh, in the, the **** study. And then, um, bleeding and under harm, uh, were some of the other categories. We really didn't find many adverse events.

Next Speaker: Just one note too about the data that we have. We pulled, we searched the sites, uh, at all sites, just in the year 2015. So when you look at this and you say, oh, there's zero reported, it's just because of that window of time. 'Cause we all know that that does occur where somebody preps the wrong tooth or somebody extracts the wrong tooth. It was just within our data sample that we did not have that occurrence.

Next Speaker: So, um, we'll start off just with looking at, um, how we evaluated pain and then we'll look at some examples that we found. So um, we sent a scale, um, that if a patient reported that their pain was say between a level of 1 and 3 that that was, um, slight pain and that it not constitute harm. If it rose to the level of moderate, um, between 4 and 6, then that, um, rose to the level of a, uh, E1, and if it was described as 7 to 10 or severe pain or if a patient used other terms like it was throbbing and stabbing and keeping me up at night, things like that, then, um, that would be, um, considered severe pain or an E2.

Next Speaker: And is that only pain because of or after treatment?

Next Speaker: Right, yes. If the patient comes in with pain, then it's not an adverse event, and that's something that we talked about too, you know, if a patient comes in with pain, and um, you provide some kind of a treatment meant to alleviate that pain but it doesn't, is that an adverse event because they leave, um, and continue to have pain even though you provided some treatment. So that generated some discussion. Um, so we, we relied a little bit on the patient's description of the pain that they were having, um, and also determined that if, um, there wasn't a pain scale and the patient came in for an emergency dental visit, um, that that would, uh, be considered a adverse event, a Level E2. Um, if the patient called and asked for and received a prescription for, um, pain medication, that could, um, constitute, uh, an adverse event of Level E2. Um, dry sockets came up a lot, um, and um, we had to decide whether dry sockets were considered, um, an infection or not, um, um, and um, ultimately in the end we did determine that dry sockets in the absence of, um, infection were not considered infection, um, and, but often, um, um, we're, um, uh, **** adverse event, and so, um, dry sockets did become, um, an adverse event for us with, with regard to the pain. And then, of course, we also worried about, um, potential drug seekers who may have complained about pain, um, and that was something that we had to look at case by case and determine if there was real pain involved or if, um, there was really an attempt to try to get medication when there wasn't pain. So a couple of the examples here, um, we called, um, uh, E2s, so um, temporary harm that was, um, moderate to severe. Um, first case the patient had a root canal, um, and then reported pain lasting all day, um, after the root canal was started, um, and patient reported taking, um, five Advils a day, um, and said, you know, pain all the time. So there wasn't a pain scale, but because the patient said that, um, he felt pain all the time and it was lasting all day after, um, root canal therapy even started, um, that rose to the level of an E2. The next one, um, some primary teeth restored, uh, with amalgam. Um, a couple weeks later the patient came back in, um, an Urgent Care visit, um, complaining of pain, and um, had reported that the pain was constant throughout the last 2 weeks. Some medication made it feel better. Um, they removed fillings and did a first pulpotomy on one of the teeth and

temporary filling on the other and 2 weeks later the patient is still having pain. Um, after doing some, um, X-rays they found that, um, K had, uh, full communication, L had a radiolucency that was, um, in the inter radicular region, and so L was extracted and a pulpotomy was performed on, uh, I think **** around on K. So all of that, um, because of the, the ongoing pain, um, that rose to the level of a, of an E2. But then there's an example of, of an E1 level where the patient reported pain 4 days after the restoration of the tooth. Um, it was determined that tooth needed to be extracted, uh, due to some external **** it carries, um, but because the patient, um, reported pain and there was no real pain level described or other indicators that it was severe pain, um, that just rose to the level of an E1. Questions about that or about pain in general? So um, some of the guidelines that we used, um, for other orofacial harm included, um, any sinus-related issue and because we were looking, um, uh, at, um, failed implants, um, we often found some, um, sinus-related issues because of a sinus perforation. Um, but any kind of a sinus infection we determined would fall under that category, um, any kind of **** would fit in that category, um, but other kinds of inflammation, um, we determined, uh, would also fit into this category. So a couple of examples here, um, and these, the first one is where there was a failed implant, um, and um, a maxillary sinus communication, and so that was, um, a level of an E2. Um, the other one, um, this was where a pediatric patient, um, probably had a corneal scratch that might have happened during, um, surgery, um, and uh, ultimately, um, antibiotics were prescribed for the patient. Um, we called this an E1, but we went back and forth on this a number of times, um, at one point called it an E2 and then went back to calling it an E1, and so we have lots of discussion and argument sometimes, especially about pain. Um, so often things that, um, really didn't have, uh, uh, a good, um, um, pain scale to ramp it up to a, um, um, pain category, um, might have been, um, ramped down to sort of an E1. In this case it was actually the corneal scratch that was, um, the other orofacial harm and, um, it was, um, resolved and antibiotics were prescribed so ultimately **** an E1. Sometimes I think we could have been convinced to go the other way. It just depended on, um, how, uh, opinionated some of the, um, other, uh, investigators were when we had our conference calls to come to consensus.

Next Speaker: So if this was an injury that didn't result in pain even though you're looking at pain, this would not rise to the level of an **** like if it was a, for instance, a damage to adjacent tooth or some kind of other injury that's not noticeable to the patient, or in this case the parent, this would not apply to your guys' criteria.

Next Speaker: Well, it would have fallen under the category of, um, damage to the adjacent tooth, right? So even though there was no pain, there was still harm if, if it was in the notation that there was damage to an adjacent tooth. So those, so that is considered a harm. We did consider that a harm.

Next Speaker: Okay, thank you. I just was not clear on that if it was a high versus some **** structure if that was a thing.

Next Speaker: Ah.

Next Speaker: Gotcha.

Next Speaker: Yeah. In that particular example it was because the chart read that the mother brought the child in the next day and there was a complaint, so we had to look at that and see that, uh, this was something that was, that happened in tandem, you know, during the procedure so we were, we were looking at that as it would not have happened had this child not been under anesthesia. It did happen. It was considered temporary in nature.

Next Speaker: So um, per our infection guidelines, um, um, sinus infection would, um, be included here. Um, we said that with infection there would be swelling and fever, malaise, um, and that any infection with fluctuant swelling, um, that may indicate, uh, I and D, that would rise to the level of an E2, um, but inflammation would be categorized under, um, soft tissue injury or inflammation, um, category not as an infection. So a couple of examples here, um, uh, with, um, an implant being placed and infection and pus, one of our key words, noticed afterwards, um, that rose to the level of an E2. Um, antibiotics were prescribed and ultimately, um, healing was observed. Um, the next one, um, there were lots of key words there, um, that, that led us to call this an infection, including, um, cellulitis that occurred, um, after, um, uh – well actually, this was, okay, so let me back up a little bit here. Um, the patient came in with, um, a sublingual abscess buccal cellulitis. Uh, a simple extraction was performed I and D, um, **** expressed and a prescription was given, um, but later patient, um, reported nausea and possible spread of the infection, uh, to the mandibular region, um, and so, um, there was probably still an abscess left behind that needed to, um, be drained, and the patient was referred for a CT scan, so um, that rose to the level of an E2. Um, so the patient came in with an infection, um, was treated and then, um, still had an infection. So the other, um, systemic hard guidelines that we, um, developed, uh, included, um, uh, just defining what is systemic harm, anaphylactic shock, um, an asthma attack, an anxiety attack or fainting, um, diabetic episode, trip-fall, bumping the head, um, death, uh, transfer to the medical emergency room without a specific diagnosis, um, although we also said that a patient fainting is not necessarily an adverse event, so it depends upon the condition that the patient arrived in and whether some treatment was performed that might have led to that, um, fainting. So a couple of examples here, um, um, there's one case where a patient had undergone extractions under general anesthesia, um, and later the patient's mother called to report that, um, the patient's right arm was slightly swollen, the face was swollen, um, she thought she heard some wheezing, the patient had vomited, um, and so there was concern that there might have been an allergic reaction to the medication and some, um, dehydration, so the patient was asked to go to the emergency department. So this rose to the level of an E2. Um, whereas the next one, um, patient had a nasal reconstruction and a graft. Um, at the post-op visit the patient complained that she had nausea, vomiting and diarrhea for 24 hours and felt that it was the antibiotics. That we call just a, uh, an E1 because, um, the patient didn't have to go to the emergency room, it wasn't any, um, uh, dehydration or, um, other problems associated with, uh, um, a reaction.

Next Speaker: So under hard tissue, which is something, um, that we can see visibly, um, our triggers here included, as I had mentioned earlier, if we found in the charts that an implant had to be removed, um, perforations. Um, any damage to bone or hard tissue that was triggered in the search words or in the codes is where we began to look at it, and these are just some of the definitions or guidelines that we use that if a patient for example had, um, experienced bone loss after the incident had already osseo integrated, then we needed to look into what were the causes of that, so that could go either way in terms of, um, whether or not there was harm to the patient. Um, so something where it is considered permanent and of, um –

Next Speaker: ****.

Next Speaker: – moderate to severe, um, is an example of **** perforation that takes place during pulpectomy. Those are all things that we would say yes, most definitely, um, there is a permanent harm that is going on and the tooth will need to be extracted. Um, in the mild to moderate an example is, um, the perforation of the tooth without anesthetic, the patient moves and the adjacent tooth or the tooth itself was right there so removal of more tooth structure, those can be repaired but there would still be original damage.

Next Speaker: I have a question about that. Um, even in the case of a patient that didn't want anesthetic and the dentist said well, I can **** without anesthetic as long as he sits still and **** and then the patient jerks, is that, is that the dentist's fault or?

Next Speaker: So one of the things that we had agreed on is that this was, um, harm occurred. We were not necessarily assigning blame. Um, the fact of the matter is is that the patient did move and extra tooth, in this example, extra tooth structure was removed, so that is a harm but we are not ascribing a blame. Um, for soft tissue injury guidelines, um, any injury to the lips, tongue, oral mucosa, gingiva, that generally happens with the burrs, with blades, all of those, and we categorize those usually temporary. I don't know of any examples where we had permanent soft tissue injuries. Um, something that we went, or here, denture sores and discomfort are not considered adverse events during the normal adaptation period, and for example at OHSU, um, our normal accepted adaptation period is 8 months. So we understand that we might be adjusting dentures that maybe a patient would have some sort of sore spots, and so we did not consider those, um, to be adverse events. But in another conversation where a denture is, um, fabricated and the phalanges are too long and the patient then gets quite a few sore spots, we can consider that under quality of care. Um, under intraoral inflammation we consider that soft tissue injury when we looked at the chart and we determined, um, the magnitude and the proportionality of it, like is this redness a sequela of a resolving infection or is this a problem that we, that was a result of some treatment. So some examples here that are of, um, temporary but moderate to severe, um, moderate to severe level is, for this example, **** flap surgery was completed and the patient lost, the sutures came out and the patient had a lot of tenderness, and so then when it was, uh, examined there was actually an exposure of connected tissue and then there was bone that was exposed, so of course the patient felt quite a bit of pain there and some necrosis had ensued. And so when the X-rays were taken, we saw that there was bone loss that had occurred, so that would have been considered more along the moderate to severe. Um, in the bottom example the removal of a crown, um, in which the buccal mucosa gets lacerated, and even though you are able to control it and it will resolve, we consider that to be, um, moderate to severe, um, temporary injury.

Next Speaker: I have a question.

Next Speaker: Yes.

Next Speaker: ****. You mentioned with the dentures and the phalanges being too long and that creates let's say ulcers and pain, and you mentioned that was a quality of care issue.

Next Speaker: Right. It could be a quality of care issue.

Next Speaker: It could be, and that would be, the quality of care issue would be the trigger or something you're targeting that in a chart for example, but is that, the ulcers are the adverse, adverse event? Am I correct or is that then because it's a quality of care, for quality of care, it's not considered – I think I'm getting confused in some regards.

Next Speaker: So it is adverse from the patient's probably perspective because they are suffering some sort of pain.

Next Speaker: Mm hmm.

Next Speaker: Um, and what we looked at in the charts was was there something that permanently harmed the patient. No. The causative agent was poor quality, and I think in a case like that what had, where we had gotten the trigger could've been from the word sore spot or ulcers, which is how we set the trigger, or it could have been from multiple visits. Did I answer your question?

Next Speaker: Yes. So then it wasn't considered. You kind of then looked at it and said that's not **** focus then because it was poor quality of care. Am I correct?

Next Speaker: We did, yes, in cases like that we considered, um, sore spots or ulcerations from a, from a long denture as a quality of care issue, not that it was a true adverse event.

Next Speaker: So nicking the gingiva with a burr because you're right there at the gingiva margin and you're removing that crown, that's not poor quality of care, that was an adverse event?

Next Speaker: That was an adverse event.

Next Speaker: Thank you.

Next Speaker: I think, um, with regard to the denture issue, um, when it's part of the normal adaptation process we didn't consider it an adverse event, but if it had been caused by, um, something that was related to the quality of the denture, um, and there was, um, ulcerations or something really caused by that, then that poor quality, the denture, would have led to an adverse event, so there would be both. But when it was sort of the norm, this is where it comes back to our, you know, when a group of our peers agree that this is an adverse event, you know, is this a rock solid adverse event or is this just what normally happens when you get a denture and you have to have, um, some adjustments done until it's, it's **** in your, your gingiva adapted to it. But yeah, if you, if you, um, had an ulcer caused by some other kind of dental treatment, um, and that's not a normal part of that treatment then it would, would have risen to a level of an adverse event right away.

Next Speaker: So paresthesia, paresthesia that occurs, um, is generally considered, um, as a nerve injury, um, nerve injury that is protracted, um, so between 6, 6 weeks to 6 months we consider that to be moderate to severe, temporary, um, E2, and if it was more than 6 months then we considered it to be permanent, um, although it could be G1 or G2 depending on the length or depending on the, um, disability that occurred. Nerve injury with paresthesia or dysesthesia lasting less than 6 weeks was categorized as an E2, and permanent or severe paresthesia or dysesthesia was considered G2, permanent, um, moderate to severe. And then in this example, um, from, for temporary nerve injury, um, for example Tooth No. 18 was determined to be non-restorable and was extracted, but then during the follow-up visit the patient complained of numbness and tingling to the lower lip region and posterior left mandible, and at the second follow-up visit the patient reported occasional aching sensation to the lower lip. So that was determined to be something like, um, to be paresthesia but that would resolve, it was an E2. But under the permanent G2, um, if a patient had **** paresthesia or dysesthesia that lasted a year or over a year and then needed additional procedures like a bone graft, then, um, it was G2.

Next Speaker: So bleeding we didn't really have a lot of guidelines. We just had to, um, note that, um, any, any, um, thing categorized in the bleeding category would include an **** or, or, **** bleeding. And then a couple of examples here, um, first one, well actually, both

were just E1s, um, because we determined that, um, they really didn't rise to the level of moderate to severe. Um, there was some bleeding after extraction. Uh, when the patient came back in there was, um, a diagnosis of torn gingival tissue and, um, active, uh, oozing of blood, and then, um, second one, um, there, the patient had had a tissue graft and a few days later came back in with bleeding. Um, the patient reported that, um, they had gone to the ER prior to coming in for their visit, um, and um, then came, um, to the, to the school for the visit. Um, they were, um, shown to have a disruptive blood clot on the palatal tissue ****. Um, they applied pressure, and um, the bleeding was stopped. And so these were all considered to be mild, um, examples of, of bleeding because it was ultimately, um, controlled and, um, no, no permanent harm or even severe harm was done. One example here of the, um, algae toxicity foreign body response, so we really didn't have any guidelines to help us with this that we came up with. Um, we didn't see many of these examples in our reviews, um, and this particular case, um, the patient seemed to have had, um, a reaction, um, waking up, um, feeling itchy and being bright red, and um, thought that, um, they were probably allergic to, um, medications. So they were just advised to take over-the-counter antihistamine and, um, um, ultimately, um, the patient, um, got another prescription for a different antibiotic. So that was, that rose to the level of an E2 because of the patient's reaction. Um, for the aspiration, um, and/or ingestion of a foreign body, um, the first one we called an F because the patient was actually transferred to the emergency department for, um, X-rays, and so according to our severity tree, um, any time a patient was transferred to the emergency department, um, it rose to the level of an F. I think if the patient hadn't been rushed to the emergency department, we probably would have called it an E2, um, because, um, they did swallow, um, something while they were in the chair, and um, although there were, weren't any consequences, um, the fact that they swallowed the item while they were in the chair, um, we considered it an adverse event. Um, what we did not consider an adverse event, um, in this category was when a patient swallowed something at home or they weren't in the dental office, um, often because there really wasn't any proof that they swallowed something. Sometimes they just thought they swallowed it, sometimes it just disappeared, um, and so without any, um, additional information as to, you know, whether or not this item was really swallowed, um, we did not consider these adverse events. So overall – oops. Overall, um, in the end what we found, um, in the final review of charts was that 16.2 percent of them contained an adverse event. Now, keep in mind that these are not all of our charts, right? These are just the ones that were, um, extracted with the triggers, and so they were supposedly the enriched, um, for, um, adverse events to begin with. Now, those common types that we identified were pain, uh, hard tissue damage, soft tissue injury and nerve injuries, um, and the severities, um, were by and large temporary. Um, 89 percent were temporary, only, uh, 10 percent were permanent, and then, uh, just 1.2 percent involved having to go to an emergency room.

Next Speaker: So identifying the harm, which is something that is, can be a challenge to agree on just as we've sort of seen here, um, it's sometimes questionable is that harm or is that quality of care. But identifying it is the first step, and then calibrating the evaluators is the next step. Um, so we had to develop the specific triggers in order to be able to extract the information out of the charts, and from that we had to then go through additional review and come to consensus, which is always also a challenge because everybody is going to have a different idea. But I think that once the definitions and terms are established, the timeframes that are established, um, you are on your way to determining whether or not an adverse event occurred.

Next Speaker: Can I ask you a question?

Next Speaker: Sure.

Next Speaker: Um, okay, so yeah, you had mentioned earlier in the presentation that the adverse events would be coded as such regardless of if they happen in the practice or out, out, outside. So you mentioned a moment ago that there is an exception to swallowing of, you know whatever it is that's been swallowed. So how, how do you account for when there was a, say an exception to the general principle when coding something? Was that like documented in some sort of manual and how did you communicate that to the reviewers, 'cause that might be helpful to us as we, you know, try to come to a consensus around coding procedures.

Next Speaker: Yeah, so it really required looking back, um, in the patient's chart, and sometimes just what the patient reported. So if a patient for example had, um, an implant placed, um, at an outside office and then came, came into the dental school, um, with peri implantitis. Um, depending upon the timeframe, if that implant was placed, you know, just within the last year, then we'd consider that an adverse event and we own it. Um, but um, the example where the patient may have swallowed a crown at home, um, we didn't call an adverse event because a) we couldn't be sure that they really swallowed it, and if they weren't sent for an X-ray to confirm that then we had no way of knowing if that really happened.

Next Speaker: So I was even wondering if like when you make those snap decisions with the coding, how do you document it that you shared that with the **** committee a calibration meeting or –

Next Speaker: Yes.

Next Speaker: Yeah. So um, we would each, uh, at each institution two of us would review the charts and look at the complaint and we would decide what category the adverse event fell into, what severity it was, and then, um, we would get together, so Dr. McFarland and I would get together, we independently review the charts and, um, try to come to some agreement as to whether thought it was an adverse event or not and what category, what, what level of severity, um, and then we would submit that consensus to the larger group. And um, all the different institutions were doing the same thing, and so we would then have kind of a group consensus conference, usually on the phone or sometimes in face-to-face meetings we would, um, uh, individually then rank the, um, adverse events or the examples of **** for adverse events. And so it was kind of just, you know, a process that involved several steps, and if we couldn't come to an agreement sometimes we had to do it over again, um, and sometimes after meeting with our advisory committee we would change our definitions, and um, have to rereview charts. And so we really relied on a summary that, um, each individual would write when they do the chart notes as well as **** since we had spreadsheets, and all that information got plugged into these spreadsheets, and so we did share all of that information. Sometimes it was just what the patient reported, right? There might not have been any records that came with them from another ****. The fact that they reported that they were treated at another dental office was sufficient, so those notes would have been entered into our spreadsheet that we had shared with everybody.

Next Speaker: Thank you.

Next Speaker: Thanks for all this. Um, it's 11:25 now and we'll take a break after this section, but I think we're fine going to 11:40 if we need to for discussion, so I especially encourage discussion among the 100 advisory committee 'cause this has been a topic of discussion in the past. So any questions?

Next Speaker: Hi. So –

Next Speaker: I don't think that side works ****.

Next Speaker: What's interesting about the adverse event types, they're all objective except pain, which is subjective. So I'm curious how your conversation with the committee has been able to come up with some sort of parameters to include pain as an adverse event, particularly when we know that some providers prescribe opioids way more than others.

Next Speaker: So yes, pain actually ended up being one of the grayest areas because it's what the patient reports plus the doctor's judgment as to whether or not this, you know, is expected or not expected or whether this is drug-seeking behavior. Um, pain was one of the hardest ones where, where the committee would have to come together and keep discussing it until we came to some consensus as to whether or not this protracted pain was, was a result of the treatment or whether, whether it was attributed to something else. Like so an exam, for example, the cases where we pulled up in the charts that there were multiple prescriptions, we had to look at that to see what was the procedure done, does this seem right that this amount of medication would be prescribed for the procedure that was done. Um, there is right now, we are still working on a **** for pain as an adverse event, um, but it is very difficult because you can't say to a patient who is reporting pain that oh no, this doesn't ****, this is one of those things where you treat to the best of your ability, but in some cases patients will be reporting things that we don't have an answer for.

Next Speaker: Okay, thank you.

Next Speaker: Mm hmm.

Next Speaker: And Rose, can I just ask you, in your results, uh, the slide shows that 16.2 percent of files reviewed contained an adverse event and then you listed pain, hard tissue, soft tissue, nerve injuries, and then, but there's no kind of percentage. This review, I was just wondering if **** for the severity was pain the most frequent of those 16.2 percent or was it nerve injuries? I mean, how was that, uh –

Next Speaker: So yeah, the order listed there is, um, the order that, uh, we found them in, um, so pain did constitute the most common type. Um, we do have numbers. Um, that particular paper hasn't been published yet, but um, it will have numbers with it. Who was it?

Next Speaker: Anne and also Eli. It's, it's expected that pain because that is the one thing patients actually present. It's pain and this and pain and that, um, so it would come up the most.

Next Speaker: Uh, how many charts did you initially draw to get to your **** and so we continue to **** what was the original that you narrowed that down from?

Next Speaker: Wasn't it twice that?

Next Speaker: And so yeah, at least twice that because, um, our triggers pulled up many more charts than we ultimately reviewed. We reviewed just a percentage of the charts that were pulled up each time because sometimes they pulled up 3, 400 charts and we couldn't review them all. So there was a, um, a process for, um, that was sort of, um, among all the different institutions to review a certain percentage of the, of the charts that were triggered.

Next Speaker: And I just wanna make a clarification **** you'll all understand that, um, that 16.2 percent of charts reviewed is not a rate of adverse events in a population. It's just the number of charts that are reviewed after being triggered with a potential for pain.

Next Speaker: That's correct.

Next Speaker: So it's the actual rate was, was unknown but would be much, much lower.

Next Speaker: Much lower, yeah. So this is actually showing us that our triggers were good.

Next Speaker: Well, you did show in the beginning that 1.24 percent of, uh, was exclusive, uh, the database, the FDA database where – but I wasn't sure whether that was on all, um, uh, adverse events or, or it was only the dental ones or?

Next Speaker: No, so from the mod database that was something like 1.4 percent of all reports to the mod database, all medical devices, um, uh, including things unrelated to dentistry, so dentistry constituted 1.4 percent of those. A lotta that was, you know, Polident, Poligrip, **** adhesives.

Next Speaker: So it seems to me that discussion of adverse events is an emotional one for patients and for reviewers, so I find the definition in this flow chart to be very helpful to remind the reviewer kind of what's an adverse event versus not and what the classifications are. I'm wondering if you can, excuse me, comment on the use of the, um, both of you coming to a consensus and then having everyone on the committee come to a consensus as a way to make sure that you have reliable data and decision making around what kind of a adverse event you're looking at, or whether you're looking at one or not.

Next Speaker: **** I'm not sure I understood the question. Sorry.

Next Speaker: So, I, I'm, I'm concerned about bias being introduced into the decision making about adverse events or not so I'm wondering if you feel that you two coming to a consensus and then, the rest of the committee coming to a consensus is a helpful step to validate the, the data about what type of adverse event you have.

Next Speaker: Yeah, um, it was really helpful, um, and sometimes people had very strong opinions and, um, have to say the oral surgeons had very strong opinions and so, um, you know, one of the examples, I guess, that, that comes up for me a lot is with regard to, um, uh, implants and peri implantitis. We initially, um, thought very differently about, um, peri implantitis and, um, one of the, um, oral surgeons that was on the, the team, um, had us completely convert towards the end, um, um, because his point was, you know, you put the implant in, so anything that then is a consequence is an adverse event, whether it's peri implantitis that ultimately goes away or if it's, um, ,that the implant falls out and so once you put a hole in that bone, you have done something permanent to the tissue and, um, regardless of what happens next, it rises to the level of an adverse event and so I think that was hard for a lot of people to accept, um, so there were lots of examples like that, where, um, somebody with a, with a very strong opinion was able to convince everybody else. Um, –

Next Speaker: So you feel that discussion that you had was a really valuable ****.

Next Speaker: It was very valuable, yeah. It was very valuable and, like I said, we went back and forth sometimes, um, from the beginning of the study to the end of the study, um,

changing our minds about what rose to the level of an E1 or an E2 or a G1 or a G2, um, and some people had expertise in certain areas and, uh, it was really valuable to, to hear from them and then, also taking, um, things that we couldn't agree on to the advisory board and having them help us sort of think clearly about it, um, so it really depended upon, you know, the, the local consensus, the bigger group consensus, a lot of arguing and discussing and then, uh, when we couldn't decide or come to a consensus, going to the advisory board. Um, some things, you know, we only had 75 percent agreement on. We didn't always get a hundred percent.

Next Speaker: Okay. Thank you.

Next Speaker: Uh, uh, Rose, I have a question that I'm not through, sure whether anybody can answer it but I noticed that there were a couple –

Next Speaker: Mm hmm.

Next Speaker: – of people from the dental board here but what, what I, my observation is that what we are discussing at the moment really has nothing to do with the pilot project. It's really about adverse events in dentistry and all the studies that had existed or have been done until now, are done on dentists. Um, that means that the dental board, assumingly, would have, um, a high ****, a high level of experience in terms of, um, uh, assessing adverse events, uh, versus harms, versus malpractice, versus this and that and the other and I'm curious as to whether existing guidelines in the dental board – I assume that there are guidelines in the dental board, uh, when they are, when, uh, when, uh, assessing these things – um, uh, whether they are congruent with the stuff that we've heard today. I mean, uh, the, this is obviously a research project, uh, but, but the, a research project that has developed, uh, guidelines about very, uh, sort of, uh, or at least attempting to be very consistent and then getting, getting a high level of reliability and validity and I'm just wondering if there is a comparable set of guidelines in the dental board, um, uh, in relation to, uh, to the dental, uh, dental board.

Next Speaker: Well, luckily, we have Dr. Blickenstaff here so I would like to hear from you next bit, Eli, the, the relationship to the pilot projects is that the board doesn't oversee these pilot projects or practitioners, it's, it's our committee and the OHA's ultimate responsibility so that's where the question of was it harm or not has come up in reviewing the charts.

Next Speaker: Oh, but I, I, obviously, I'm aware of that, uh, but, uh, but what I was kind of, uh, the way I was trying to go was, you know, it would be un, unusual for OHA, let's say, to come up with a level of definitions, uh, uh, that would be totally, I mean, different from what is sort of general practice in the dental, uh, fields today, right? So and I assume that that's why we are having this discussion, I mean, uh, to try and see if we were able to, to establish a level playing field, where everybody kind of gets assessed in the same way and from the same kind of criteria so that was really why I was, uh, I was curious.

Next Speaker: Okay, thanks and I, I think the first thing we found was that there isn't a lot of work, uh, being done on this anyway. That's why we, uh, had this presentation from these two today so do you have any comments, Dan?

Next Speaker: The board really does not have, uh, a set of guidelines, other than the Dental Practice Act, which is bare, basically, minimally competency and so each case is looked at individually and, um, I, that's the best I can tell you right now.

Next Speaker: I'd like to comment on that.

Next Speaker: Uh, excuse me, one, one comment to that – sorry Brandon – um, and that's why we're trying to get to some kind of evidence-based, um, um, base **** here, I think.

Next Speaker: So the dentistry is practice in a lot of different way, I think everyone around this table knows that and the, uh, in my experience with the board, the, the rules are written, um, in a minimally competent way just so that you have latitude to treat the patient in front of you; however, um, when, when error occurs, I would say 75 to 80 percent of the time, the board unanimously votes that no, uh, there was no harm was done in terms of omission or extra work done needlessly. That said, when it's, when there has been a, a vote to, to reprimand, uh, that will hold up in court, 'cause that's the, that's the definition that ultimately is, uh, required, then it's always, I would say 98 percent unanimous decision when it comes to the people at group, as you kind of agreed, that, that, that, the definition of harm has occurred, based on either the action or reaction, so that's how the, that works that out in different ****.

Next Speaker: So any final comments on, on how this all applies to our pilot project or our chart reviews? That, that was our, our main intent here to get back to.

Next Speaker: Yeah, we can talk more about this in, in the afternoon. We'll still, we'll be ****.

Next Speaker: And it may be that you're all just getting that break. So thank, thank you very much. This, this was a great presentation ****. **** let, let's do take a break but let's try to keep it to 5 minutes and we'll catch up from there.

Next Speaker: How are you? It's nice to see you.

Next Speaker: Yeah, thank you. You too.

Next Speaker: **** time for –

Next Speaker: I think so ****.

Next Speaker: **** time for *****?

Next Speaker: I did. In a ****.

Next Speaker: **** threshold of consensus is and we'll talk more about that amongst people who are reviewers this afternoon. Um, and now, we have some updates from the project.

Next Speaker: So pilot project 100 submitted a modification, um, to add nit – wait **** - um, to add nitrous oxide to our practice ****. The reason why we did this is, um, we received feedback from OHA advising members had expressed interest in our DHATs, um, administer nitrous oxide, um, to patients. Um, presently DHAT trainees are not allowed to administer or treat patients for nitrous oxide. Um, at both CT **** there is a need to manage patients who may have dental anxiety. Obviously, **** help and see a lot of patients who have mental illness or ***** trauma. The current state guidelines are Arizona, Minnesota and Vermont all have nitrous oxide as part of their dental care practice ****. So as part of our modifications, um, we requested that our trainees complete a training course of at least 14 hours of instruction in the use of nitrous oxide from a dental school or dental hygiene program in

accordance with the nitrous oxide ****. The trainees must submit a completed nitrous oxide application to the work and health **** dental director and the supervising dentist must also, um, hold a valid nitrous oxide, um, **** administered from it and, um, we request that the nitrous oxide only be permitted under indirect supervision and upon approval by OHA, the DHATs may begin administering nitrous oxide or working on patients who are on nitrous oxide administered by a **** and then, um, the patients will sign a DHAT treatment consent and a nitrous oxide form, consent form at each visit. And that's our modification request.

Next Speaker: Any other updates on how the projects going, –

Next Speaker: And also, uh, –

Next Speaker: – anything like that?

Next Speaker: – and also, um, **** has actually completed the OHS You Tube **** course, um, this past Saturday and Sunday.

Next Speaker: Yeah, any questions, comments on the nitrous oxide modification request?

Next Speaker: I have some comments. Um, the OARU referenced the O004, uh, sorry, it turns off every 5 seconds – um, the 0260040, that ru, rule references the, um, training and hours described for licensed dentists to perform nitrous oxide, um, kind of in, um, uh, in kinda context here, the, the board grants a, a licensed dentist to prescribe, uh, exalytics without additional permits, based on the existing treatment, um, for education ****. Um, so kind of asking or asking to be, uh, or –

Next Speaker: ****.

Next Speaker: – is that better?

Next Speaker: Yeah.

Next Speaker: Yep.

Next Speaker: Thank you.

Next Speaker: That's better.

Next Speaker: So in, so in a sense, we're asking some, we're asking to view a series of training, um, but the prerequisites are wildly different. Dental school or **** school for that matter, so my recommendations for the OHA to consider, um, what would bridge that gap between what physiology, airway management, obstructive airway, um, all the different, um, uh, diseases, uh, you have acute otitis media, um, all the different things that go into that to decide whether that's a acceptable, um, uh, ****, uh, up to and including additional airway management courses. Um, in addition, that there is also a series that's not listed on these applications that is, includes a, um, uh, **** wide enough to have, um, a structure come in and out of, um, suction that is also, uh, uh, workable in a power outage, lighting system that's in, in addition to a power outage. All these things that aren't listed on the application but is implied both the O, OAR that's not listed here, so, um, based on the misadventures of sedation –

Next Speaker: It's, it's ****.

Next Speaker: – that's happened in, in this region, I think it's worthwhile for the OHA to consider additional, um, measure to, before they grant nitrous oxide. Um, one of the things that the board is, the board has, um, uh, looked at recently, is that a fair number of the population, um, particularly ones that are vulnerable, um, have a baseline, um, anti-anxiety medications, which then, would by definition, throw them into **** sedation and I don't think anyone here really thinks DHAT should be providing minimal sedation. This is a complicated question, not just a simple one, that requires a **** and I think there should be some discussion.

Next Speaker: Yeah, thank you and just as a reminder, this, this issue came up in the first place because a request from the advisory committee about, uh, why aren't the DHATs doing nitrous so that, we, we will look at those points but that is where the **** came from. Any comments on that?

Next Speaker: I mean, we are going to leave it up to OHA and then we can have a more ongoing discussion, um, if additional courses are needed to amend our modification. I mean, and our DHATs do take continuing edocua, education courses as well so you would have to add some **** courses. I mean, that's acceptable too but we try to, um, make this application similar to what the current state requirements are.

Next Speaker: For DHATs in other states.

Next Speaker: For DHATs, exactly.

Next Speaker: Some of those states are, we're referencing hygienists who are also DHATs. For instance, Arizona.

Next Speaker: Yes.

Next Speaker: It's not apples to apples.

Next Speaker: And, um, this'll all be addressed in the feedback survey we send out too, so we, we won't be making a decision ****.

Next Speaker: Can I ask a question? Since you're, uh, um, would you comment on the – is that better? – um, on the, uh, decreased number of irreversible operative procedures? Looks like 80 percent, it looks like, ****?

Next Speaker: Yes. Um, I actually was in a practice, I was hired last May and I had months to write the standard operating procedures manual and do it in **** meeting so, um, it was decided that, that Nora, uh, the DHAT wouldn't be completing any irreversible procedures until I had implemented the SOP and it was understood **** so the SOP, everything that I taught them was implemented starting September 24th.

Next Speaker: ****.

Next Speaker: Yeah, we just, the clinics need enough time, right, to read through the manual and to ask me any follow-up questions as well.

Next Speaker: All right, we're on schedule or even ahead of schedule so any other conversation, discussion? We'll still have the com, comment period, um, coming up before we, we take a break, we can leave, uh, or, uh, adjourn. Yeah.

Next Speaker: Um, I just wanted to introduce Dr. Hogan.

Next Speaker: Okay.

Next Speaker: Hi there. Um, thank you for letting me come and, and visit. Um, I, um, and not a polished speaker, um, and I have my hair in my Doc McStuffins, um, um, doo, is what my, my patients say, um, mostly because I was up at about 2:30 to catch my, **** o'clock flight to get here so if I'm a little, you know, even less than polished, that's why, um, but I'm definitely more of a clinician but, um, in my clinic, we had, um, a dental health aide therapist for going on 3 years now, um, and, so I am part of the advisory, um, committee to this project, um, and I will speak a little bit to my background there. Um, to note, about the nitrous, I believe probably NARA set up those, the rooms are set up so that you can get, um, a gurney in there and they have, they must follow, if they're using nitrous already, so I would say that that's pretty safe and I would also guess that most of those are gonna be kids that they're gonna be using nitrous on, that probably won't be using, on other medications. Um, so these guys prepared my, um, incredible PowerPoint so let's see how exciting it is. Um, let me just give you a little bit of background. So I, I said that I'd been supervising, um, a dental therapist for 3 years now. Um, we have two students that are up in Alaska that will return, um, in June 2019 and, um, it's a little bit different in Washington State and the fact that, um, we don't have a pilot project so as a sovereign nation, ****, um, there were really no regulations. We said we were gonna do this. We're not gonna wait for a legislator to do that and so, um, we did that but we needed to create our own licensing board and so that was a big, um, that was a, that was a big endeavor. We followed CHAP, um, we, um, adapted and adopted those procedures. Um, in addition to that, um, I've been a long-standing member of our dental association. Um, um, prior to being ****, I was at Seamar Community Health Center, which is, um, one of the largest **** health center, centers in western Washington, um, and I, um, have always been extremely active in my dental association. Um, even as a student, I was president of that, um, and so I am very cautious about the controversy over dental therapy but that being said, once I got to the tribe and I saw, um, the dramatic, um, **** what was going on in Alaska could also be, um, replicated down, um, in our community, um, I fully supported that. It also helped that I was able to visit Alaska multiple times and really see the students and their education, um, and talked a lot about their supervising dentists. Um, so I guess that's what I bring, um, to this, uh, advisory committee, is my experience, my experience, also, implementing a dental therapist into our funding. Um, so this is really our purpose is, um, to act as ****, um, using our experience and our expertise, um, on clinical procedure protocols, calibrating, um, different types of supervising dentists, data flexion and use, pol, policies that impact pilot success, um, modifications and overall project implementation. Um, you know, now, um, we can have dental therapists on tribal lands, after we had, um, Daniel Kennedy there for the first year. During that first year, we had a number of legislators come visit, um, a lot of, um, press releases went out. Um, we had a ton of visitors and this was actually one of the first bills that was passed in 20, it was, it was the first bill that was passed, um, in 2017, um, unanimously in the Senate and with a very, very large majority, um, in our House, so, um, I don't know where I was going with that, sorry, that's the early morning ****. Um, we, um, have a number of members and we all, um, bring something different to the advisory committee. Mine is really on the grounds clinical, um, through the, um, the formulation of our licensing board, um – oh, I think that is where I was going was to talk about, um, really calibrating, um, and setting guidelines. Um, one of the things that we have done, talking about safety and quality, 'cause that was such a huge issue, was to create a quality improvement, quality, um, quality

assurance plan, which was very difficult 'cause there's not there much out there for dental, um, but we had someone from Indian **** Services, um, Dr. Holiday. Um, we had **** center representatives. We had Dr. Mary Willard, who runs the Alaska program, um, and knows the students well. Um, we have Dr. Frank, a pediatric dentist, um, from Florida, who I know will also like to come out here and speak, um, and then, our, um, oh, each pilot program has the representatives and I think you guys know those ****, um, the community member, um, and then myself. Um, so things that we do, reviewed and providing comments to, to the state on recent pilot rule amendments. Um, we review the data, um, we review issues that come up in **** like ni, nitrous oxide sedation modifications, um, and I'm talking, I think, in the next session or sometime soon, I'm talking about prim, primary 18 instructions and so if these guys say oh, well some of the dentists we know are uncomfortable with this, were probably referring to me. I guess that's it.

Next Speaker: Rachel, that was a great presentation. It's almost ****.

Next Speaker: Okay.

Next Speaker: Now, any other comments, conversation from anyone?

Next Speaker: Bruce, I just wanna follow up to, we have an announcement about our pilot project. Um, Christina **** do that.

Next Speaker: Okay.

Next Speaker: ****.

Next Speaker: Is it possible to ask, uh, Dr. Hogan any questions?

Next Speaker: Yeah ****.

Next Speaker: I just wanted to under, huh?

Next Speaker: Yes.

Next Speaker: I, oh, I just wanted to understand, so you don't actually train DHATs in Washington, you, you import them from Alaska.

Next Speaker: Me, so we, yes – do we have the mic on?

Next Speaker: No.

Next Speaker: Okay.

Next Speaker: It's not on. No, we do not train. Not yet but we're going to. But, um, we do not train any of, uh, so we brought down Daniel as an experienced therapist, which was a wonderful experience for us because he also trained me and, um, I'm working with a number of other supervising dentists up in Alaska, um, but we will bring back our students and then, we'll do the preceptor shift very similar to what happens here in Oregon and across the State of Alaska, um, but at this point, we are in, we're formulating an education program that will, hopefully, open in 2020 but, um, and the clinical site would be in our **** dental clinic, um, and all of you are welcome to come visit. We have a beautiful res and we have an awesome clinic

with water sight view and we're expanding so we'll have enough room for everybody, um, but currently, no. We're not training.

Next Speaker: Hi friends. I got another chair. Um, so we just wanted to report to the advisory committee that Ben Stewart has left the project. Um, Ben is an experienced provider that had a really good rapport with his patients and was committed to providing safe and objective, um, care. Not every provider is comfortable or able to work in a highly scrutinized environment of a pilot project and that was a factor in his departure. Um, we are limited in what we can discuss regarding his departure given labor and privacy laws, um, but we did wanna assure the committee that patient **** is not a factor in his departure. Uh, we just didn't want you to be surprised. Uh, he left the project in October so we didn't, when we, it has officially been reported to the state but when it is officially reported in the next quarter, we didn't want anybody from the advisory committee wondering why the first time they heard about it was 3 months from now, so, happy to field questions.

Next Speaker: He's the dentist?

Next Speaker: He's the DHAT.

Next Speaker: Oh, the DHAT, thank you.

Next Speaker: I have a comment. I think that's, interesting piece to consider is training the dentist, Dr. Hogan, like getting the dentist ready to work with the DHAT. I think that's a huge piece that sometimes everybody overlooks and it's not just the DHAT themselves but, but the dentist **** work with.

Next Speaker: And not just, um, the dentist but the local staff.

Next Speaker: The ****. Yeah.

Next Speaker: I mean, hygienists and your assistants and front desk and how do you schedule and, um, make that whole transition, um, smooth and it's much more difficult here with all of the amount of paperwork, um, to make sure all of those checks and balances are, are done, like everyone needs to know how to do that and I think that if you, in any dental office, when you're working with, um, a large staff, you hold all of your staff really accountable to help get, you know, all of that stuff done so.

Next Speaker: I think it also helps with the volume, um, extractions and primary teeth extractions and ****.

Next Speaker: That's right.

Next Speaker: Yeah. All right. An any comments from the room before we go to, uh, the phone and then public comments? Anyone about anything? Okay. And any comments, any comments from the phone? Uh, uh, Linda, Jill?

Next Speaker: ****.

Next Speaker: Yeah. ****.

Next Speaker: Um, before we switch over to public comment, we're gonna have, um, just a quick reminder that we will have a DHAT survey after this. Uh, it will come back either

tomorrow or Wednesday. Uh, there is an opportunity for you to ****, uh, **** members **** on things that have been presented today and, uh, how the meeting went, so please fill out the surveys, um, and we really appreciate it and, again, we will not share the names of people, of responses, so. Um, there's that and then, the next meeting will be March, Monday, March 4th at, at 10, at the same building, same location.

Next Speaker: All right.

Next Speaker: Uh, **** question?

Next Speaker: Yes, go ahead ****.

Next Speaker: Thank you. A thought came to mind. There are often times when you're looking at things from the **** perspective. There are impossible things that come up and you're unable to account for, that might occur and, um, eventually cause somebody to decide to leave the program like that but knowing that it was a fact, I don't know if there have been thoughts in regards to like screening for candidates and kind of doing what we can to prepare those that might be coming into the **** to help mitigate that risk or is it just a risk that we'll have to deal with when that comes up? So.

Next Speaker: So, um, Dr. Ita and, and Dr. Roganstenswa can talk to this as well too. We have, um, done a lot in the last year to really help provide more support to all of the providers, both the dentists and the, and the DHATs that are part of the project. Um, we learned a, we've learned a lot in the last couple of years and the, the project has changed a lot in the last couple of years, from where we started to where we are now, so, um, all of our new students coming back, we feel like they're just gonna come and have a much stronger foundation to stand on when they get here and have a lot more support, not just from us within the project but outside as well.

Next Speaker: But also, I mean, DHATs are humans too, right? So as dentists and hygienists, um, they are, they are general **** in clinics. I mean, I think we can all in this room say that we had, this is probably not our, you know, we've worked at multiple places, right? So, I mean, general work can be accepted just based on looking for new jobs or family situation changing, things like that.

Next Speaker: This is Kelly Jake on the phone. Eh, do I have time for a comment, a question?

Next Speaker: Sure, Kelly.

Next Speaker: Uh, this is going back to the nitrous oxide, um, discussion and I appreciated the report that was brought to us and I appreciated the, um, the comments from around the table there. So my question is where are we in the process with that? What, what, uh, is OHA doing something about the nitrous now or what has come back to our committee? Where are we at in the process of the nitrous situation?

Next Speaker: Yeah. Uh, thanks Kelly. The application's been submitted and now we're reviewing it with the committee's input. So any timeline on that?

Next Speaker: **** the timeline.

Next Speaker: I don't –

Next Speaker: Sarah knows the timeline when we do and ****.

Next Speaker: Yeah.

Next Speaker: Anything else? And then let's move onto to public comment and if people around the table think of something, we're still 10 minutes out. Public comment?

Next Speaker: Is there a –

Next Speaker: There's no one on the list.

Next Speaker: There's no one on the list.

Next Speaker: Okay. Well, anything else, Kelly, Kate? I think we've covered it, um, we, we'll reconvene at 1, right Kelly? For the, –

Next Speaker: Um, yes.

Next Speaker: – for the afternoon session, those that are staying. Um, otherwise, thanks all for coming, um, the sun's out and enjoy the rest of the day.

Next Speaker: Um, ****?

Next Speaker: Yes, ****.

Next Speaker: Hi, how are ya?

Next Speaker: Okay.

Next Speaker: She **** too so I got to go there and ****.

Next Speaker: Are you going ****.

Next Speaker: It's the very last ****.

Next Speaker: Probably. Uh, you're gonna need to give me a minute to go finish printing this.

Next Speaker: It was ****.

Next Speaker: Uh.

Next Speaker: Um, but not a ****.

Next Speaker: **** guidelines ****.

Next Speaker: No, I don't. I don't ****.

Next Speaker: We could start around **** but ****.

Next Speaker: Well, –

Next Speaker: But it's ****.

Next Speaker: – I think it's ****.

Next Speaker: **** somewhere. Since they changed it.

Next Speaker: Um, I, ****.

Next Speaker: We're not to **** care. Yeah, we're not ****.

Next Speaker: Uh, nope, I'm not. ****.

Next Speaker: And whoever's staying for the afternoon session, we have boxed lunches on the counter back here and ****. I guess Sarah's –

Next Speaker: She's got something ****.

Next Speaker: So I'd like to ****.

Next Speaker: Yeah.

Next Speaker: Yeah, **** yeah, so.

Next Speaker: I, and I loved it **** 'cause I ****.

Next Speaker: **** use that one.

Next Speaker: Okay, um.

Next Speaker: Yes, ****.

Next Speaker: Oh.

Next Speaker: Yes.

Next Speaker: Okay. Okay, yes. Um, –

Next Speaker: Yes.

Next Speaker: I got two lectors.

Next Speaker: Oh, thank, thank you.

Next Speaker: Um, I think one should be, uh, ****.

Next Speaker: Yeah, just ****.

Next Speaker: Well, I get that **** there's *****.

Next Speaker: Yeah, oh sure.

Next Speaker: So comfortable.

Next Speaker: Oh, ****.

Next Speaker: Really upset you, huh?

Next Speaker: Yeah ****.

Public Comments: No Public Comments

Meeting Adjourned at 12:22pm

PUBLIC HEALTH DIVISION
Center for Prevention and Health Promotion
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DATE: November 27, 2018

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, division 10 – "Dental Pilot Project Program"

FROM: Jana Fussell, Hearing Officer

cc: Cate Wilcox; Manager
Maternal and Child Health Section

Brittany Hall, Administrative Rules Coordinator
Oregon Health Authority, Public Health Division

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Period

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Hearing Officer Report

Date of Hearing: October 16, 2018

Purpose of Hearing: To receive testimony regarding the Oregon Health Authority (Authority), Public Health Division, Oral Health Program's proposed permanent amendment of administrative rules in chapter 333, division 10 "Dental Pilot Projects" to clarify the rules so that applicants and approved projects can better understand the applicable requirements and possible consequences for failing to adhere to requirements. Due to reorganization and significant amount of revision to the current rule text, the Authority is proposing to repeal current administrative rules 333-010-0400 through 333-010-0470 and replace them with new rule language, administrative rules 333-010-0700 through 333-010-0820.

Hearing Officer: Jana Fussell

Testimony Received: Two individuals provided oral testimony at the hearing. This testimony is briefly summarized as follows:

Eli Schwarz KOD, DDS, MPH, PhD, FHKAM, FCDSHK, FACD, FRACDS, Professor and Chair, Department of Community Dentistry, OHSU School of Dentistry

Dr. Schwarz was a member of both the original and the current Rules Advisory Committees (RACs) and is also the project director for dental pilot project #200. He stated that the RAC was a good process and that he is generally in support of the proposed rules. He did however outline a number of suggested changes that are also summarized in his written comments, attached to this report as "Exhibit 1":

333-010-0700, Purpose: In Dr. Schwarz's written comments he stated that "this new set of rules may be seen as the outcome of the state's careful attention to both pilot projects practicality and the project process," further stating that he "would have preferred the rules to be enforced for new projects going forward only" but does "recognize the need for the existing projects to be accountable to the new rule set." In his oral testimony, he stated that he will work with the Oregon Health Authority on how to transition into the new rules and requested a transition process that would be surmountable.

333-010-0710, Definitions: Dr. Schwarz opined that the rules have been strengthened overall by a more detailed list of definitions. However, he questioned the necessity or utility of the new position "Project Dental Director" stating that there is a great potential for role confusion between this position and "Project Director" and "Supervisor". A number of dentists are already involved in the project, including (4) Clinical Evaluator; (5) Clinical Instructor; and (21) Supervisor. Dr. Schwarz pointed out that "a few locations where the Project Dental Director is mentioned in the rules also mentions the Project Director, indicating that the Project Dental Director is really a redundant role". He also pointed out how requiring an additional dentist for project management may negatively impact the finances of the project, as called out in the financial impact statement. He urged reconsideration of the need for the Project Dental Director and requested it be removed from the rules.

333-010-0770: Informed Consent: Dr. Schwarz opined in his written comments that "it seems unnecessary and redundant to be so prescriptive in the rules that specific language is required and then require the project to submit a consent form for approval as part of its proposal." He stated in his oral testimony that the language chosen in section (3) of the rule is confusing and requested that the specific language for the consent form be dropped from the rule. The rule should simply require that there is an approved consent form, detailing in rule what the consent form should reflect.

333-010-0790, Authority Responsibilities: Dr. Schwarz opined that "it is a good addition to the rules that the Advisory Committee has been defined." However, "the constitution of this committee is heavily laden with professionals and one important group seems to be missing, the recipient community who is involved in the project." He proposed the addition of subparagraph (v) to paragraph (2)(a)(A) to read "Individuals representing the target population served by the project".

333-010-0800, Project Modifications: Dr. Schwarz stated that the "Rules Advisory Group had some discussion about the degree to which modifications could be made to a project during its conduct" and pointed out that OAR 333-010-0800 does allow for minor modifications and examples of such are mentioned in subsections (2)(a) – (c). He

opined that due to the nature of being a 'pilot project' "we are oftentimes in new and unfamiliar territory". For this reason, he opined that "it would seem reasonable to let the need for a minor modification be determined by a consensus discussion among the three involved parties, the project, OHA, and the Advisory Committee. It seems that enough knowledgeable people are engaged in the conversation, and if there is general agreement that a modification might be useful to include in the ongoing project, it should be allowed to happen." He proposed changes to the text to reflect this more flexible approach to minor modifications.

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Dr. Schwarz for his comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

Please see responses below to the comments received by the Authority:

333-010-0700, Purpose
The Oregon Health Authority (OHA) has one coordinator position for the Dental Pilot Project Program, and it would be too difficult to manage current pilot projects under one set of rules and new projects under a different set of rules. The new administrative rules allow pilot projects operating before December 1, 2018 to have until June 1, 2019 to come into compliance with the new rules.

OHA will work with existing projects to assist them in coming into compliance with the new administrative rules. OHA will provide existing dental pilot projects with an outline of possible deficiencies within their already approved pilot projects no later than December 31, 2018.

333-010-0710, Definitions
Based upon feedback received during public comment, OHA has revised the definition of "Project Dental Director" to be more flexible and allow a dental hygienist to function in the role of the Project Dental Director. The modified language under "333-010-0710 Dental Pilot Projects: Definitions" is:

> "(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist or dental hygienist:
> (a) Licensed in the State of Oregon; or
> (b) A dentist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 679.020 or 679.025; or
> (c) A dental hygienist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 680.020."

The purpose of a Project Dental Director is to require inclusion of a licensed dentist or dental hygienist to provide technical assistance and oversight to pilot projects which might otherwise seek to operate without an individual who has the subject matter expertise required to support a dental pilot project.

Supervising dentists are often located at one pilot site and are unable to provide the oversight of an entire project, which may encompass many different pilot sites. To that end, there is nothing in the new administrative rules, as written, which require the Supervising Dentist and Project Dental Director to be two distinct individuals. This role may be filled by one individual assigned a dual role.

333-010-0770, Informed Consent

Upon the recommendation of the Department of Justice, OHA has chosen to include specific language that must be followed for informed consent. However, based upon feedback received during public comment, OHA has modified language under (2)(a) and (3) of "333-010-0770 Dental Pilot Projects: Informed Consent" to be less confusing:

> "(2)(a) An explanation of the role and status of the trainee, any certification or licenses a trainee may hold, the education and training of the trainee and the availability of the trainee's supervisor for consultation;"
>
> "(3) At a minimum, the following language must be included on the document that requests consent to be treated by the dental pilot project:
>
> > 'I _____ [name of patient or person acting on patient's behalf] have received information about this dental pilot project and provider type. I have been given the opportunity to ask questions and have them fully answered. I have read and understand the information and I agree to the trainee of this project providing me treatment.'"

333-010-0790, Authority Responsibilities

OHA agrees that the Advisory Committee should include members that represent the target population served by a dental pilot project. OHA has revised language under (2)(a)(A) of "333-010-0790 Dental Pilot Projects: Authority Responsibilities" to reflect this:

> "(2) Advisory committee. The Authority may convene an advisory committee for each approved dental pilot project.
> (a) Individuals eligible to serve on an advisory committee include but are not limited to:
> (A) Representatives from:
> (i) The Oregon Board of Dentistry;
> (ii) Professional dental organizations or societies;
> (iii) Educational institutions;
> (iv) Health systems; and
> (v) Individuals representing the target population served by the pilot project."

333-010-0800, Project Modifications

OHA received several public comments that indicated the proposed administrative rules around project modifications did not follow the original legislative intent of Senate Bill 738 and allow for needed flexibility and innovation. In response of these concerns, OHA has revised language under "333-010-0800" to give pilot projects the ability to make changes and modifications that may not have been anticipated at the beginning of a pilot project. OHA has outlined a process which will seek input from an Advisory

Committee should a request for modification be submitted by the pilot project. Language has been removed that would require a project sponsor to submit a new application.

The modified language under "333-010-0800 Dental Pilot Projects: Project Modifications" is:

> "(1) Any modifications to an approved project shall be submitted in writing to program staff, except as specified in section (4) of this rule. All modifications require Authority approval. Modifications include, but are not limited to the following:
> (a) Changes in selection criteria for trainees, supervisors, or employment/utilization sites;
> (b) Addition of employment/utilization sites; and
> (c) Changes in the scope of practice for trainees.
> (2) Upon receipt of a request for a modification approval, the Authority will inform the project sponsor in writing on the timeline for review of the request and decision response deadline.
> (3) If the Authority has convened an advisory committee for an approved project, the Authority may confer with the advisory committee regarding the proposed modification.
> (4) Changes in project staff or instructors are not considered a modification and do not require prior approval by program staff, but shall be reported to the program staff within two weeks after the change occurs along with the curriculum vitae for the new project staff and instructors.
> (5) The Authority may approve or deny a request for modification. A modification may be denied if:
> (a) It does not demonstrate that the project can meet the minimum standards or other provisions in these rules; or
> (b) The modification would result in a substantial change to underlying purpose and scope of the pilot project as originally approved.
> (6) Projects are not permitted to implement the proposed modification until approval has been rendered by the Authority."

Richie Kohli, Associate Professor, Department of Community Dentistry, OHSU School of Dentistry

Dr. Kohli requested to clarify a comment made by Dr. Schwarz regarding consent and whether or not it should be required in rule to be "IRB approved consent". She urged caution that the rules should not require an "IRB approved consent" for each of the procedures since the procedures are approved by the Oregon Health Authority and the pilot project.

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Dr. Kohli for her comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

The proposed administrative rules do not require an IRB approval process. Organizations and project sponsors may be required to complete IRB within their own institutions or organizations prior to a project implementation; however, this is not a process governed by OHA or these administrative rules.

Other Comments: Thirteen individuals or organizations submitted written comments to the Authority within the period allotted for public comment. These comments are briefly summarized as follows:

Senator Laurie Monnes Anderson, Oregon Senate District 25

Senator Monnes Anderson noted the importance of oral health, a shortage of dental professionals and the difficulties of accessing dental care for low-income children. In 2011 she sponsored Senate Bill 738, permitting the Oregon Health Authority (OHA) to approve pilot projects to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

She commended OHA's "extraordinary dedication to strict oversight and monitoring of patient safety and quality of care." She stated that: "When they have identified possible concerns or shortcomings in a pilot, they have been quick to implement corrective action plans and increased communications with pilot project staff to resolve potential problems." The Senator observed that: "OHA has an important role to balance protecting the public while maintaining and preserving SB 738's flexibility to test innovative oral health practices." She stated her appreciation of OHA for recognizing that the governing administrative rules may need to be amended as needed and recognized that the Rules Advisory Committee had "participants that represent a broad spectrum of interests." In relation to the proposed rules, Senator Monnes Anderson relayed that she has received "feedback from more than one stakeholder group" and that there "is concern some of the revised rule language is not consistent with legislative intent." She encouraged OHA to stay true to the legislative intent of Senate Bill 738.

Senator Monnes Anderson's written comments are attached to this report as "Exhibit 2."

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Sen. Monnes Anderson for her comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

In response to feedback received during public comment, the Oregon Health Authority agrees that certain portions of the proposed rules may not be within the original legislative intent of Senate Bill 738. Due to the concerns raised, OHA has revised language in several sections to better align rule language with legislative intent.

333-010-0790, Authority Responsibilities
OHA conducts site visits as part of its oversight responsibilities to monitor for patient safety, compliance with the approved application, etc. The proposed rule language around site visits had OHA assessing trainee competency, which is a task required of a project sponsor and not OHA. OHA has revised language under (3)(a)(D) of "333-010-0790 Dental Pilot Projects: Authority Responsibilities" to eliminate assessing trainee competency:

"(3) Site visits.
(a) Site visits shall include, but are not limited to:
(A) Determination that adequate patient safeguards are being utilized;
(B) Validation that the project is complying with the approved or amended application;
(C) Interviews with project participants and recipients of care; and
(D) Reviews of patient records to monitor for patient safety, quality of care, minimum standard of care and compliance with the approved or amended application."

333-010-0800, Project Modifications
OHA received several public comments that indicated the proposed administrative rules around project modifications did not follow the original legislative intent of Senate Bill 738. In response to these concerns, OHA has revised language under "333-010-0800" to give pilot projects more flexibility. OHA has outlined a process which will seek input from an Advisory Committee should a request for modification be submitted by the pilot project. Language has been removed that would require a project sponsor to submit a new application.

The modified language under "333-010-0800 Dental Pilot Projects: Project Modifications" is:

"(1) Any modifications to an approved project shall be submitted in writing to program staff, except as specified in section (4) of this rule. All modifications require Authority approval. Modifications include, but are not limited to the following:
(a) Changes in selection criteria for trainees, supervisors, or employment/utilization sites;
(b) Addition of employment/utilization sites; and
(c) Changes in the scope of practice for trainees.
(2) Upon receipt of a request for a modification approval, the Authority will inform the project sponsor in writing on the timeline for review of the request and decision response deadline.
(3) If the Authority has convened an advisory committee for an approved project, the Authority may confer with the advisory committee regarding the proposed modification.
(4) Changes in project staff or instructors are not considered a modification and do not require prior approval by program staff, but shall be reported to the

program staff within two weeks after the change occurs along with the curriculum vitae for the new project staff and instructors.
(5) The Authority may approve or deny a request for modification. A modification may be denied if:
(a) It does not demonstrate that the project can meet the minimum standards or other provisions in these rules; or
(b) The modification would result in a substantial change to underlying purpose and scope of the pilot project as originally approved.
(6) Projects are not permitted to implement the proposed modification until approval has been rendered by the Authority."

Deborah Loy

Ms. Loy explained her past extensive involvement with Senate Bill 738 and expressed "significant concerns about the draft rules". She opined that: "Many of the changes are inconsistent with SB 738's intent." Her written comments, attached to this report as "Exhibit 3", detail her concern that: "If the pilot original rules needed to be revised the changes should have been limited to the specific issues and a scalpel approach." Ms. Loy does not support the proposed rules as drafted. Her written comments identify and discuss her serious concerns with specific "themes seen in the proposed rules."

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Ms. Loy for her comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

OHA did its best to notify interested parties of the application process to serve on a Rules Advisory Committee (RAC) to amend rule language for dental pilot projects. OHA released a news release on May 4, 2018 and sent the announcement to all individuals who served on the previous RAC in 2012 at the email addresses on file. The announcement was also sent via GovDelivery to individuals who have subscribed to receive updates on the Dental Pilot Project Program, as well as dental professional organizations and community partners. For future updates, you can register online at http://www.healthoregon.org/dpp to receive them by email or text.

OHA proposed to repeal and replace the administrative rules based on the recommendation from the Department of Justice that the rules be reorganized. A majority of the original administrative rule content remains the same but is in a different location.

Senate Bill 738 authorizes the Oregon Health Authority to approve dental pilot projects. OHA does not have the ability to cede its authority to an Advisory Committee or any other entity. The new administrative rules do not place dental pilot projects under the jurisdiction of the Oregon Board of Dentistry.

The new administrative rules also do not implement any changes to the criteria around the didactic or training criteria that a pilot project must demonstrate.

In response to feedback received during public comment, OHA agrees that certain portions of the proposed rules may not be within the original legislative intent of Senate Bill 738. Due to the concerns raised, OHA has revised language in several sections to better align rule language with legislative intent. Please see the Agency response to Senator Monnes Anderson's comments above for specific sections that were modified.

333-010-0710, Definitions
OHA received a couple of public comments suggesting that the definition of "Project Dental Director" was too restrictive. In response of these concerns, OHA has revised the "Project Dental Director" definition in section (16) under "333-010-0710 Dental Pilot Projects: Definitions" to mean an individual who is actively responsible for oversight of the dental pilot project and who is a dentist or dental hygienist. Please see the Agency response to Eli Schwarz's comments above for the specific language.

The original administrative rules that went into effect on February 4, 2013 included specific language regarding which organizations could sponsor a pilot project. OHA amended the rules in 2016 to add language to the definition of "Sponsor" to allow coordinated care organizations and dental care organizations to sponsor projects. These specific organizational types did not exist when the statute was passed in 2011. Based on feedback from the current Rules Advisory Committee, OHA modified the definition of "Sponsor" under (19) of "333-010-0710 Dental Pilot Projects: Definitions" to add "tribal organization or clinic" to the list of organizations which can sponsor dental pilot projects.

333-010-0790, Authority Responsibilities
The original administrative rules, as written, did not provide a process which outlined what the Authority could require in the event that corrective action was needed by a pilot project. Based on the recommendation by the Department of Justice, OHA clarified the process under (3)(g) of "333-010-0790 Dental Pilot Projects: Authority Responsibilities":

> "(g) Following a site visit the Authority will:
> (A) Within 60 calendar days, issue a written preliminary report to the sponsor of findings of the site visit, any deficiencies that were found, and provide the sponsor with the opportunity to submit a plan of corrective action;
> (i) A signed plan of correction must be received by the Authority within 30 calendar days from the date the preliminary report of findings was provided to the project sponsor;
> (ii) The Authority shall determine if the written plan of correction is acceptable no later than 30 calendar days after receipt. If the plan of correction is not acceptable to the Authority, the Authority shall notify the project sponsor in writing and request that the plan of correction be modified and resubmitted no later than 10 business days from the date the letter of non-acceptance was mailed to the project sponsor;

(iii) The project sponsor shall correct all deficiencies within 30 calendar days from the date of correction provided by the Authority, unless an extension of time is requested from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction.
(iv) If the project sponsor does not come into compliance by the date of correction reflected on the approved plan of correction, the Authority may propose to suspend or terminate the project as defined under OAR 333-010-0820, Suspension or Termination of Project.
(B) Within 90 calendar days of receipt of a plan of correction, issue a final report to the sponsor; and
(C) If there are no corrections needed, the Authority will issue a final report within 180 calendar days."

Jennifer Lewis-Goff, MPA, Government Affairs Director, Oregon Dental Association (ODA)

ODA participated in the OHA Rules Advisory Committee and Ms. Lewis-Goff expressed "general support for the proposed changes." She highlighted support for the "thoroughness required in the evaluation and informed consent sections" and "the minimum standards section." Ms. Lewis-Goff's written comments, attached to this report as "Exhibit 4", also detail and discuss a number of "key areas" where they encourage "modifications to the proposed language."

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Ms. Lewis-Goff for her comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

Please see responses below to the comments received by the Authority:

333-010-0700, Purpose
OHA received a couple of public comments requesting that more time be given to existing pilot projects to come into compliance with the new administrative rules. Upon the recommendation of the Department of Justice, OHA has chosen to keep the proposed language as is and allow current pilot projects until June 1, 2019 to come into compliance with the new rules.

OHA will work with existing projects to assist them in coming into compliance given the complexity of the new administrative rules and any changes that might be required including training, personnel changes, standard operating procedure implementation, and project oversight by the project sponsor. OHA will provide existing dental pilot projects with an outline of possible deficiencies within their already approved pilot projects no later than December 31, 2018.

333-010-0710, Definitions

Based on the recommendation of the Department of Justice, OHA has selected to keep the proposed language the same for the definition of "Adverse Events" under (1) of "333-010-0710 Dental Pilot Projects: Definitions". The Oregon Dental Practice Act (DPA) does not define the term "harm" within the DPA.

Based upon feedback received during public comment, OHA has revised the definition of "Supervisor" to better align with the language in Senate Bill 738. The definition will require that this individual is a dentist. The modified language under (21) of "333-010-0710 Dental Pilot Projects: Definitions" is:

> "(21) "Supervisor" means an individual, licensed in the State of Oregon to practice dentistry, designated by the sponsor to oversee trainees at each approved employment/utilization site, with the skills necessary to teach trainees the scope of practice outlined in the approved project."

333-010-0760, Minimum Standards
OHA did not add a definition for "Minimum Standard of Care" in the administrative rules since is not defined or used in the Oregon Dental Practice Act (DPA). The Rules Advisory Committee specified and borrowed language from the DPA to include throughout "333-010-0760 Dental Pilot Projects: Minimum Standards", which outlines how approved dental pilot projects are to provide for patient safety.

333-010-0790, Authority Responsibilities
Based on the recommendation of the Department of Justice, OHA has selected to keep the proposed language the same for the "Advisory Committee" under (2) of "333-010-0790 Dental Pilot Projects: Authority Responsibilities". OHA has developed a charter that outlines the responsibilities and expectations of an Advisory Committee member. To assist with scheduling, OHA provides meeting dates up to 6 months in advance to Advisory Committee members.

333-010-0800, Project Modifications
OHA received several public comments that indicated the proposed administrative rules around project modifications did not follow the original legislative intent of Senate Bill 738. In response of these concerns, OHA has revised language under "333-010-0800" to give pilot projects more flexibility. Please see the Agency response to Senator Monnes Anderson's comments above for the specific language.

Cheryle A. Kennedy, Tribal Council Chairwoman, The Confederated Tribes of the Grande Ronde Community of Oregon

Chairwoman Kennedy wrote that: "We view this new set of rules as the outcome of the state's careful attention not just to the pilots but also to the process." Stating that they "generally support the proposed rules", her written comments, attached to this report as "Exhibit 5", detail and discuss specific provisions of those rules concurring in some language and suggesting revised language when deemed advisable.

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Chairwoman Kennedy for her comments and feedback on the proposed changes to the administrative rules for the Dental Pilot Project Program.

Please see responses below to the comments received by the Authority:

333-010-0700, Purpose
OHA will work with existing projects to assist them in coming into compliance with the new administrative rules before the deadline of June 1, 2019. OHA will provide existing dental pilot projects with an outline of possible deficiencies within their already approved pilot projects no later than December 31, 2018.

333-010-0710, Definitions
Upon the recommendation of the Department of Justice, OHA has selected to keep the proposed language the same for the definition of "Adverse Events" under (1) of "333-010-0710 Dental Pilot Projects: Definitions". The Oregon Dental Practice Act (DPA) does not define the term "harm" within the DPA.

OHA agrees with the suggested language change for the definition of "Employment/utilization site". OHA has revised the language under (10) of "333-010-0710 Dental Pilot Projects: Definitions" to reflect this:

> "(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to populations that evidence has shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees."

OHA received a couple of public comments suggesting that the definition of "Project Dental Director" was too restrictive. In response of these concerns, OHA has revised the "Project Dental Director" definition in section (16) under "333-010-0710 Dental Pilot Projects: Definitions" to mean an individual who is actively responsible for oversight of the dental pilot project and who is a dentist or dental hygienist. Please see the Agency response to Eli Schwarz's comments above for the specific language.

333-010-0770, Informed Consent
Upon the recommendation of the Department of Justice, OHA has chosen to include specific language that must be followed for informed consent. However, based upon feedback received during public comment, OHA has modified language under (2)(a) and (3) of "333-010-0770 Dental Pilot Projects: Informed Consent" to be less confusing. Please see the Agency response to Eli Schwarz's comments above for the specific language.

333-010-0790, Authority Responsibilities
OHA agrees that the Advisory Committee should include members that represent the target population served by a dental pilot project. OHA has revised language under

(2)(a)(A) of "333-010-0790 Dental Pilot Projects: Authority Responsibilities" to reflect this. Please see the Agency response to Eli Schwarz's comments above for the specific language.

333-010-0800, Project Modifications
OHA received several public comments that indicated the proposed administrative rules around project modifications did not follow the original legislative intent of Senate Bill 738. In response of these concerns, OHA has revised language under "333-010-0800" to give pilot projects more flexibility. Please see the Agency response to Senator Monnes Anderson's comments above for the specific language.

Karen Shimada, MPH, Executive Director; and Gary Allen, DMD, Chair, Board of Directors, Oregon Oral Health Coalition (OrOHC)

Ms. Shimada and Dr. Allen wrote that OrOHC "was actively involved with the passage of Senate Bill 738 which created the Oregon Dental Pilot Projects and have been enthusiastic about the growth of pilot projects in the state and the innovative nature of the pilots."

Ms. Shimada and Dr. Allen wrote to support the rulemaking process and the proposed rules, saying that "we view this new set of rules as the outcome of the state's careful attention not just to the pilots but also to the process." Ms. Shimada and Dr. Allen offered comments on specific rules, which are attached to this report as "Exhibit 6".

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Ms. Shimada and Dr. Allen for their comments. Please see the response to similar and/or identical questions under the Agency response to Chairwoman Cheryle A. Kennedy's comments above.

Kelle Little, RDN, Health and Human Services Administrator, Coquille Indian Tribe Community Health Center

Ms. Little stated that the Coquille Indian Tribe is one of the sites designated in Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. She further stated that "as the first pilot project approved by the Oregon Health Authority (OHA) we have first-hand experience with the existing rules and over the course of the last two years, we have 'piloted' many of the new rules." The Coquille Indian Tribe is "encouraged that there will be more definition to the pilot process for all participants to better understand what is required before and during implementation of a project."

Ms. Little's written comments, attached to this report as "Exhibit 7", state that the Coquille Indian Tribe supports a number of rules as written, and supports the remaining rules with revisions detailed in her comments.

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Ms. Little for her comments. Most of her comments were similar and/or identical to ones submitted by Chairwoman Cheryle A. Kennedy. Please review the Agency response to Chairwoman Cheryle A. Kennedy's comments above.

333-010-0760, Minimum Standards
Based on the recommendation of the Department of Justice, OHA has chosen to keep the proposed language outlined in section (10)(a)(A) under "333-010-0760 Minimum Standards" the same. The purpose of (10)(a)(A) is to monitor project activities and compliance, and is not meant to directly reference race, ethnicity, language, and disability (REAL-D). Data must comply with agency requirements and any other applicable statutes, including but not limited to REAL-D.

Joe Finkbonner, RPh, MHA, Executive Director, Northwest Portland Area Indian Health Board (NPAIHB)

Mr. Finkbonner stated that the NPAIHB is the sponsor of Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. Like Ms. Little, he stated that "as the first pilot project approved by the Oregon Health Authority (OHA) we have first-hand experience with the existing rules and over the course of the last two years, have 'piloted' many of the new rules." He further stated that "we support the commitment of OHA throughout this rulemaking process to remain faithful to the intent of SB 738," and "we specifically support the project oversight by the Oregon Health Authority's Public Health Division Dental Director".

Also like Ms. Little, Mr. Finkbonner opined that the NPAIHB is supportive of a number of the rules as written and supports the remaining rules with revisions detailed in his comments, which are substantially similar to Ms. Little's comments above. Mr. Finkbonner's written comments are attached to this report as "Exhibit 8".

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Mr. Finkbonner for his comments. Please see the response to similar and/or identical questions under the Agency response to Chairwoman Cheryle A. Kennedy's comments above.

Jacqueline Mercer, MA, Chief Executive Officer, Native American Rehabilitation Association of the Northwest (NARA, NW)

Ms. Mercer stated that NARA, NW is a participant of Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. Like Ms. Little and Mr. Finkbonner, she stated that as the first pilot project approved by the Oregon Health Authority they have "experienced these rule changes first hand in this project" and that "it has been changeling [sic] and even difficult at times". She further stated that NARA, NW is

"hopeful that a more defined definition to the pilot process" will help "all participants to better understand what is required before and during implementation of a project".

Also like Ms. Little and Mr. Finkbonner, Ms. Mercer opined that NARA, NW is supportive of a number of the rules as written and supports the remaining rules with revisions detailed in her comments, which are substantially similar to Ms. Little's and Mr. Finkbonner's comments above. Ms. Mercer's written comments are attached to this report as "Exhibit 9".

Agency response:
The Oregon Health Authority, Oral Health Program, thanks Ms. Mercer for her comments. Please see the response to similar and/or identical questions under the Agency response to Chairwoman Cheryle A. Kennedy's comments above.

Frank Catalanotto, DMD, Professor, Department of Community Dentistry and Behavioral Science, University of Florida College of Dentistry; Rachael Hogan, DDS, Dental Director, Swinomish Indian Tribal Community; Allyson Lecatsas, MBA, Director of Health Services, NARA Northwest, Inc; Kelle Little, RDN, Health and Human Services Administrator, Coquille Indian Tribe Community Health Center; Victoria Warrren-Mears, PhD, RDN, FAND, Director, NW Tribal Epidemiology Center, Northwest Portland Area Indian Health Board

These five individuals submitted written comments on behalf of Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project Advisory Committee. They wrote that the "...Advisory Committee was established to amongst other goals, monitor and evaluate the safety, effectiveness, and overall success of the project." The individuals submitted written comments addressing specific revisions to some of the rules that are significantly similar to revisions requested by Ms. Little, Mr. Finkbonner and Ms. Mercer above. They further stated that with the suggested changes outlined in their written comments, the rules as amended "will increase the success of NPAIHB and clinic staff to successfully implement the existing and new requirements, allow the Oregon Health Authority to continue to provide careful oversight for patient safety and quality of care, and ultimately best serve the AI/AN communities receiving care from our participating clinics".

The Pilot Project #100 Advisory Committee's written comments are attached to this report as "Exhibit 10".

Agency response:
The Oregon Health Authority, Oral Health Program, thanks these individuals for their comments. Please see the response to similar and/or identical questions under the Agency response to Chairwoman Cheryle A. Kennedy's comments above.

Exhibit 1

OHSU

October 29, 2018

Oregon Health Authority

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To Whom It May Concern.

Re: Notice of proposed rulemaking Chapter 333, Oregon Health Authority, Public Health Division (Dental Pilot Project rules related to SB738).

It is my pleasure to submit the following comments to the draft revised rules to the dental pilot project rules. I was a member of the first Rules Advisory Committee as well as the latest committee and I am also the project director for dental pilot project #200. The following comments are in line with my comments delivered at the public hearing on October 16, 2018.

333-010-700. In principle, I am in support of this rule making process and of these proposed rules. Over the last three years, OHA has shown remarkable commitment to the success not just of our individual pilot project, but to the process. Their careful oversight and monitoring of the pilot projects has both enabled the growth and evolution of strong pilot projects in the state and ensured patient safety. This new set of rules may be seen as the outcome of the state's careful attention to both pilot projects practicality and the project process. Although I would have preferred the rules to be enforced for new projects going forward only, I do recognize the need for the existing projects to be accountable to the new rule set. We believe that we will be able to comply with this within the time frame provided under OAR 333-010-0700(4) and will work with OHA towards this goal.

333-010-0710. The rules have been strengthened overall by a more detailed list of definitions. I question the necessity or utility of the new position "Project Dental Director". There is a great potential for a lot of role confusion between this position and Project Director and Supervisor. The definitions lay out a number of dentists who are involved in the project:

0710 (4) Clinical Evaluator, the external, unaffiliated dentist;

0710 (5) Clinical Instructor; conducting clinical training;

0710 (16) Project Dental Director, whose role partially overlaps with the Project Director; and

0710 (21) Supervisor, whose role is also to oversee the dental training components.

The few locations where the Project Dental Director is mentioned in the rules also mentions the Project Director, indicating that the Project Dental Director is really a redundant role. Apart from the fact that Project management is not really the central skillset of a dentist, it also seems that OHA recognizes that this addition to the role players may negatively impact the finances of the project as it is especially called out in the financial impact statement (p.2 of 34).

It is proposed to reconsider the need for the Project Dental Director and remove this from the rules.

333-010-0770. This section addresses the contents of the consent process, which is in line with expectations to such a process. It seems unnecessary and redundant to be so prescriptive in the rules that specific language is required (0770 (3) because of potential differences between projects. It would make more sense to list the various expectations to the contents (as is done in (1) through (4)) and then require the project to submit a consent form for approval as part of its proposal. During the review process, it can be assessed whether the required information is present and is consistent with the goals and procedures of the project.

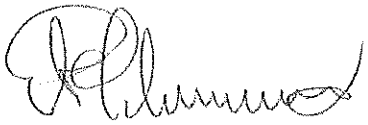
333-010-0790. It is a good addition to the rules that the Advisory Committee has been defined. The constitution of this committee is heavily laden with professionals and one important group seems to be missing, the recipient community who is involved in the project.

It is proposed to add to 0790 (2)(a)(A): (v) Individuals representing the target population served by the project.

333-010-800. The Rules Advisory Group had some discussion about the degree to which modifications could be made to a project during its conduct. This section does allow for minor modifications and examples of such are mentioned in (2)(a)-(c). Considering that we are oftentimes in new and unfamiliar territory (otherwise a pilot project might not be relevant), it would seem reasonable to let the need for a minor modification be

determined by a consensus discussion among the three involved parties, the project, OHA, and the Advisory Committee. It seems that enough knowledgeable people are engaged in the conversation, and if there is general agreement that a modification might be useful to include in the ongoing project, it should be allowed to happen. It is proposed to amend the language in 0800 (3) or to insert a new subsection 0890 (x) to reflect this more flexible approach to minor modifications.

Yours Sincerely,



Eli Schwarz KOD, DDS, MPH, PhD

Exhibit 2

HALL Brittany A

From: Sen MonnesAnderson <Sen.LaurieMonnesAnderson@oregonlegislature.gov>
Sent: Saturday, October 27, 2018 10:48 AM
To: Public Health Rules
Subject: OAR 333-010, Dental Pilot Projects

Oral health is vital for sustaining overall health, to getting good nutrition, and communicating with others. Oral disease often brings disabling pain and can even worsen heart and respiratory conditions and auto- immune diseases. A 2006 study by the Oregon Department of Human Services, Public Health Division, found that 61 percent of Oregon's counties endure some type of shortage of dental professionals. A 2008 study by the Government Accountability Office also highlighted the difficulties of accessing dental care for low income children.

In 2011 I sponsored Senate Bill 738, permitting the Oregon Health Authority (OHA) to approve pilot projects to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

Since OHA approved the first two pilots in 2016, I have been encouraged by OHA's extraordinary dedication to strict oversight and monitoring of patient safety and quality of care. When they have identified possible concerns or shortcomings in a pilot, they have been quick to implement corrective action plans and increased communications with pilot project staff to resolve potential problems. There have been no adverse events or patient harm reported to or observed by OHA in the course of either of the pilot projects. OHA has an important role to balance protecting the public while maintaining and preserving SB738's flexibility to test innovative oral health practices.

I can also appreciate OHA for recognizing that the original Oregon Administrative Rules created did not anticipate every decision that would need guidance, and then for establishing a process to amend the rules for the benefit of Oregonians that are now being and may be served by the pilots. The Rule-making Advisory Committee had participants that represent a broad spectrum of interests, including representatives from the Board of Dentistry, the Oregon Dental Association, the Oregon Dental Hygiene Association, each of the pilot projects, and a potential pilot project.

Since the public release of the proposed rules I have received feedback from more than one stakeholder group. There is concern some of the revised rule language is not consistent with legislative intent. While I applaud OHA's process to amend the rules, I encourage you to stay "true to legislative intent of the original legislation.

Thank you for considering my input on the public rule-making for OAR 333-010, Dental Pilot Projects

Senator Laurie Monnes Anderson
503 986 1725
900 Court St NE S-211
Salem, OR 97301

Exhibit 3

October 22, 2018

Brittany Hall, Rules Coordinator
OHA/Public Health Division
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

RE: Chapter 333 Dental Pilot Project Program

Brittany Hall,

I only recently became aware the 'Dental Pilot Project Program' rules were being revised. I participated in SB738 mediation, engaged in the legislative process leading to its passage, and was a member of the original rules advisory committee. I also participated in the legislative process since SB738 passed related to bills introduced to change/modify it. I share this information simply to illustrate my understanding of SB 738.

I have significant concerns about the draft rules. Many of the changes are inconsistent with SB738's intent. Those close to the pilots have shared a documentation issue arose in one of the pilots. I agree pilots are responsible to safe and appropriate dental practices, however, the rule revision process should not be used to overcorrect. It should not be seized as an opportunity to negate SB738's legislative intent.

When providing comment to draft rules, generally I can respond to text in the draft and provide input. In the case of these rules they are so misaligned I am unable to respond in that manner. By repealing the original rules in their entirety and doing a total rewrite it is a cannon rather than scalpel approach to revising the 'Dental Pilot Project Program' rules.

At the time SB 738 was passed (2011) there was a dental access problem, especially for Oregon's most vulnerable citizens. This problem continues. SB738 allows for the development of innovative dental (workforce) practices to test dental access solutions that Oregon might consider, and it is just as relevant today.

Pilots were 'not' to be under the same requirements/oversight as dental formal education. They were 'not' to be under jurisdiction of the Oregon Board of Dentistry (OBD). This did not mean they were free to do whatever without regard to public safety and standard of care. It meant approved pilots would be under the 'Authority' and their requirements but given flexibility' to test innovative pilot workforce practices outside dental higher education and the OBD. If the pilot original rules needed to be revised the changes should have been limited to the specific issues and a scalpel approach.

One of the issues for revision appears to be the need for the Authority to clarify pilot requirements and oversight. The original rules could have been changed without eroding pilot flexibility. An example, revised language might have given the Authority

more allowance to empower the pilot advisory group to make 'formal' corrective action recommendations. The Authority might have given itself greater allowance to impose 'formal' corrective actions and consequences. If a pilot did not comply with the Authority's requirements or corrective actions they might suspend/terminate it (including immediately if there was an imminent risk of public harm). This type of 'specific' language could have addressed oversight concerns while balancing that outcome with preserving flexibility and legislation intent.

If there were issues in the original rules related to the Authority needing to be clearer on its requirements requesting a pilot, or their criteria for approving/denying, or its expectations for an approved pilot to do internal monitoring/oversight and have policy and procedures related to such revisions could have been tied to administrative changes again specific to the concerns versus making sweeping changes as seen in the draft rules.

I have 'serious' concerns with themes seen in the proposed rules, they are as follows:

- Repealing the original rules and replacing them with the draft rule language as written erode pilot flexibility needed to operate and test innovative dental workforce practices.
- The rules as written erode/limit the safe harbor created by SB738. As written they overcorrect for any perceived/specific issues.
- Draft language 'limits' organizations eligible to be 'sponsor' of pilots (a limit not found in SB738).
- Proposed rules emphasize dental didactic/clinical training and oversight comparable to dental higher education and/or OBD. This was not legislative intent.
- The rules and new requirements make it difficult for any organization wanting to train untrained' and/or 'non-dental' personnel. They are geared to training dental personnel, whereas they should be inclusive of 'all' SB738's legislative goals.
- The Authority's draft rules changes do not preserve legislative intent. Protecting the public and maintaining SB738's legislative intent is not mutually exclusive. At the time SB738 was passed it was not widely supported by organized dentistry (which is likely to be the same today). Even so, it was passed and is law.

SB 738 is a unique and special legislation passed in 2011 by our state. I strongly recommend 'not' repealing the original rules. Revisions of the original rules should be limited to changes 'specific' to the issues/concerns and not used as a vehicle to undermine legislative intent. I am greatly concerned about the sweeping changes in the draft rules. I do not support the draft rules as written.

Sincerely,

Deborah Loy
dloy54@gmail.com

Exhibit 4

oregon dental ASSOCIATION | ADA

Brittany Hall
Rules Coordinator
800 NE Oregon St.
Portland, Oregon 97232
Submitted via email

October 26, 2018

Ms. Hall:

Thank you for the opportunity to comment on the proposed changes to the Dental Pilot Project Rules in Chapter 333, Division 10. As advocates of the original dental pilot project authorizing legislation, the Oregon Dental Association (ODA) appreciates the OHA's attempt to clarify the rules so both applicants and projects have a better understanding of requirements and processes. Further, we believe that better clarity in the rules will translate to increased patient safety.

As participants in the OHA Rules Advisory Committee (RAC), we were able to provide feedback throughout this process and wish to convey general support for the proposed changes. Specially, we appreciate the thoroughness required in the evaluation and informed consent sections. Additionally, we think the proposed rules in the minimum standards section move these rules towards better alignment with some of the Board of Dentistry requirements for other dental practitioners.

There are a few key areas, however, where our feedback during the RAC process was not incorporated into the proposed changes. We would like to again encourage these modifications to the proposed language.

333-010-0700: Dental Pilot Projects Purpose

Section 4 allows current dental pilot projects to have six months to come into compliance with these new rules. We believe that these revised rules are designed to increase patient safety and transparency. We believe current projects should be held accountable to these reasonable standards within three months of implementation. A shorter time frame is in the best interest of Oregonians being served through these pilot projects.

333-010-0710: Definitions

Adverse Event: We encourage you to define "harm" within this definition.

Supervisor: We believe that supervisors in the project should only be dentists. SB 738 requires that all projects operate under the general supervision of a dentist, and we believe that the original legislation's intent was for a dentist to be the immediate supervisor of the trainee.

Minimum Standard of Care: We believe there should be better clarity over the standard of care expected by participants within the pilot projects. Pilot project participants should be held to the same standard of care to which every other licensed dental practitioner in the state are held, as

required by the original authorizing language. This refers to quality, outcome, and appropriateness of care. (Note: the term *minimum standard of care* is used on p. 30 of rules)

333-010-0790 Dental Pilot Projects: Authority Responsibilities

(2): Advisory Committee. The Authority ***may*** *convene an advisory committee for each approved dental pilot project.*

We encourage you to change this to a "shall" requirement. Dental pilot project advisory committees offer essential technical and clinical expertise and guidance to OHA throughout the oversight of these projects. Further, the advisory committees are the only opportunity for public participation and monitoring of projects' progress, success, and concerns.

(e) An advisory committee member must: …

We are concerned with the usage of the word "must" in this section. We are concerned that should a committee member miss an advisory committee meeting, or have a scheduling conflict with a site visit, that their participation in the committee will be terminated. It is critical to have clinical expertise from practitioners on these committees, but those practitioners are also humans who have jobs, families, and unforeseen conflicts that do arise. We would be frustrated to see a committee advisory member be dismissed from their volunteer role, simply because a personal or professional conflict prevented attendance at a required event. As we have seen thus far, participation in pilot project advisory committees are a significant time commitment that may be impossible for one person to fulfill 100% of the time.

333-010-0800: Dental pilot project modifications:(b): changes in employment/utilization sites

We strongly believe that changes in the employment/utilization sites should not be considered minor modifications. Original applications should include all possible location sites. Minor modifications are not subject to public comment periods, and the public should have the opportunity to be aware of and comment on where pilot projects will operate and who the projects will treat. Further, project location sites can alter the scope and type of pilot project and should be fully vetted as done through the original application approval process. Projects should be able to foresee potential sites at the time of their application and include those sites within that application.

Thank you again for the opportunity to comment on these rules. We understand the workload required to develop these changes and appreciate the agency's attentiveness to drafting rules that will improve the pilot project process moving forward.

Sincerely,

Jennifer Lewis-Goff

Jennifer Lewis-Goff

Government Affairs Director

Exhibit 5

The Confederated Tribes of the Grand Ronde Community of Oregon

Umpqua Molalla Rogue River Kalapuya Chasta

Tribal Council
Phone (503) 879-2301
Fax (503) 879-5964

1-800-422-0232
9615 Grand Ronde Road
Grand Ronde, OR 97347

October 29, 18

Submitted via email: publichealth.rules@state.or.us

OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

Re: Dental Pilot Project Program -- Comments on Proposed Changes to Administrative Rules, Chapter 333, Division 10

To whom it may concern:

The Grand Ronde Tribe is writing in support of the proposed changes to Administrative Rules, Chapter 333, Division 10 "Dental Pilot Project Program." Over the last three years, the Oregon Health Authority (OHA) has shown a strong commitment to the success of the dental pilot projects. Their thoughtful and careful oversight and monitoring of the pilot projects has both enabled the growth and evolution of strong, innovative pilot projects in the state and ensured patient safety. We view this new set of rules as the outcome of the state's careful attention not just to the pilots but also to the process. While we generally support the proposed rules, we offer the following comments on the proposed changes:

Dental Pilot Projects; Purpose (333-010-700)

We support adoption of the proposed language in OAR 333-010-0700. The proposed purpose of the pilot project is in line with Senate Bill 738. Grand Ronde is in support of OAR 333-010-0700(4) which provides pilot sites a reasonable amount of time to come into compliance with the new rules.

Dental Pilot Projects; Definitions (333-010-0710)

Grand Ronde supports the robust list of definitions in OAR 33-010-0710 however, we offer the following comments on these specific definitions:

OAR 333-010-0710 (1) "Adverse Event" – later in the rules in OAR 333-010-0760 (9), projects are required to notify OHA if an adverse incident with a patient occurs. This could be confused to provide two different definitions for "Adverse Event". In order to ensure consistency with this definition used later in the rule, we propose using the more specific language in section 333-010-0760 (9) to define adverse event. We suggest that 333-010-0710 (1) be revised as follows:

(1) "Adverse event" means any incident involving a patient in the care of a trainee which results in disability or permanent damage, requires medical or surgical intervention or results in death.

OAR 333-010-0710 (10) "Employment/utilization site" – We are concerned future projects that are striving to serve vulnerable populations, which, like tribal populations, are often overlooked and underfunded for research, may be challenged by the specific term "evidence-based studies." It is often the case that vulnerable subsets of some populations are not disaggregated from evidence-based studies on the population as a whole, or that research dollars have simply not been spent to investigate populations that a pilot project could serve. We are therefore recommending to replace "evidence-based studies" with "evidence" which can include other forms of information to support disease rates and access. We suggest that 333-010-0710 (10) be revised as follows:

(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence ~~based studies have~~ has shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

OAR 333 -010-0710 (16) "Project Dental Director" – We remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director that is a dentist because the whole scope of practice of the pilot will fall outside of the scope of other providers but within the scope of a dentist, there could be instances where a group or organization may want to propose a different management structure. For example, in the case of a pilot project where the scope of practice is wholly within the scope of practice of a hygienist or other practitioner, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of oral health providers when appropriate. We suggest that 333-010-0710 (16) be revised, as follows:

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project who is a dentist or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice.

Dental Pilot Projects; Informed Consent (333-010-0770)

Grand Ronde supports the adoption of OAR 333-010-0770 on informed consent and offers the following comment:

We suggest that "whether the trainee is licensed or unlicensed" be struck from OAR 333-010-0770 (2)(a) and that the sentence be amended to detail **any** licenses or certifications a trainee may hold so it reads, "An explanation of the role and status of the trainee, ~~whether the trainee is licensed or unlicensed~~ **any licenses or certifications the trainee holds**, the education and training of the trainee and the availability of the trainee's supervisor for consultation".

We believe that this may be less confusing to patients about whether or not a license is necessary in order to perform the treatment they are receiving. In some cases, pilot projects may be piloting a new provider type that is not currently licensed in Oregon. We agree that patients may want to know if their provider hold any licenses or certifications to provide dental care but it is important not to inadvertently confuse patients about whether or not the practitioner providing their procedure that day is licensed to do so.

Dental Pilot Projects; Authority Responsibilities (333-010-0790)

Grand Ronde supports the adoption of OARs 333-010-0790 and offers the following comment:

We suggest that OAR 333-010-0790 (2)(a) be amended to include "representation from the community served by the pilot project". It is vitally important that ANY advisory committee include representation from the community served. Tribes are sovereign nations and American Indians/Alaska Natives (AI/AN) face the most striking health disparities in the country and lead almost every major disease category in morbidity and mortality. Systemic inadequacies exist within the US healthcare system and those disparities are even more prevalent in the oral health care system. AI/AN people may disengage from the oral healthcare system because of mistrust, skepticism that their needs will be met, concerns about stereotypes, and experiences of discrimination in the oral healthcare setting. Health inequities are further perpetuated by the chronic and disproportionate underrepresentation of AI/AN oral health professionals in the workforce and the lack of culturally responsive oral healthcare and oral health education available. The pilot projects in Oregon present a unique opportunity for Tribal nations to partner with the state to bring innovative, community based, tribally-led solutions to our clinics. This is true not just for Tribal communities but for any medically underserved community. Representation by those communities is necessary to ensure that the solutions are piloted with communities and not on communities and that the unique needs of those communities are reflected in the solutions proposed.

Specifically, we request these changes to 333-010-0790(2):

(2) Advisory committee. The Authority may convene an advisory committee for each approved dental pilot project.
(a) Individuals eligible to serve on an advisory committee include but are not limited to:
(A) Representatives from:
(i) The Oregon Board of Dentistry;
(ii) Professional dental organizations or societies;
(iii) Educational institutions; ~~and~~
(iv) Health systems; and
(v) Individuals representing the community served by the pilot project.

Dental Pilot Projects; Project Modifications (333-010-0800)

Grand Ronde supports the adoption of OAR 333-010-0800 and offers the following comment:

We believe that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project, the state's advisory committee (when one

exists) and OHA dental director and staff because of the requirement to submit a new application for modifications not determined to be minor. The nature of pilot projects is to test new and innovative or previously untested oral health care models /providers and the advisory committee, project, and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come from that learning process. It might be valuable for the pilot project staff, the OHA dental director, and the pilot sites, when in agreement that a change needs to be made, have the ability to make modifications. This could include additions to scope of practice, addition or modification of training protocols, additional populations to be served, etc.

OAR 333-010-0800 (2)(d) Changes that have been deliberated with the advisory committee (as defined by OAR 333-010-0790 (2)) and when one exists and agreed upon by the project sponsor, utilization site, project dental director, and Authority, that would reasonably improve or expand the pilot project.

Other Provisions (333-010-720 to 0760, 0780, 0810, and 0820)

Grand Ronde supports the adoption of OARs 33-010-0720, 0730, 0740, and 0750, 0760, 0780 related to application and approval processes, minimum standards, and evaluation and monitoring by sponsor.

We also support the adoption of OARs 333-010-0810 and 0820.

Thank you for the opportunity to provide comments on chapter 333- 010-0700 through 333-010-0820 of the Oregon Administrative Rules. Please contact me at 503.879.2304 or email me at Cheryle.Kennedy@grandronde.org for further questions or information.

Sincerely,

Cheryle A. Kennedy
Tribal Council Chairwoman

Exhibit 6

OREGON ORAL HEALTH COALITION

Improving general health through oral health for all Oregonians

Phone: 971.224.1038
Mailing: PO BOX 3132, Wilsonville, OR 97070
Visit: www.orohc.org

Oregon Health Authority
Brittany Hall
800 NE Oregon St Suite 930
Portland, OR 97232

Re: Notice of Proposed Rulemaking Chapter 333, Oregon Health Authority, Public Health Division

Submitted via email

To Whom it May Concern:

The Oregon Oral Health Coalition (OrOHC) is a 501c3 nonprofit organization registered in the state of Oregon with diverse stakeholders. OrOHC provides support and leadership to professional and advocacy groups, local and state government agencies, and other organizations working to achieve optimal oral health for all Oregonians. By organizing our stakeholders' unique strengths into a collective force for optimal oral health, we at OrOHC are able to create connections, pool resources, and maximize the benefits of the oral health care industry for all citizens.

OrOHC was actively involved with the passage of Senate Bill 738 which created the Oregon Dental Pilot Projects and have been enthusiastic about the growth of pilot projects in the state and the innovative nature of the pilots.

We are writing in support of this rule making process and of these proposed rules. Over the last three years, OHA has shown remarkable commitment to the success not just of the individual pilot projects but to the process. Their careful oversight and monitoring of the pilot projects has both enabled the growth and evolution of strong pilot projects in the state and ensured patient safety. We view this new set of rules as the outcome of the state's careful attention not just to the pilots but also to the process. We offer the following comments on the current draft rules:

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Throughout the document, additional language is noted in **bold**, original language left unchanged is *italicized*, and deleted language is struck through.

We support adoption of OAR 333-010-0700. The proposed purpose of the pilot project is in line with Senate Bill 738. OrOHC is in support of OAR 333-010-0700(4) which provides pilot sites a reasonable amount of time to come into compliance with the new rules. This is indicative of the thoughtful process OHA has developed in working closely with the pilot sites.

OrOHC supports the robust list of definitions in OAR 333-010-0710 however, we remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director that is a dentist as the whole scope of practice of the pilot will fall under the scope of a dentist, there could be instances where a group or organization may want to propose a pilot project where the scope of practice is wholly within the scope of practice of a hygienist or other practitioner, and in those cases, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of providers when appropriate.

We offer the following amendment:

(16) "Project Dental Director" means an individual who is actively responsible for oversite of the dental pilot project who is a dentist **or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice.**
(a) Licensed in the State of Oregon; or¶
(b) Authorized to practice in the State of Oregon but is exempt from state licensure under ORS 679.020 or 679.025.¶

OrOHC supports the adoption as proposed of OARs 333-010-0720, 0730, 0740, and 0750, 0760, 0780 related to application and approval processes, minimum standards, and evaluation and monitoring by sponsor.

OREGON ORAL HEALTH COALITION

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Visit: www.orohc.org

OrOHC supports the adoption of OAR 333-010-0770 and offers the following comment:

We suggest that "whether the trainee is licensed or unlicensed" be struck from OAR 333-010-0770 (2)(a) and that sentence amended to detail **any** licenses or certifications a trainee may hold:

(a) *"An explanation of the role and status of the trainee, ~~whether the trainee is licensed or unlicensed~~* ***any licenses or certifications the trainee holds,*** *the education and training of the trainee and the availability of the trainee's supervisor for consultation".*

We believe that this may be less confusing to patients about whether or not a license is necessary in order to perform the treatment they are receiving. In some cases, pilot projects may be piloting a new provider type that is not currently licensed in Oregon. We agree that patients may want to know if their provider hold any licenses or certifications to provide dental care but think it is important not to inadvertently confuse patients about whether or not the practitioner providing their procedure that day is licensed to do so.

OrOHC supports the adoption of OARs 333-010-0790 and offers the following comment:

We suggest that OAR 333-010-0790 (2)(A) be amended to include "representation from the target population served by the pilot project" and OAR 333-010-0790 (2)(B) be amended to include "representation from the local community oral health coalition (if applicable)". Including representation from the target population will help ensure that those populations have a voice in the shaping of projects that affect their community. Additionally, not all communities have a local coalition, but if they do, it would be valuable to include representation from that coalition in the advisory committee as they could bring valuable expertise to the advisory committee.

(2) Advisory committee. The Authority may convene an advisory committee for each approved dental pilot project.

OREGON ORAL HEALTH COALITION

Improving general health through oral health for all Oregonians

Phone: 971.224.1038
Mailing: PO BOX 3132, Wilsonville, OR 97070
Visit: www.orohc.org

(a) Individuals eligible to serve on an advisory committee include but are not limited to:
(A) Representatives from:

(i) The Oregon Board of Dentistry;
(ii) Professional dental organizations or societies;
(iii) Educational institutions; ~~and~~
(iv) Health systems; **and**
(v) Individuals representing the target population served by the pilot project.

(B) Individuals with an interest in public health, oral health or expanding access to medical and dental care **including but not limited to:**
(i) Representation from the local community oral health coalition (if applicable).

OrOHC supports the adoption of OAR 333-010-0800 and offers the following comment:

OrOHC believes that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project, the state's advisory committee and OHA dental director and staff. The nature of pilot projects is to test new and innovative or previously untested ideas and systems, and the advisory committee, project, and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come from that learning process. It might be valuable for the three entities, when in agreement that a change needs to be made, are not constrained from doing so by the burden of having to submit a new application. This could include additions to scope of practice, addition or modification of training protocols, additional populations to be served, etc.

OAR 333-010-0800 **(2)(d) Changes that have been deliberated through the advisory committee (as defined by OAR 333-010-0790 (2) if applicable) and agreed upon by the project sponsor, utilization site, project dental director, and Authority, that would reasonably improve or expand the pilot project.**

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Finally, OrOHC supports the adoption of OARs 333-010-0810 and 0820 as proposed.

Thank you for the opportunity to provide comments on chapter 333- 010-0700 through 333-010-0820 of the Oregon Administrative Rules. Please contact Karen Shimada, OrOHC Executive Director for further questions or information. (karen.shimada@ocdc.net)

On behalf of the OrOHC Board of Directors,

Sincerely,

Karen E. Shimada, MPH
Executive Director
OrOHC

Gary Allen, DMD
Chair, Board of Directors
OrOHC

Exhibit 7

COQUILLE INDIAN TRIBE
Community Health Center
P.O Box 3190 · Coos Bay, OR 97420-0407
Phone: (541) 888-9494 Fax: (541) 888-3431
800-344-8583 www.coquilletribe.org

October 31, 2018

Submitted via email: publichealth.rules@state.or.us

OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

Re: Dental Pilot Project Program
Comments on Proposed Changes to Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects"

Dear Madam/Sir:

The Coquille Indian Tribe is a federally recognized tribe which provides comprehensive health and human service to American Indians/Alaskan Natives and the general public throughout its federally designated primary service delivery area of Coos, Curry, Jackson, Lane and Douglas counties. We appreciate the opportunity to provide comments on the proposed changes to the Administrative Rules, Chapter 333, Division 10, "*Dental Pilot Projects.*"

General comments:

The Coquille Indian Tribe is one of the sites designated in Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. As the first pilot project approved by the Oregon Health Authority (OHA). We have first-hand experience with the existing rules and over the course of the last two years, we have "piloted" many of the new rules. This has been a dynamic and sometimes challenging endeavor, but we have been committed to both the process and our project goals throughout. We are encouraged that there will be more definition to the pilot process for all participants to better understand what is required before and during implementation of a project.

We support the commitment of OHA throughout this rulemaking process to remain faithful to the intent of SB 738, the legislation that enacted the pilot project program. We specifically support the project oversight by the Oregon Health Authority's Public Health Division Dental Director. The staff charged with administering the

program have built it from the ground up. They have the most knowledge of the process and projects while providing extraordinary dedication to strict oversight and monitoring of patient safety and quality of care.

Specific Comments:

We support 333-010-7200 through 333-010-7500; 333-010-7800 and 333-010-0810 as written. We support the rules as proposed in the remaining sections, with the following revisions:*

333-010-0700 Dental Pilot Projects: Purpose
(4) A dental pilot project that was approved and was operating before December 1, 2018, has until June 1, 2019, to come into compliance with the minimum standards in OAR 333-010-0760.

In order to decrease chances of misinterpretation of new rule requirements, and increase the likelihood of projects being able to meet this timeline, we believe existing dental pilot projects would benefit from the following language:

[4] A dental pilot project that was approved and was operating before December 1, 2018, has 6 months after OHA notifies the project of any additional rule requirements to come into compliance with the minimum standards in OAR 333-010-0760. OHA will notify existing projects of these requirements within 30 days of rule passage.

333-010-0710 Dental Pilot Projects: Definitions
(1) "Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable.

The definition of adverse events has been researched and debated in medical and dental communities, in each of the dental pilot projects, and in the Rules Advisory Committee but there is not a universal definition. In order to ensure consistency with a definition used later in the rule, we propose using the more specific language in section 333-010-0760 (9):

(1) "Adverse event" means any incident involving a patient in the care of a trainee which results in disability or permanent damage, requires medical or surgical intervention, or results in death.

333-010-0710 Dental Pilot Projects: Definitions
(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence-based studies have shown have the highest disease

* Pilot Project #100 comments in plain text, proposed rules in ***bold italics***

rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

We are concerned future projects that are striving to serve vulnerable populations, which are often overlooked and underfunded for research, may be limited by the specific term "evidence-based studies." It is often the case that vulnerable subsets of some populations are not disaggregated from evidence-based studies on the population as a whole, or that research dollars have simply not been spent to investigate populations that a pilot project could serve. We are therefore recommending to replace "evidence-based studies" with "evidence" which can include other forms of information to support disease rates and access.

333-010-0710 Dental Pilot Projects: Definitions
(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist.

We remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director who is a dentist, because the whole scope of practice of the pilot will fall outside of the scope of other providers but within the scope of a dentist, there could be instances where a group or organization may want to propose a different management structure. For example, in the case of a pilot project where the scope of practice is of a hygienist or other practitioner, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of oral health providers when appropriate. We suggest that 333-010-0710 (16) be revised, as follows:

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project who is a dentist <u>or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice</u>.

333-010-0760 Dental Pilot Projects: Minimum Standards
(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data.

Pilot Project #100 continues to have serious concerns about the ability to anonymize client level REAL-D data. It is the case that reporting a person's race, age, gender, and other demographic data could easily identify them with their protected medical information, especially in a small homogeneous clinic. OAR 943-070-0000 does not require that REAL-D data be client level. Reporting REAL-D in aggregate easily meets the worthwhile purpose of the OAR 943-070-0000 to "improve the ability of the Authority, Department, community stakeholders, elected

officials, and other decision makers to recognize, address, target and eliminate inequities experienced by distinct racial, cultural, and linguistic communities, and by people with disabilities. Based on local, state, and national best practices, these standards allow the Authority and Department to meet federal reporting expectations; compare Oregon's progress with national trends; improve quality service delivery; and ensure equitable allocation of resources."

We therefore propose the following addition to end of this section:

(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data except that any demographic data that can compromise patient privacy is allowed to be shared in aggregate instead of at the client level to meet REAL-D requirements.

333-010-0770 Dental Pilot Projects: Informed Consent
(2) Written information about the project and who will be providing treatment must include, but is not limited to: (a) An explanation of the role and status of the trainee, whether the trainee is licensed or unlicensed, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

We believe the language above does not account for providers who have a license, but are piloting new procedures not currently in their license; for providers who may hold other qualifying certifications, and may confuse patients about whether a license is necessary in order to perform the treatment.

We propose the following language for 333-010-0770 Dental Pilot Projects:

Informed Consent (2)(a): An explanation of the role and status of the trainee, any certification or licenses a trainee may hold, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

333-010-0770 Dental Pilot Projects: Informed Consent
(3) At minimum the following language must be included on the document that requests consent to be treated by the dental pilot project: "I [name of patient or person acting on patient's behalf] have read and understand the above information concerning treatment I can receive from this dental pilot project and I agree to the trainee of the project providing me treatment."

We propose the OHA-approved language that Pilot Project #100 is currently using on its informed consent forms, which conveys the same information and consent, but does not confuse the patient with language that implies they are being treated by "the project":

I [name of patient or person acting on patient's behalf] have received information about [provider/project]. I have been given an opportunity to ask questions and have them fully answered. I understand the nature of being cared for by the trainee and that consenting to treatment by the trainee does not constitute assumption of risk on my part.

333-010-0790 Dental Pilot Projects: Authority Responsibilities
(2)(a) Individuals eligible to serve on an advisory committee include but are not limited to: (A) Representatives from:

Because the voices of those being served by these projects are necessary in determining pilot success, evaluating effectiveness and offering ideas and solutions for challenges facing the pilot, we propose adding: (v) Individuals representing the target population served by the project.

333-010-0800 Dental Pilot Projects: Project Modifications
(2) Minor modifications may include but are not limited to:

We believe that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project and OHA dental director and staff (and when relevant, Advisory Committee). The nature of pilot projects is to test new and innovative or previously untested models of care. The project and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come from that learning process. This could include additions to scope of practice, addition or modification of training protocols, or additional populations to be served.

We therefore propose the following language be added to OAR 333-010-0800 (2): (d) Changes that have been deliberated and agreed upon by the project sponsor, utilization site, project dental director, and Authority that would reasonably improve or expand the pilot project.

We thank you for this opportunity to provide comments and recommendations on proposed changes to the Administrative Rules, Chapter 333, Division 10, "*Dental Pilot Projects.*" We look forward to further engagement with OHA on the dental pilot projects serving our tribal communities.

Very truly yours,

Kelle Little, RDN

Kelle Little, RDN
Health and Human Services Administrator
Coquille Indian Tribe Community Health Center

M9737

Exhibit 8

NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD

Burns-Paiute Tribe
Chehalis Tribe
Coeur d' Alene Tribe
Confederated Tribes of Colville
Confederated Tribes of Coos, Lower Umpqua, and Siuslaw Indians
Confederated Tribes of Grand Ronde
Confederated Tribes of Siletz
Confederated Tribes of Umatilla
Confederated Tribes of Warm Springs
Coquille Tribe
Cow Creek Tribe
Cowlitz Tribe
Hoh Tribe
Jamestown S'Klallam Tribe
Kalispel Tribe
Klamath Tribe
Kootenai Tribe
Lower Elwha Klallam Tribe
Lummi Tribe
Makah Tribe
Muckleshoot Tribe
Nez Perce Tribe
Nisqually Tribe
Nooksack Tribe
NW Band of Shoshone Tribe
Port Gamble S'Klallam Tribe
Puyallup Tribe
Quileute Tribe
Quinault Tribe
Samish Indian Nation
Sauk-Suiattle Tribe
Shoalwater Bay Tribe
Shoshone-Bannock Tribe
Skokomish Tribe
Snoqualmie Tribe
Spokane Tribe
Squaxin Island Tribe
Stillaguamish Tribe
Suquamish Tribe
Swinomish Tribe
Tulalip Tribe
Upper Skagit Tribe
Yakama Nation

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OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

Re: Dental Pilot Project Program
Comments on Proposed Changes to Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects"

Dear Madam/Sir:

The Northwest Portland Area Indian Health Board (NPAIHB) is tribal organization established under the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638, representing the 43 federally-recognized Indian Tribes in Idaho, Oregon, and Washington on health care issues. NPAIHB works closely with our member tribes on health promotion, disease prevention and public health policy that best serves our tribes and American Indians/Alaska Natives (AI/AN). We appreciate the opportunity to provide comments on the proposed changes to the Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects."

General comments:

NPAIHB is the sponsor of Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. As the first pilot project approved by the Oregon Health Authority (OHA) we have first-hand experience with the existing rules and over the course of the last two years, have "piloted" many of the new rules. This has been a dynamic and sometimes challenging endeavor, but we have been committed to both the process and our project goals throughout. We are encouraged that there will be more definition to the pilot process for all participants to better understand what is required before and during implementation of a project.

We support the commitment of OHA throughout this rulemaking process to remain faithful to the intent of SB 738, the legislation that enacted the pilot project program. We specifically support the project oversight by the Oregon Health Authority's Public Health Division Dental Director. The staff charged with administering the program have built it from the ground up, have the most knowledge of the process

and projects, and have shown extraordinary dedication to strict oversight and monitoring of patient safety and quality of care.

Specific Comments:

We support 333-010-7200 through 333-010-7500; 333-010-7800 and 333-010-0810 as written. We support the rules as proposed in the remaining sections, with the following revisions:*

333-010-0700 Dental Pilot Projects: Purpose
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In order to decrease chances of misinterpretation of new rule requirements, and increase the likelihood of projects being able to meet this timeline, we believe existing dental pilot projects would benefit from the following language:

[4] A dental pilot project that was approved and was operating before December 1, 2018, has 6 months after OHA notifies the project of any additional rule requirements to come into compliance with the minimum standards in OAR 333-010-0760. OHA will notify existing projects of these requirements within 30 days of rule passage.

333-010-0710 Dental Pilot Projects: Definitions
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The definition of adverse events has been researched and debated in medical and dental communities, in each of the dental pilot projects, and in the Rules Advisory Committee and that there is not a universal definition. In order to ensure consistency with a definition used later in the rule, we propose using the more specific language in section 333-010-0760 (9):

(1) "Adverse event" means any incident involving a patient in the care of a trainee which results in disability or permanent damage, requires medical or surgical intervention or results in death.

333-010-0710 Dental Pilot Projects: Definitions
(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence-based studies have shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

We are concerned future projects that are striving to serve vulnerable populations, which are often overlooked and underfunded for research, may be limited by the specific term "evidence-based studies." It is often the case that vulnerable subsets of some populations are not disaggregated from evidence-based studies on the population as a whole, or that research dollars have simply not been spent to investigate populations that a pilot project could serve. We are therefore recommending to replace

* Pilot Project #100 comments in plain text, proposed rules in ***bold italics***

"evidence-based studies" with "evidence" which can include other forms of information to support disease rates and access.

333-010-0710 Dental Pilot Projects: Definitions
(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist.

We remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director that is a dentist because the whole scope of practice of the pilot will fall outside of the scope of other providers but within the scope of a dentist, there could be instances where a group or organization may want to propose a different management structure. For example, in the case of a pilot project where the scope of practice is wholly within the scope of practice of a hygienist or other practitioner, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of oral health providers when appropriate. We suggest that 333-010-0710 (16) be revised, as follows:

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project who is a dentist or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice.

333-010-0760 Dental Pilot Projects: Minimum Standards
(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data.

Pilot Project #100 continues to have serious concerns about the ability to anonymize client level REAL-D data. It is the case that reporting a person's race, age, gender, and other demographic data could easily identify them with their protected medical information, especially in a small homogeneous clinic. OAR 943-070-0000 does not require that REAL-D data be client level. Reporting REAL-D in aggregate easily meets the worthwhile purpose of the OAR 943-070-0000 to "improve the ability of the Authority, Department, community stakeholders, elected officials, and other decision makers to recognize, address, target and eliminate inequities experienced by distinct racial, cultural, and linguistic communities, and by people with disabilities. Based on local, state, and national best practices, these standards allow the Authority and Department to meet federal reporting expectations; compare Oregon's progress with national trends; improve quality service delivery; and ensure equitable allocation of resources."

We therefore propose the following addition to end of this section:

(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data except that any demographic data that can compromise patient privacy is allowed to be shared in aggregate instead of at the client level to meet REAL-D requirements.

333-010-0770 Dental Pilot Projects: Informed Consent

***(2) Written information about the project and who will be providing treatment must include, but is not limited to:* (a) An explanation of the role and status of the trainee, whether the trainee is licensed or unlicensed,-the education and training of the trainee and the availability of the trainee's supervisor for consultation;**

We believe the language above does not account for providers that have a license, but are piloting new procedures not currently in their license; for providers that may hold other qualifying certifications, and may confuse patients about whether a license is necessary in order to perform the treatment.

We propose the following language for 333-010-0770 Dental Pilot Projects:

Informed Consent (2)(a): An explanation of the role and status of the trainee, any certification or licenses a trainee may hold,-the education and training of the trainee and the availability of the trainee's supervisor for consultation;

333-010-0770 Dental Pilot Projects: Informed Consent
(3) At minimum the following language must be included on the document that requests consent to be treated by the dental pilot project: "I [name of patient or person acting on patient's behalf] have read and understand the above information concerning treatment I can receive from this dental pilot project and I agree to the trainee of the project providing me treatment."

We propose the OHA-approved language that Pilot Project #100 is currently using on its informed consent forms, which conveys the same information and consent, but does not confuse the patient with language that implies they are being treated by "the project:"

I [name of patient or person acting on patient's behalf] have received information about [provider/project]. I have been given an opportunity to ask questions and have them fully answered. I understand the nature of being cared for by the trainee and that consenting to treatment by the trainee does not constitute assumption of risk on my part.

333-010-0790 Dental Pilot Projects: Authority Responsibilities
(2)(a) Individuals eligible to serve on an advisory committee include but are not limited to: (A) Representatives from:

Because the voices of those being served by these projects are necessary in determining pilot success, evaluating effectiveness and offering ideas and solutions for challenges facing the pilot, we propose adding: (v) Individuals representing the target population served by the project.

333-010-0800 Dental Pilot Projects: Project Modifications
(2) Minor modifications may include but are not limited to:

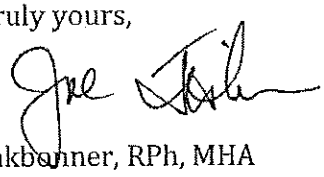
We believe that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project and OHA dental director and staff (and when relevant, Advisory Committee). The nature of pilot projects is to test new and innovative or previously untested models of care and the project and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come

from that learning process. This could include additions to scope of practice, addition or modification of training protocols, or additional populations to be served.

We therefore propose the following language be added to OAR 333-010-0800 (2):
(d) Changes that have been deliberated and agreed upon by the project sponsor, utilization site, project dental director, and Authority that would reasonably improve or expand the pilot project.

We thank you for this opportunity to provide comments and recommendations on proposed changes to the Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects." We look forward to further engagement with OHA on the dental pilot projects serving our tribal communities. If you have questions or would like more information about our recommendations discussed above, please contact Christina Peters, Pilot Project #100 project director at (206) 349-4364 or by email to cpeters@npaihb.org.

Very truly yours,



Joe Finkbonner, RPh, MHA
Executive Director
Northwest Portland Area Indian Health Board

Exhibit 9

October 31, 2018

Submitted via email: publichealth.rules@state.or.us

OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

Re: Dental Pilot Project Program
Comments on Proposed Changes to Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects"

Dear Madam/Sir:

The Native American Rehabilitation Association of the Northwest is a Native owned and run Urban Indian Health Program operating in the Portland metropolitan Area. NARA, NW has been in existence and serving Native Americans in the Portland area since 1970. In the spring of 2016, NARA, NW opened the first Native American dental clinic in the Portland Metropolitan area. Dental access for Native Americans has long been a problem and issue, as well as dental access for other underserved populations. We appreciate the opportunity to provide comments on the proposed changes to the Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects."

General comments:

NARA, NW is a participant of Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project. As the first pilot project approved by the Oregon Health Authority (OHA) we have seen with the existing rules and over the course of the last two years, and experienced these rule changes first hand in this project. It has been changeling and even difficult at times. However, we are committed to the Pilot Project and future pilot projects in Oregon. We are hopeful that a more defined definition to the pilot process for all participants to better understand what is required before and during implementation of a project.

We support the commitment of OHA throughout this rulemaking process to remain faithful to the intent of SB 738, the legislation that enacted the pilot project program. We specifically support the project oversight by the Oregon Health Authority's Public Health Division Dental Director. The staff whom are administering the program have built it from the ground up, have the most knowledge of the process and projects, and have shown extraordinary dedication to strict oversight and monitoring of patient safety and quality of care.

Specific Comments:

We support 333-010-7200 through 333-010-7500; 333-010-7800 and 333-010-0810 as written. We support the rules as proposed in the remaining sections, with the following revisions:*

333-010-0700 Dental Pilot Projects: Purpose
(4) A dental pilot project that was approved and was operating before December 1, 2018, has until June 1, 2019, to come into compliance with the minimum standards in OAR 333-010-0760.

In order to decrease chances of misinterpretation of new rule requirements, and increase the likelihood of projects being able to meet this timeline, we believe existing dental pilot projects would benefit from the following language:

[4] A dental pilot project that was approved and was operating before December 1, 2018, has 6 months after OHA notifies the project of any additional rule requirements to come into compliance with the minimum standards in OAR 333-010-0760. OHA will notify existing projects of these requirements within 30 days of rule passage.

333-010-0710 Dental Pilot Projects: Definitions
(1) "Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable.

The definition of adverse events has been researched and debated in medical and dental communities, in each of the dental pilot projects, and in the Rules Advisory Committee and that there is not a universal definition. In order to ensure consistency with a definition used later in the rule, we propose using the more specific language in section 333-010-0760 (9):

(1) "Adverse event" means any incident involving a patient in the care of a trainee which results in disability or permanent damage, requires medical or surgical intervention or results in death.

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* Pilot Project #100 comments in plain text, proposed rules in ***bold italics***

333-010-0710 Dental Pilot Projects: Definitions
(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence-based studies have shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

We are concerned future projects that are striving to serve vulnerable populations, which are often overlooked and underfunded for research, may be limited by the specific term "evidence-based studies." It is often the case that vulnerable subsets of some populations are not disaggregated from evidence-based studies on the population as a whole, or that research dollars have simply not been spent to investigate populations that a pilot project could serve. We are therefore recommending to replace "evidence-based studies" with "evidence" which can include other forms of information to support disease rates and access.

333-010-0710 Dental Pilot Projects: Definitions
(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist.

We remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director that is a dentist because the whole scope of practice of the pilot will fall outside of the scope of other providers but within the scope of a dentist, there could be instances where a group or organization may want to propose a different management structure. For example, in the case of a pilot project where the scope of practice is wholly within the scope of practice of a hygienist or other practitioner, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of oral health providers when appropriate. We suggest that 333-010-0710 (16) be revised, as follows:

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project who is a dentist or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice.

333-010-0760 Dental Pilot Projects: Minimum Standards

(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data.

Pilot Project #100 continues to have serious concerns about the ability to anonymize client level REAL-D data. It is the case that reporting a person's race, age, gender, and other demographic data could easily identify them with their protected medical information, especially in a small homogeneous clinic. OAR 943-070-0000 does not require that REAL-D data be client level. Reporting REAL-D in aggregate easily meets the worthwhile purpose of the OAR 943-070-0000 to "improve the ability of the Authority, Department, community stakeholders, elected officials, and other decision makers to recognize, address, target and eliminate inequities experienced by distinct racial, cultural, and linguistic communities, and by people with disabilities. Based on local, state, and national best practices, these standards allow the Authority and Department to meet federal reporting expectations; compare Oregon's progress with national trends; improve quality service delivery; and ensure equitable allocation of resources."

We therefore propose the following addition to end of this section:

(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data except that any demographic data that can compromise patient privacy is allowed to be shared in aggregate instead of at the client level to meet REAL-D requirements.

333-010-0770 Dental Pilot Projects: Informed Consent
(2) Written information about the project and who will be providing treatment must include, but is not limited to: **(a) An explanation of the role and status of the trainee, whether the trainee is licensed or unlicensed,-the education and training of the trainee and the availability of the trainee's supervisor for consultation;**

We believe the language above does not account for providers that have a license, but are piloting new procedures not currently in their license; for providers that may hold other qualifying certifications, and may confuse patients about whether a license is necessary in order to perform the treatment.

We propose the following language for 333-010-0770 Dental Pilot Projects:

Informed Consent (2)(a): An explanation of the role and status of the trainee, any certification or licenses a trainee may hold,-the education and training of the trainee and the availability of the trainee's supervisor for consultation;

333-010-0770 Dental Pilot Projects: Informed Consent
(3) At minimum the following language must be included on the document that requests consent to be treated by the dental pilot project: "I [name of patient or person acting on patient's behalf] have read and understand the above information concerning treatment I can receive from this dental pilot project and I agree to the trainee of the project providing me treatment."

We propose the OHA-approved language that Pilot Project #100 is currently using on its informed consent forms, which conveys the same information and consent, but does not confuse the patient with language that implies they are being treated by "the project:"

I [name of patient or person acting on patient's behalf] have received information about [provider/project]. I have been given an opportunity to ask questions and have them fully answered. I understand the nature of being cared for by the trainee and that consenting to treatment by the trainee does not constitute assumption of risk on my part.

333-010-0790 Dental Pilot Projects: Authority Responsibilities
(2)(a) Individuals eligible to serve on an advisory committee include but are not limited to: (A) Representatives from:

Because the voices of those being served by these projects are necessary in determining pilot success, evaluating effectiveness and offering ideas and solutions for challenges facing the pilot, we propose adding: (v) Individuals representing the target population served by the project.

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(2) Minor modifications may include but are not limited to:

We believe that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project and OHA dental director and staff (and when relevant, Advisory Committee). The nature of pilot projects is to test new and innovative or previously untested models of care and the project and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come from that learning process. This could include additions to scope of practice, addition or modification of training protocols, or additional populations to be served.

We therefore propose the following language be added to OAR 333-010-0800 (2):

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We thank you for this opportunity to provide comments and recommendations on proposed changes to the Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects." We look forward to further engagement with OHA on the dental pilot projects serving our tribal communities. If you have questions or would like more information about our recommendations discussed above, please contact Christina Peters, Pilot Project #100 project director at (206) 349-4364 or by email to cpeters@npaihb.org.

Sincerely,

, Chief Operations Officer

for Jacqueline Mercer, MA
Chief Executive Officer
Native American Rehabilitation Association of the Northwest

Exhibit 10

October 31, 2018

Submitted via email: publichealth.rules@state.or.us

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Portland, Oregon 97232

Re: Dental Pilot Project Program
Comments on Proposed Changes to Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects"

Dear Madam/Sir:

The Pilot Project #100 Oregon Tribes Dental Health Aide Therapist Pilot Project Advisory Committee was established to amongst other goals, monitor and evaluate the safety, effectiveness, and overall success of project. In this capacity, the undersigned members have reviewed the proposed rule amendments, which will have a direct impact on Pilot Project #100. We believe that the rules as amended, with the following changes, will increase the success of NPAIHB and clinic staff to successfully implement the existing and new requirements, allow the Oregon Health Authority to continue to provide careful oversight for patient safety and quality of care, and ultimately best serve the AI/AN communities receiving care from our participating clinics:*

333-010-0700 Dental Pilot Projects: Purpose
(4) A dental pilot project that was approved and was operating before December 1, 2018, has until June 1, 2019, to come into compliance with the minimum standards in OAR 333-010-0760.

In order to decrease chances of misinterpretation of new rule requirements, and increase the likelihood of projects being able to meet this timeline, we believe existing dental pilot projects would benefit from the following language:

[4] A dental pilot project that was approved and was operating before December 1, 2018, has 6 months after OHA notifies the project of any additional rule requirements to come into compliance with the minimum standards in OAR 333-

* Pilot Project #100 Advisory Committee comments in plain text, proposed rules in ***bold italics***

010-0760. OHA will notify existing projects of these requirements within 30 days of rule passage.

333-010-0710 Dental Pilot Projects: Definitions
(1) "Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable.

The definition of adverse events has been researched and debated in medical and dental communities, in each of the dental pilot projects, and in the Rules Advisory Committee and that there is not a universal definition. In order to ensure consistency with a definition used later in the rule, we propose using the more specific language in section 333-010-0760 (9):

(1) "Adverse event" means any incident involving a patient in the care of a trainee which results in disability or permanent damage, requires medical or surgical intervention or results in death.

333-010-0710 Dental Pilot Projects: Definitions
(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence-based studies have shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

We are concerned future projects that are striving to serve vulnerable populations, which are often overlooked and underfunded for research, may be limited by the specific term "evidence-based studies." It is often the case that vulnerable subsets of some populations are not disaggregated from evidence-based studies on the population as a whole, or that research dollars have simply not been spent to investigate populations that a pilot project could serve. We are therefore recommending to replace "evidence-based studies" with "evidence" which can include other forms of information to support disease rates and access.

333-010-0710 Dental Pilot Projects: Definitions
(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist.

We remain concerned that OAR 333-010-0710 (16) requiring a "Project Dental Director" to be a dentist is unnecessarily limiting. While most projects will need to have a dental director that is a dentist because the whole scope of practice of the pilot will fall outside of the scope of other providers but within the scope of a

dentist, there could be instances where a group or organization may want to propose a different management structure. For example, in the case of a pilot project where the scope of practice is wholly within the scope of practice of a hygienist or other practitioner, it would be appropriate for a hygienist or other practitioner to act as project dental director. We believe the OAR would be strengthened to include other categories of oral health providers when appropriate. We suggest that 333-010-0710 (16) be revised, as follows:

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project who is a dentist or other oral health care provider for whom the scope of practice within the project falls entirely within that provider's scope of practice.

333-010-0760 Dental Pilot Projects: Minimum Standards
(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data.

Pilot Project #100 continues to have serious concerns about the ability to anonymize client level REAL-D data. It is the case that reporting a person's race, age, gender, and other demographic data could easily identify them with their protected medical information, especially in a small homogeneous clinic. OAR 943-070-0000 does not require that REAL-D data be client level. Reporting REAL-D in aggregate easily meets the worthwhile purpose of the OAR 943-070-0000 to "improve the ability of the Authority, Department, community stakeholders, elected officials, and other decision makers to recognize, address, target and eliminate inequities experienced by distinct racial, cultural, and linguistic communities, and by people with disabilities. Based on local, state, and national best practices, these standards allow the Authority and Department to meet federal reporting expectations; compare Oregon's progress with national trends; improve quality service delivery; and ensure equitable allocation of resources."

We therefore propose the following addition to end of this section:

(10) (A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data except that any demographic data that can compromise patient privacy is allowed to be shared in aggregate instead of at the client level to meet REAL-D requirements.

333-010-0770 Dental Pilot Projects: Informed Consent
(2) Written information about the project and who will be providing treatment must include, but is not limited to: **(a) An explanation of the role and status of**

the trainee, whether the trainee is licensed or unlicensed, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

We believe the language above does not account for providers that have a license, but are piloting new procedures not currently in their license; for providers that may hold other qualifying certifications, and may confuse patients about whether a license is necessary in order to perform the treatment.

We propose the following language for 333-010-0770 Dental Pilot Projects:

Informed Consent (2)(a): An explanation of the role and status of the trainee, any certification or licenses a trainee may hold, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

333-010-0770 Dental Pilot Projects: Informed Consent
(3) At minimum the following language must be included on the document that requests consent to be treated by the dental pilot project: "I [name of patient or person acting on patient's behalf] have read and understand the above information concerning treatment I can receive from this dental pilot project and I agree to the trainee of the project providing me treatment."

We propose the OHA-approved language that Pilot Project #100 is currently using on its informed consent forms, which conveys the same information and consent, but does not confuse the patient with language that implies they are being treated by "the project:"

I [name of patient or person acting on patient's behalf] have received information about [provider/project]. I have been given an opportunity to ask questions and have them fully answered. I understand the nature of being cared for by the trainee and that consenting to treatment by the trainee does not constitute assumption of risk on my part.

333-010-0790 Dental Pilot Projects: Authority Responsibilities
(2)(a) Individuals eligible to serve on an advisory committee include but are not limited to: (A) Representatives from:

Because the voices of those being served by these projects are necessary in determining pilot success, evaluating effectiveness and offering ideas and solutions for challenges facing the pilot, we propose adding: (v) Individuals representing the target population served by the project.

333-010-0800 Dental Pilot Projects: Project Modifications
(2) Minor modifications may include but are not limited to:

We believe that the minor modifications as defined in the rules should be expanded to include modifications that are a result of deliberations by the project and OHA dental director and staff (and when relevant, Advisory Committee). The nature of pilot projects is to test new and innovative or previously untested models of care and the project and OHA staff are in a learning process throughout the pilot. It is possible that improvements and positive refinement of the approved project could come from that learning process. This could include additions to scope of practice, addition or modification of training protocols, or additional populations to be served.

We therefore propose the following language be added to OAR 333-010-0800 (2): (d) Changes that have been deliberated and agreed upon by the project sponsor, utilization site, project dental director, and Authority that would reasonably improve or expand the pilot project.

We thank you for this opportunity to provide comments and recommendations on proposed changes to the Administrative Rules, Chapter 333, Division 10 "Dental Pilot Projects." We look forward to further engagement with OHA on the dental pilot projects serving our tribal communities. If you have questions or would like more information about our recommendations discussed above, please contact Christina Peters, Pilot Project #100 project director at (206) 349-4364 or by email to cpeters@npaihb.org.

Very truly yours,

Frank Catalanotto, DMD
Professor, Department of Community Dentistry and Behavioral Science
University of Florida College of Dentistry

Rachael Hogan, DDS
Dental Director, Swinomish Indian Tribal Community

Allyson Lecatsas, MBA
Director of Health Services, NARA Northwest, Inc.

Kelle Little, RDN
Health and Human Services Administrator
Coquille Indian Tribe Community Health Center

Victoria Warren-Mears, PhD, RDN, FAND
Director, NW Tribal Epidemiology Center
Northwest Portland Area Indian Health Board

Definition & Classification

Table 1 Definition and classification system used to identify dental AEs

AE definition	Physical harm that is moderate or severe due to treatment within a specific time frame
AE type	1. Allergy/toxicity/foreign body response
	2. Aspiration/ingestion of foreign bodies
	3. Infections
	4. Wrong-site, wrong-procedure, and wrong-patient errors
	5. Bleeding
	6. Pain
	7. Hard tissue injury
	8. Soft tissue injury
	9. Nerve injury
	10. Other systemic complications
	11. Other orofacial complications
	12. Other harm
AE severity	E1: temporary minimal harm E2: temporary moderate-to-severe harm G1: permanent minimal harm G2: permanent moderate-to-severe harm

Abbreviation: AE, adverse event.

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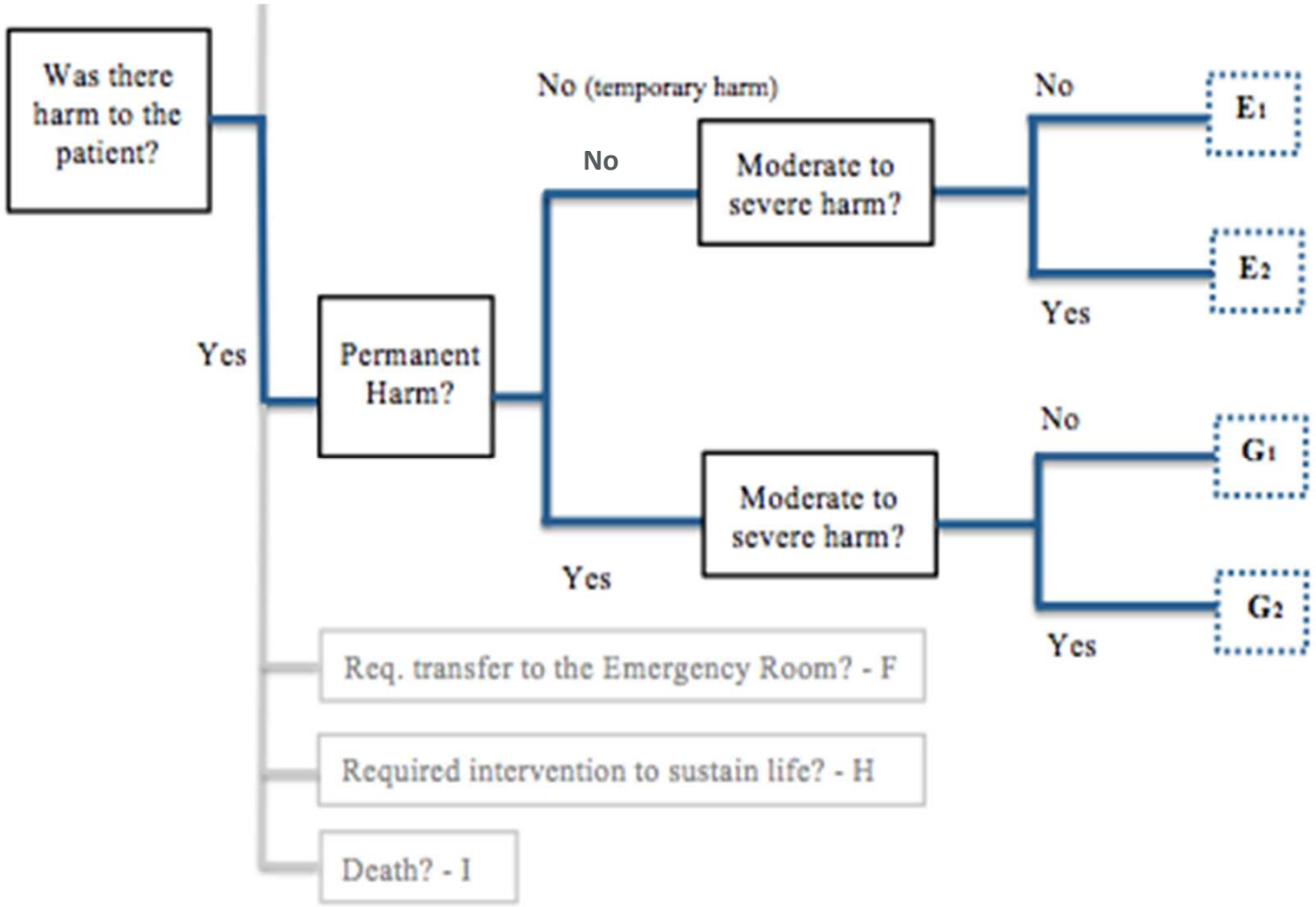
Severity



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CENTER FOR PREVENTION AND HEALTH PROMOTION
Oral Health Program
Kate Brown, Governor

Oregon Health Authority

800 NE Oregon St, Ste 825
Portland, Oregon 97232-2186
Office: 971-673-1563
Cell: 509-413-9318
Fax: 971-673-0231
www.healthoregon.org/dpp

Dental Pilot Project Program Advisory Committee Charter

I. Description of the Dental Pilot Project Program

Senate Bill 738 was passed by the Oregon State Legislature in 2011. This bill allows the Oregon Health Authority (OHA) to approve Dental Pilot Projects once an application has been approved. The goal of the Dental Pilot Projects is to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy of teaching new skills to existing categories of dental personnel; developing new categories of dental personnel; accelerating the training of existing categories of dental personnel; or teaching new oral health care roles to previously untrained persons. OHA may approve a dental pilot project that is designed to operate for three to five years or a sufficient amount of time to evaluate the validity of the pilot project and evaluate the quality of care, access, cost, workforce and efficacy.

Projects must achieve at least one of the following:

1. Teach new skills to existing categories of dental personnel
2. Develop new categories of dental personnel
3. Accelerate the training of existing categories of dental personnel
4. Teach new oral health care roles to previously untrained persons

II. Oregon Health Authority Dental Pilot Project Program Responsibilities

OHA is responsible for processing initial pilot project applications, approving projects and monitoring approved pilot projects. Program staff shall review approved projects and the assessment shall include but is not limited to reviewing progress reports and conducting site visits. The program is responsible for ascertaining the progress of the project in meeting its stated objectives and in complying with program statutes and regulations.

III. Purpose of the Dental Pilot Project Program Advisory Committee:

The purpose of the Dental Pilot Project Program Advisory Committee (Committee) is to provide advice to OHA regarding approved projects. OHA will convene the Committee to gather its members' collective knowledge, experience, expertise, and insight to assist the OHA is meeting its responsibilities. Members will be asked to review and provide advice on project

training, protocols, progress reports and other project issues as needed throughout the duration of the pilot project. Although the Committee provides advice to the agency, OHA makes all final decisions.

IV. Committee Details and Membership:

The Committee is an interdisciplinary team composed of representatives of dental boards, professional organizations, other state regulatory bodies and interested parties that have applied to participate in evaluating a Dental Pilot Project and are approved by OHA. Committee members must not be involved in the specified project in any way in order to be a member of the Committee.

A. Committee Size. The Committee shall not consist of more than 15 members, except that additional members may be added by OHA. If a member resigns from the Committee before the end of his or her term OHA will accept applications for a new member. OHA makes the final determination on acceptance of applications.

B. Process for Membership. Prospective members are required to complete an application.

C. Member Qualifications. Members may include, but are not limited to representatives from the following entities:

- Dental Care Organization(s)
- Dental care providers and allied dental care professionals
- Dental policy subject matter experts
- Federally Qualified Health Centers
- Oregon Board of Dentistry
- Oregon Dental Association
- Oregon Dental Hygiene Association
- Oregon Dental Hygiene Education Program
- Oregon Health and Sciences University (School of Dentistry)
- Oregon Oral Health Coalition
- Community health workers
- Representatives of OHP member advocate organizations
- Representatives of underserved and vulnerable populations or their advocacy groups

D. Term of Office. The term of office for each member is two years. The term begins on the approval date of the initial application with the option to be reappointed for two addition terms. A Committee member cannot serve more than six consecutive years.

E. Payment/Reimbursement. Dental Pilot Project Advisory Committee members are non-paid but eligible travel expenses will be reimbursed according to State of Oregon guidelines. Members are not allowed to accept gifts, meals, lodging, etc. provided by the sponsor of a pilot project or provided on behalf of the sponsor. Members are prohibited from contacting any staff member or sponsor of a pilot project outside of the confines of the Site Visits. A member's questions or concerns about a pilot project should be voiced during a site visit or raised with the Dental Pilot Project Program manager.

F. Removal of Committee Members. OHA may remove a member who is unable to meet the responsibilities of a member or regularly attend meetings.

V. Meetings:

Dental Pilot Projects operate under two distinct phases, the training/education phase and the utilization/employment phase. OHA will determine committee meeting frequency depending on which phase a project is currently operating under. OHA staff will facilitate all meetings.

- OHA will call meetings during the training phase as dictated by project and committee member needs
- Meeting frequency during the utilization/employment phase will be quarterly unless the OHA and the Committee agrees to a different frequency
- Meetings will be held at times that are agreed upon by OHA and a majority of the committee members; Meetings will be held during State of Oregon normal operating business hours
- Additional meetings may be called as dictated by project needs
- Members are required to attend the Dental Pilot Project Advisory Committee Annual Meeting

VI. Committee Members Expectations:

- Attendance at meetings
- Review materials as needed; provide feedback by deadlines
- Respect others' views of issues brought before the committee
- Engage and participate in discussions
- Bring issues forward for discussion in a professional and timely manner
- Use best-practices, evidence-based and data-driven models for analysis and evaluation of issues
- Be open to learning from one another

VII. Committee Member Responsibilities & Rules:

- Advise OHA on:
    - The efficacies of training, competencies and the collection of data
    - Project protocols related to the ongoing assurance of patient safety
    - The evaluation of project progress reports as needed
    - Dental pilot project issues, should they arise
- Participate and attend at least one site visit of a dental pilot project during each year of the pilot project
- Committee operates under an email intensive environment; Members are responsible for reviewing materials in a timely matter and responding as requested by deadlines

VIII. Review of Charter

This charter will be periodically reviewed and updated at OHA's discretion.

NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD

Burns-Paiute Tribe
Chehalis Tribe
Coeur d' Alene Tribe
Colville Tribe
Coos, Suislaw & Lower Umpqua Tribe
Coquille Tribe
Cow Creek Tribe
Cowlitz Tribe
Grand Ronde Tribe
Hoh Tribe
Jamestown S'Klallam Tribe
Kalispel Tribe
Klamath Tribe
Kootenai Tribe
Lower Elwha Tribe
Lummi Tribe
Makah Tribe
Muckleshoot Tribe
Nez Perce Tribe
Nisqually Tribe
Nooksack Tribe
NW Band of Shoshone Tribe
Port Gamble S'Klallam Tribe
Puyallup Tribe
Quileute Tribe
Quinault Tribe
Samish Indian Nation
Sauk-Suiattle Tribe
Shoalwater Bay Tribe
Shoshone-Bannock Tribe
Siletz Tribe
Skokomish Tribe
Snoqualmie Tribe
Spokane Tribe
Squaxin Island Tribe
Stillaguamish Tribe
Suquamish Tribe
Swinomish Tribe
Tulalip Tribe
Umatilla Tribe
Upper Skagit Tribe
Warm Springs Tribe
Yakama Nation

November 8, 2018

Dr. Bruce Austin, Dental Director
Oregon Health Authority
800 NE Oregon St.
Portland, OR 97232

Dear Dr. Austin,

Pilot Project #100 is requesting to modify our Dental Pilot Project Application and Evaluation and Monitoring Plan, to allow DHAT trainees to administer and treat patients on nitrous oxide (NO) under indirect supervision.

Justification: The Alaska Dental Therapy Education Program does not teach the use of NO as it is not a practical sedation method when DHATs are travelling to villages, and temperature control is unstable. The OHA Pilot Project #100 Advisory Committee has asserted that the use of nitrous oxide is best practice and that patients, especially pediatrics, in Oregon are best served if this form of sedation is an option. The pilot project sites currently use NO in their clinics, and we agree that it would be beneficial to patient and providers to enable this addition to the scope with the appropriate training, supervision and monitoring.

"The American Academy of Pediatric Dentistry (AAPD) recognizes nitrous oxide/oxygen analgesia/anxiolysis inhalation (minimal sedation) as a safe and effective technique to reduce anxiety, produce analgesia and enhance effective communication between a patient and the health care provider. Almost 90% of pediatric dentists administer nitrous oxide to their patients to reduce or eliminate anxiety and pain during dental procedures. Nitrous oxide/oxygen administration provides multiple benefits to both patient and dentist. For the patient, nitrous oxide/oxygen provides anxiety relief and analgesia (pain control) that is safe and quickly reversed with minimal side effects."[1]

We also believe adding this to the scope of practice is consistent with other states utilizing dental therapists. According to Minnesota 2009 Session Laws, Chapter 95, Article 3, Subd. 4, the scope of practice for a Dental Therapist includes the administration of nitrous oxide under general supervision.

Impact on the project: The goal of this modification is to expand the patient population the DHATs are able to treat including anxious adults, children, or those with special needs.

In order to ensure safety and trainee competence, the following summary of modifications are proposed to our Evaluation and Monitoring Plan. Explicit changes are attached with proposed modifications indicated in yellow highlight:

(Over)

2121 SW Broadway, Suite 300 · Portland, OR 97201
19201 L Street NW, Suite 420 · Washington, DC 20036
Main Office: (503) 228-4185 · Fax: (228) 228-8182 · www.npaihb.org

1. PN9 Training: Add requirement of OHA approval of NO sedation application, which includes completion of a 14-hour Nitrous Oxide Training course in compliance with OAR 818-026-0040.
2. IC1 Informed Consent: Add reference to NO consent forms
3. NO consent forms from both clinics (to be added to Appendix D)
4. Evaluation and Monitoring Plan Appendix E: Add NO sedation code to approved CDT code list
5. Evaluation and Monitoring Plan Appendix F: Add NO to chart review
6. Evaluation and Monitoring Plan Appendix G: Add NO to practice plan, stipulating only under indirect supervision, and only after completing training course in compliance with OAR 818-026-0040.

If you have any further questions or concerns, please contact Christina Peters, Native Dental Therapy Initiative Project Director or Dr. Gita Yitta, Pilot Project #100 Dental Director.

Sincerely,

Joe Finkbonner, RPh, MHA
Executive Director, Northwest Portland Area Indian Health Board

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[1] Use of Nitrous Oxide for Pediatric Dental Patients. Pediatr Dent. 2017 Sep 15;39(6):273-277.

NITROUS OXIDE APPLICATION FORM Pilot Project 100 (Adapted from the form used for Nitrous Oxide Permits by the State of Oregon)

Name_____

Mailing Address_____Business Phone _____

Business Address _____

City_____State_____Zip _____

Please note:

Any of the following will result in automatic rejection of the application and delay the application process:

- **Application must be completed on a typewriter or a computer.**
- **Copying or duplicating another's application in part or in total.**
- **Questions are not answered completely.**
- **Missing forms, certificates, or proof of training.**
- **Copying, cutting and/or pasting from other written material into the application or listing "see attached". (i.e., literature, DPA, publications). Applications must be completed using your own protocols.**

I have read and understand the above information: _____

SIGNATURE

I. TRAINING

1) Describe and **provide evidence of your formal training in nitrous oxide** (use additional sheets if necessary)
Use additional sheets if necessary

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

2) Describe the formal education and in-office training your anesthesia assistant(s) has/have:

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

3) Provide copies of your anesthesia assistant's (s') valid and current Health Care Provider BLS/CPR level, or its equivalent, course completion documentation.

4) Briefly describe your minimum training standards for personnel who assist you with anesthesia.

II. PREOPERATIVE

1) Briefly describe your preoperative evaluation procedures.

2) Describe your minimum health standards for nitrous oxide administration, how you document your preoperative evaluation.

3) List contraindications for nitrous oxide administration.

4) What pre-induction instructions do you give patients? Do you have an instruction sheet which you give the patient? (Attach a copy.)

5) Attach a copy of your informed consent form if you have one.

6) Attach a copy of your health history form.

III. OPERATIVE

Describe your nitrous oxide administration procedures, listing dosages used, and documentation of monitoring.

IV. POSTOPERATIVE

Describe your standards for discharge.

V. EMERGENCY

1) Describe your emergency protocol (i.e., time line or algorithm) and explain what responsibilities your staff members have.

2) Do you have regularly scheduled emergency drills? ☐ yes ☐ no If yes, how often? _____
Date of most recent drill. _____

3) Describe your emergency kit.

a) List the drugs it contains and what each drug is used for.

b) What airway emergency equipment is available?

c) How do you ensure emergency kit contents are kept current?

I certify that the above statements are true. I acknowledge that by applying to the OHA as part of Pilot Project #100 for the ability to use nitrous oxide, I consent to the conduct of office evaluations.

Signature_____ Date _____

Adverse Events in Dentistry

DATE: December 3, 2018

PRESENTED BY: Rose McPharlin, DDS and Karla Kent, PhD

Objectives

- Describe our process for defining, identifying, and classifying Adverse Events from dental patient charts
- Provide examples of AEs we identified by consensus
- Discuss examples of Quality of Care events (“non-AEs”)
- Discuss the challenges we faced

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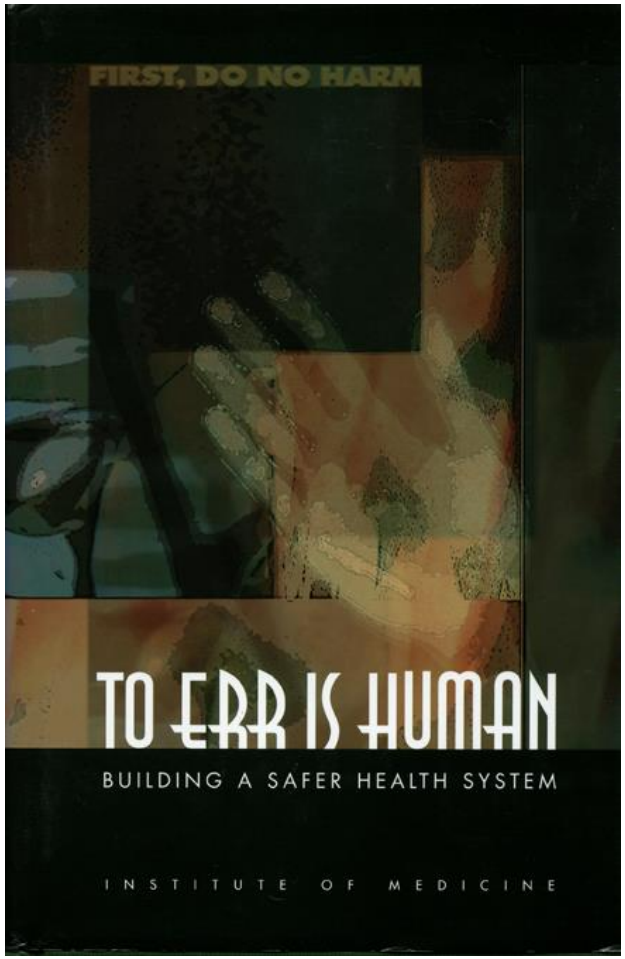
Background

- Non-maleficence as a guiding principle[1]
- Studies in medicine show healthcare as one of least safe industries in the world[2]
- Institute of Medicine report “To Err is Human” 2000
  - AEs caused by medical errors are 8th leading cause of death in U.S.
- Patient safety is uncharted territory for dental profession
- Dearth of information about the occurrence of adverse events (AE) in the dental office[3]
- ADA CODA (Commission on Dental Accreditation) Accreditation Standards for Dental Education Programs



Terms and Tools

- FDA MAUDE database: Manufacturer and User Facility Device Experience –182 publications which contained 270 cases of harm to patients associated with dental treatment (1996-2011)[4]
- IHI—Institute for Healthcare Improvement developed strategy of employing global trigger tools[5][6]
- Trigger: easily identifiable focused item in a patient record that can help lead to the identification of an AE[7]

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Definitions of "Adverse Event"

- IOM: an injury resulting from a medical intervention (i.e., not due to the underlying clinical condition of the patient)
- AHRQ: Injury caused by medical care
- IHI: Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization or that results in death
- FDA: Undesirable experience associated with the use of a medical product in a patient

What is not an AE?

- Causes or precursors to AEs
  - Errors
  - Near misses
  - Poor/unacceptable quality of care
- Natural course of disease

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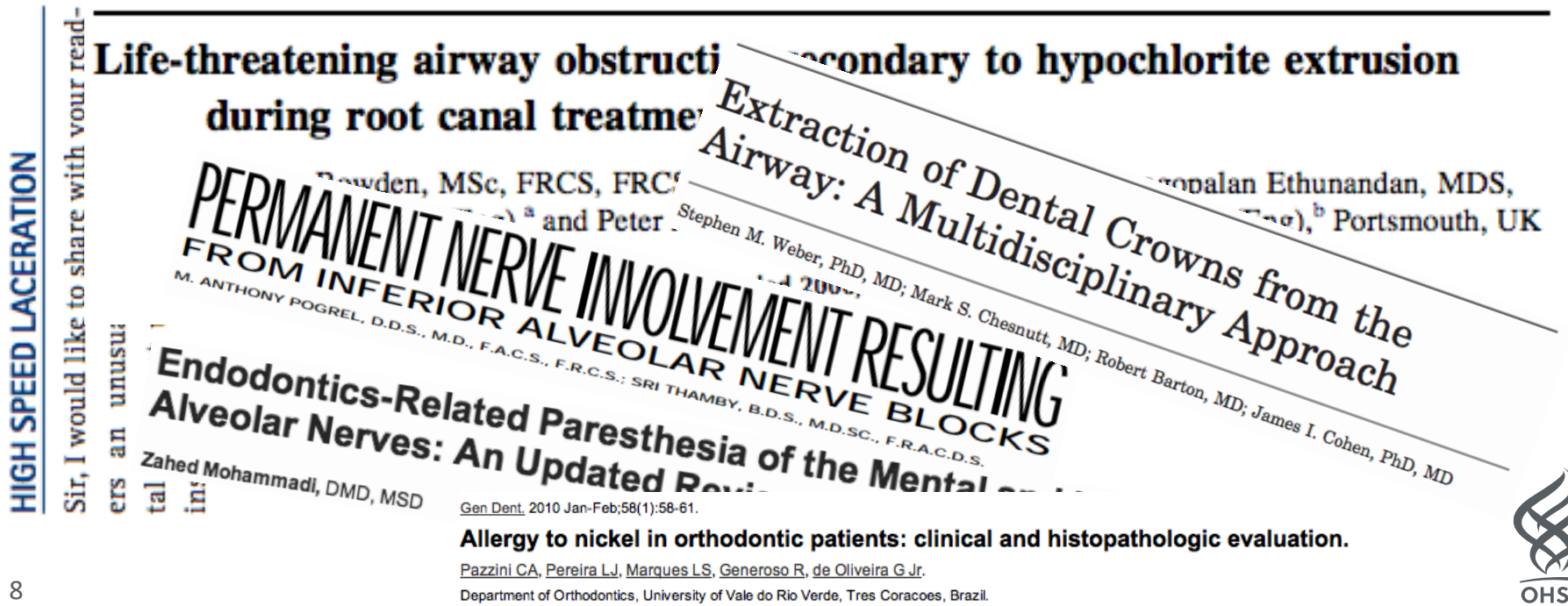
Reported Dental AEs from FDA Maude Database

- AEs involving dental devices: 28,046 (1.4%) of reports between 1996 and 2011
  - Aspiration
  - Edema due to sodium hypochlorite extrusion
  - Sublingual thrombosed vein (laceration)
  - Death
- Need to identify other AEs occurring in dental setting

Our Definition

- Physical harm due to treatment within a timeframe relevant to the clinical scenario



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Definition Guidelines

- Hazards or potential harm are not AEs
- In the absence of harm; errors, negligence, blame, accusations, or malpractice are not AEs
- Do not include omissions
- Quality of care issues in the absence of harm are not AEs.
- Harm may be temporary or permanent (E2, G2). Include moderate to severe harm (as level 2). Include minimal/mild temporary or permanent harm (Level 1: E1, G1)
- All level 2 AEs must be totally defensible (rock solid, significant, important); will a group of our peers readily agree that this is not an AE because it is a result of the disease or condition, within a reasonable range of the standard of care. These may be classified as level 1
- Does not matter if treatment occurred internal (at the institution) or externally (outside the institution)
- Repeated treatment attempts with poor prognosis (heroic dentistry) without harm is not an AE (e.g. repeated attempt to restore teeth)
- Temporary loss of function in the absence of harm (any level) is not an AE.
- *Severely debilitated teeth from decay, restoration, or RCT which fracture or fail (without full coverage or protection) are not AEs unless directly related to the treatment*
- *Disease progression of a tooth (i.e. life cycle of a tooth) is not an AE*

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Definition & Classification

Table 1 Definition and classification system used to identify dental AEs

AE definition	Physical harm that is moderate or severe due to treatment within a specific time frame
AE type	1. Allergy/toxicity/foreign body response
	2. Aspiration/ingestion of foreign bodies
	3. Infections
	4. Wrong-site, wrong-procedure, and wrong-patient errors
	5. Bleeding
	6. Pain
	7. Hard tissue injury
	8. Soft tissue injury
	9. Nerve injury
	10. Other systemic complications
	11. Other orofacial complications
	12. Other harm
AE severity	E1: temporary minimal harm E2: temporary moderate-to-severe harm G1: permanent minimal harm G2: permanent moderate-to-severe harm

Abbreviation: AE, adverse event.

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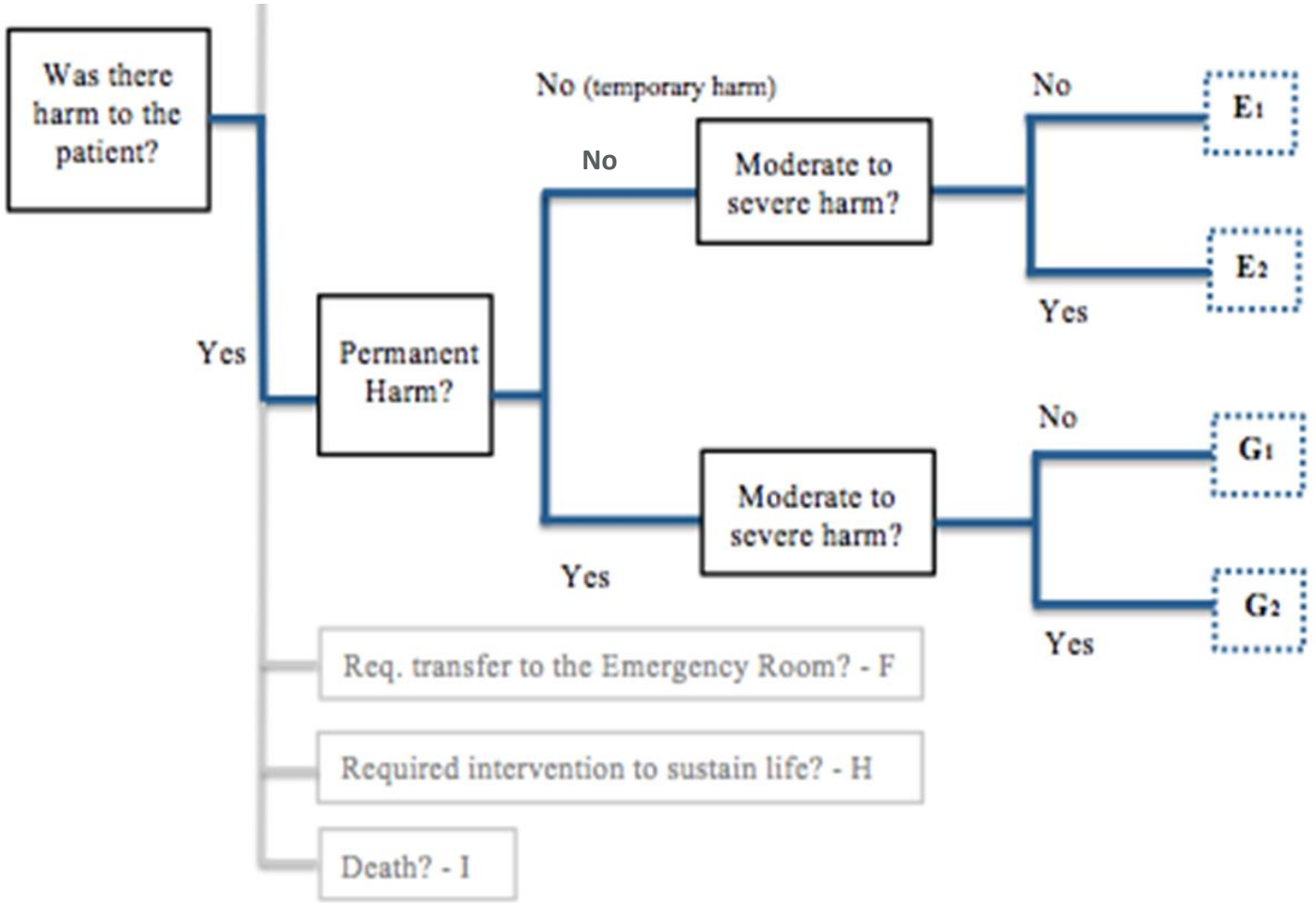
Severity


Was there harm to the patient?
Yes
Permanent Harm?
No (temporary harm)
No
Moderate to severe harm?
No
E1
E2
Yes
Yes
Moderate to severe harm?
No
G1
G2
Yes
Req. transfer to the Emergency Room? - F
Required intervention to sustain life? - H
Death? - I

Severity Guidelines

- Use following to help determine severity:
  - Intensity (0-10 scale)
  - Duration (time period of harm: acute, chronic, number of days or weeks or months)
  - Frequency (How often does the harm occur during time period of harm: rare, sometimes, often, always)

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Triggers to identify AEs

- Failed Implants
- Post-Surgery Complications
- Soft Tissue Injury
- Nerve Injury
- Extraction following RCT/Crown/Filling
- Allergy/Toxicity/Foreign Body
- Aspiration/Ingestion of Foreign body

Categories

Table 4 Classification of dental adverse events

AE categories	AE count	Examples
Pain	57	Severe pain, pain due to dehiscence
Infection	16	Abscess, trismus, dry socket, infection postperiodontal procedure
Hard tissue damage	11	Tooth damage, root canal perforation, bone damage after implant placement
Nerve injury	6	Numbness, paresthesia
Soft tissue injury	5	Necrosis, laceration
Other orofacial complications	2	Facial pain, sinus perforation
Allergy/toxicity/foreign body response	1	Drug allergy
Aspiration/ingestion of foreign bodies	1	Ingestion of foreign bodies such as prosthesis
Other systemic complications	1	Vomiting
Wrong-site, wrong-procedure, wrong-patient errors	0	
Bleeding	0	
Other harm	0	
Total	100	

Abbreviation: AE, adverse event.

Pain - Guidelines

- Pain scale (or equivalent based on scale)
  - 1-3 = Slight Pain = No harm (or +)
  - 4-6 = Moderate Pain = E1 (or ++)
  - 7-10 = Severe Pain = E2 (or +++ or more)
  - Throbbing, stabbing, jabbing, pounding, pulsating, pain classified as severe pain
- *In absence of a pain scale, the patient's description leads the reviewer to determine it is moderate pain ("experiencing a lot of pain") it is an AE at level E1*
- In absence of a pain scale, the patient's description leads the reviewer to determine it is severe pain ("can't sleep", "killing me") it is an AE at level E2
- In absence of a pain scale, if patient comes in for an emergency dental visit with complaint of pain it is an AE at level E2
- In absence of a pain scale, If a patient or representative calls and receives a RX for pain management it is an AE at level of E2
- Dry sockets (osteitis) in presence of pain is an AE (classify as Pain). In the absence of pain, documentation of dry socket is not an AE
- Potential drug seekers with a chief complaint of pain (scale 4-10) is reviewable as an AE (do not automatically exclude)

OHSU

Pain - Examples

- **E2:** Patient (PT) had root canal treatment (RCT) on #18 and reported pain lasting all day since RCT started. PT takes 5 Advils per day and claims he feels pain ALL the time.
- **E2:** Tooth K & L restored with amalgam; two weeks later pt has pain & comes in for emergency visit; pain has been constant throughout the last two weeks; Tylenol makes it feel better but pain comes back. Fillings removed, first step pulpotomy on L; temp filling on K. Two weeks later, pt still having pain, radiographic findings: K has pulpal communication; L has radiolucency interradicular. Extracted L; Pulpotomy (formocresol) and Stainless Steel Crown on K
- **E1:** Pt reports pain 4 days after restoration of tooth #27. Future treatment advised during restoration was extraction (dx: external resorption and caries).

OHSU

Other oro-facial harm - Guidelines

- All sinus related issues (e.g sinus perforation) fit in this category
- Sinus infection should be categorized under Infection
- Trismus fits in this category
- *Extra-oral Inflammation (redness, hot, swelling and pain) should be classified as Other oro-facial considering magnitude/proportionality*

Other oro-facial harm - Examples

- **E2**: Implant failed # 2-4. Implant removed. Implant caused granulation tissue and maxillary sinus communication and bony defect.
- **E1**: Pt had painful, watery eye evening after surgery and was advised that it might be a foreign body or corneal scratch. Patients mother reported that diagnosis of eye was corneal scratch; antibiotics prescribed by outside provider.

Infection - Guidelines

- Sinus infection should be categorized under infection
- In general, with infection there is swelling, pus, fever, malaise, etc
- *Infections with fluctuant swelling that may indicate I&D =E2*
  - Inflammation should be classified as Soft Tissue injury/inflammation

Infection – Examples

- **E2**: Implant on #21 was placed, infection and pus noticed in that area. Antibiotics prescribed and by #21 was healing well.
- **E2**: #31 carious and vestibular and sublingual abscess, buccal cellulitis; simple extraction; I & D, purulence expressed; Rx for augmentin, flagyl, lortab, peridex; pt returns 2 days for re-eval; pt has nausea and possible spread of infection to submandibular region with erythema of overlying skin; may still be abscess needing to be drained; pt referred for CT scan

Other Systemic Harm - Guidelines

- All systemic complications should be reviewable as a potential AE
  - Anaphylactic shock
  - If allergen is known for Anaphylactic shock, also classify as Allergy/Toxicity/FB response
  - Asthma attack
  - Anxiety attack/fainting
  - Behavioral complications
  - Diabetic episode
  - Trip, fall, bump head
  - Death
  - Transfer to the medical ER without a specific diagnosis
  - Patient fainting is not necessarily an AE

Other systemic harm - Examples

- **E2**: Under general anesthesia, PT had undergone extraction of #1, 16,17 and 32. PT then underwent surgical exposure of #30 and #31. PT's mother called to report that PT's right arm was slightly swollen, face was swollen, and she thought she heard some wheezing. PT had vomited 4x since surgery. Due to concern about possible allergic reaction to Lortab and dehydration, provider asked PT to go to ED.
- **E1**: Pt had nasal reconstruction and costochondral graftdone; on post-op visit pt complained that she had nausea, vomiting and diarrhea for 24 hours; she feels it is the antibiotics

OHSU

Hard Tissue Injury - Guidelines

- Includes damage to the tooth or bone including an implant that has been damaged resulting in bone loss
- Lateral perforation of root during a RCT is a G1. Non-reparable = G2
- Failure of implant to osseointegrate in a short period of time after 6 months is an AE
- Bone loss around an implant after osseointegration is an AE even in the presence of predisposing conditions (e.g. generalized periodontitis, poor oral hygiene)

Hard Tissue Injury - Examples

- **G2**: Furcation perforation of tooth #3 during pulpectomy procedure; tooth was non-restorable and pulpectomy was completed to alleviate an infection. Tooth is going to be extracted.
- **G1**: During prep of #30 without LA, pt jerked and bur gouged buccal enamel outside of prep outline; repaired with composite

OHSU

Soft Tissue Injury - Guidelines

- Includes intra and extra-oral soft tissue injuries (lips, tongue, oral mucosa, gingiva)
- Includes injuries to the extra-oral skin and skin in general
- Denture sores and discomfort are not considered AEs during normal adaptation period
- Intra-oral Inflammation (redness, hot, swelling and pain) should be classified as Soft Tissue Injury considering magnitude/proportionality

OHSU

Soft Tissue Injury - Examples

- **E2**: Gingival flap surgery was completed on #4,5,6 region. Post-op visit reveals PT lost sutures 3 days post-op in the surgical areas of #4,5,6 and tenderness to palpation. Visual exam reveals a 15mm diameter exposure of connective tissue and a 3mm exposure of palatal bone was noted near #4. Slight tissue necrosis was noted. Pre-op Radiograph reveals vertical bone loss of #5, 6 with # 4 missing. # 5 has a bone loss of about 3 mm on distal side and about 5.5 mm on medial side. No radiograph was taken after surgery or at post-op visit.
- **E2**: While removing PFM crown with crown cutting bur provider lacerated near the mucosa of #31. Bleeding was controlled.

Nerve Injury - Guidelines

- Paresthesia that presents with numbness with or without perception of pain is classified as nerve injury only
- Nerve injury that persists for less than 6 weeks is E1, between 6 weeks to 6 months =E2, and more than 6 months =G1, more than 6 months with loss of function (i.e. drooling), inability to eat or smile) pain, other sequelae =G2
- Nerve injury with paresthesia or dysesthesia (pain, burning and tingling when touched) lasting less than 6 weeks is an E2
- Permanent severe paresthesia or dysesthesia = G2.

Nerve Injury - Examples

- **E2**: #18 was determined to be a non-restorable carious tooth and was extracted. During follow-up visit, PT complained of numbness and tingling of her lower lip region and numbness in the posterior left mandibular region. At 2nd week follow-up visit, PT reported occasional aching sensation to lower left lip.
- **G2**: Pt reports some residual left IAN paresthesia/dysesthesia chin over one year after bone graft to augment implant site #19

OHSU

Bleeding - Guidelines

- Includes frank bleeding and also bleeding into tissue (e.g. hematoma)

Bleeding - Examples

- **E1**: Patient had tooth #3 extracted in AM by outside clinic. Patient presented to our emergency clinic in the afternoon complaining that area is profusely bleeding. On exam area #3 shows torn gingival tissue and is actively oozing blood.
- **E1**: Pt had tissue graft and three days later came in with profuse bleeding. Had gone to ER prior to scheduled visit; disrupted blood clot on palatal tissue donor site; pressure applied and hemostasis achieved.

Allergy/Toxicity/FB Response - Examples

- **E2**: Extraction of #18, 20, 22, 29 and 31 was performed and prescriptions for Pen VK and Hydrocodone 5/325 were written. PT called emergency line on stating that he had woken up in the am feeling itchy and noticed that he was bright red all over his body, POD2 status post (s/p) multiple dental extractions. PT stated that he had been given Vicodin, Pen VK, no history (hx) of prior allergy. Provider told PT that he should take OTC antihistamine and observe if rash resolves. If he does not improve, he should present to the Emergency Room (ED) or Primary Care Physician (PCP) for evaluation. If at any point he develops difficulty breathing or swallowing, he should report to ED immediately.12/22 A Prescription (Rx) was phoned in for erythromycin, later changed to clindamycin due to cost.

Aspiration/Ingestion of FB - Examples

- **F:** While performing oral prophylaxis, ultrasonic scaler tip fractured and PT may have swallowed or aspirated the scaler tip. PT was immediately rushed to ED. KUB revealed a radiopaque foreign object in the area of the duodenum, measuring approximately 1 cm. PT was informed that her airways were clear and that she will pass the foreign body.
- **Not an AE**: Pt called and said she swallowed part of temporary crown placed on #12 two months ago. Removed remaining temporary crown and old cement. Tried in crown on #12. Pre-cementation x-rays were taken. Contacts and occlusion adjusted. Margin was acceptable. Crown fit well. RelyX used to cement crown. Excess cement removed. Post-cement x-ray was taken. Crown was light cured.

OHSU

W-SPP (wrong site, patient, procedure) - Examples

- **G2**: Root canal cavity preparation was completed on #18 instead of #19. Now #18 now needs RCT, Post/Buildup and crown
- **G1**: Tooth #31 was extracted instead of the day's plan to extract #30. Tooth #31 had lost a crown and had periapical radiolucency on both roots and would have needed retreat endo or extraction.

Our results

- 16.2% of charts reviewed (1,885) contained an AE by our definition
- Most common types identified:
  - Pain
  - Hard Tissue
  - Soft Tissue
  - Nerve Injuries
- Severity
  - Temporary 89.2%
  - Permanent 9.6%
  - Transfer to ER 1.2%

OHSU

Conclusion

- Identifying harm is the first step to improving the quality and safety of oral healthcare. By developing seven specific triggers and a process to identify harm, we were able to measure adverse events in dental electronic health records, which is one of the first steps to mitigating harm in our dental patients. (2)

OHSU

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- Muhammad Walji, PhD
  - Department of Diagnostic and Biomedical Sciences, School of Dentistry, University of Texas Health Science Center, Houston, Texas, United States
- Elsbeth Kalenderian, DDS, MPH, PhD,
  - Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California, 707 Parnassus Avenue, San Francisco, CA 94143-0758, United States (e-mail: elsbeth.kalenderian@ucsf.edu)

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Additional Resources

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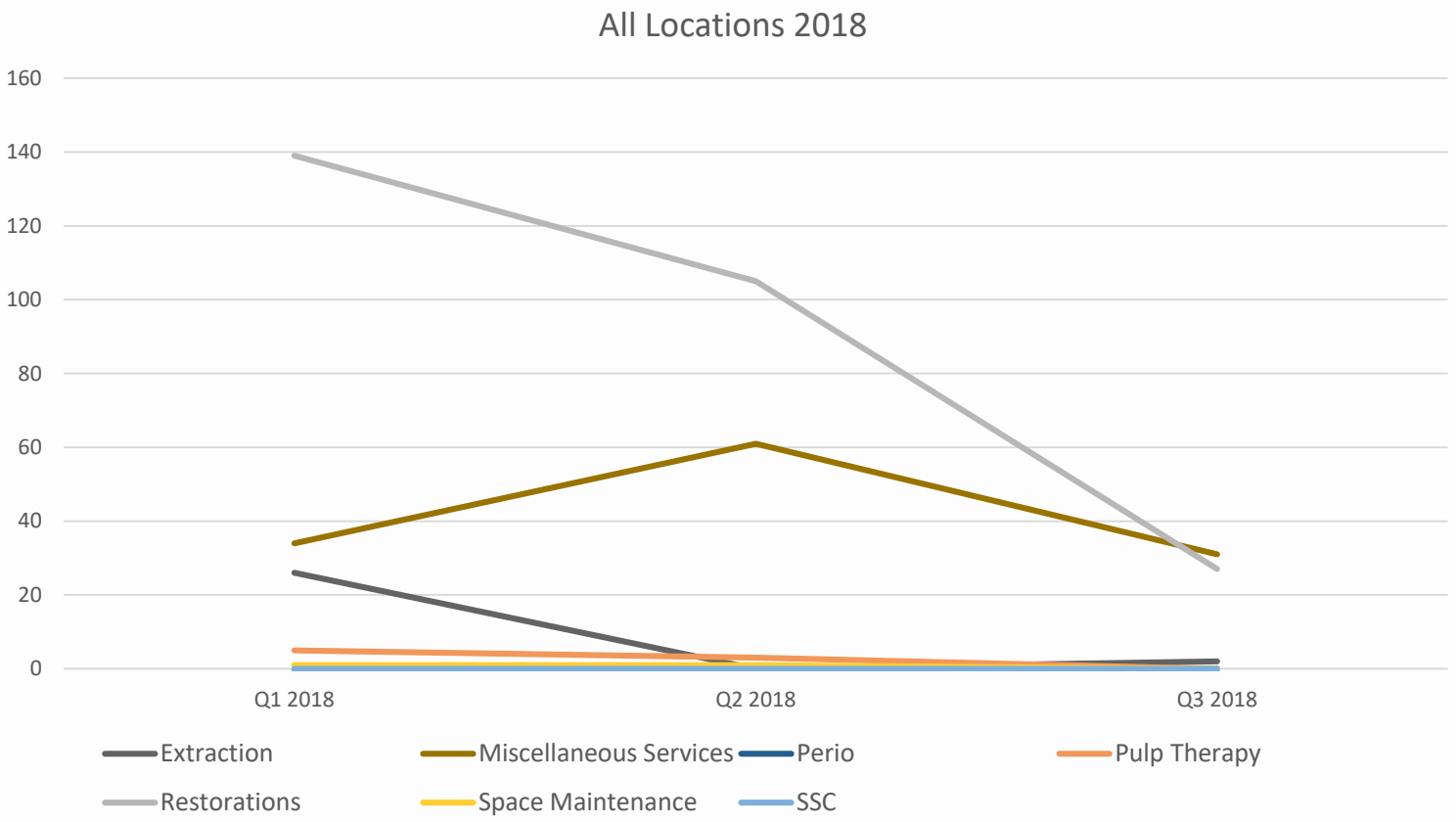
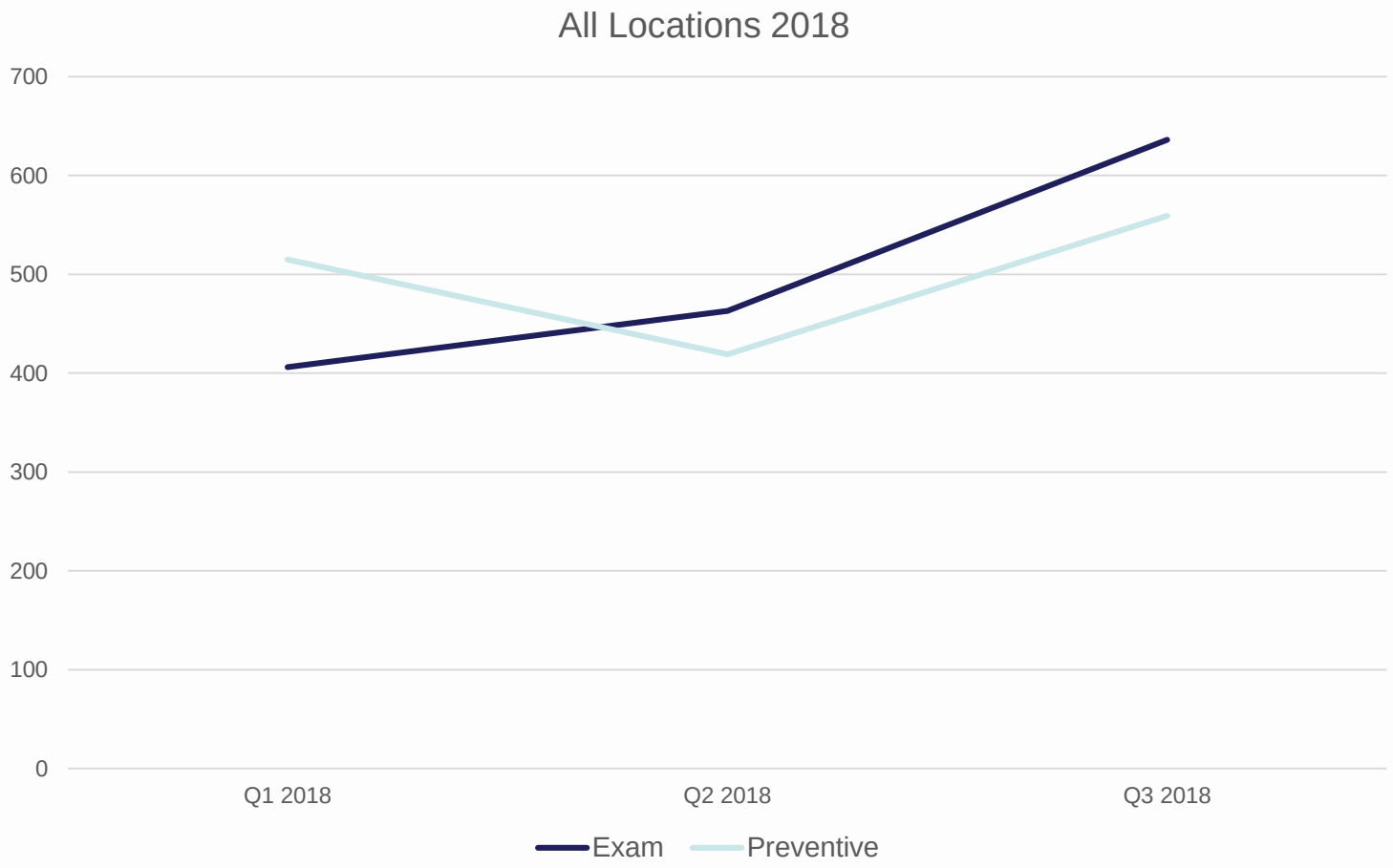
OHSU

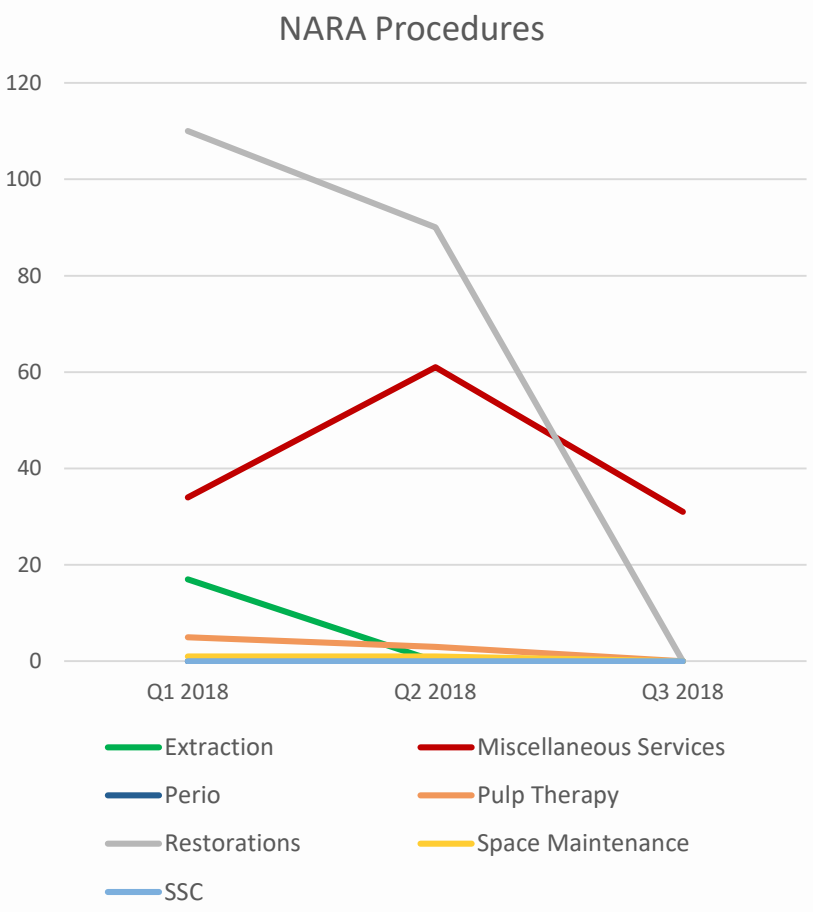
Thank You

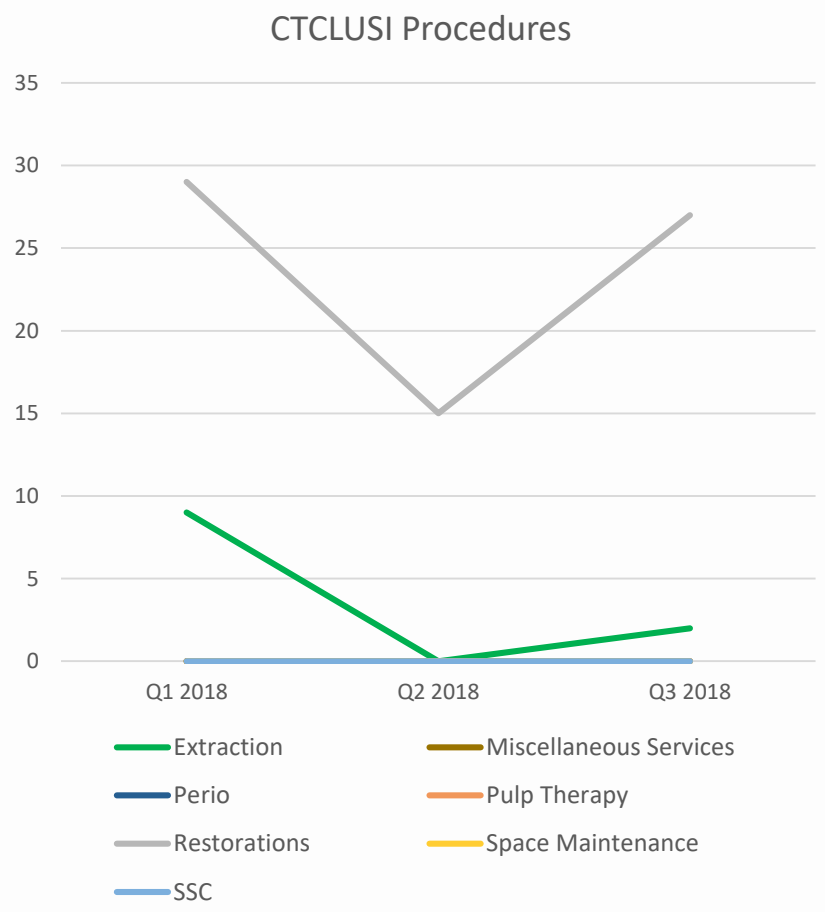
2018 Quarter 3 Data Summary

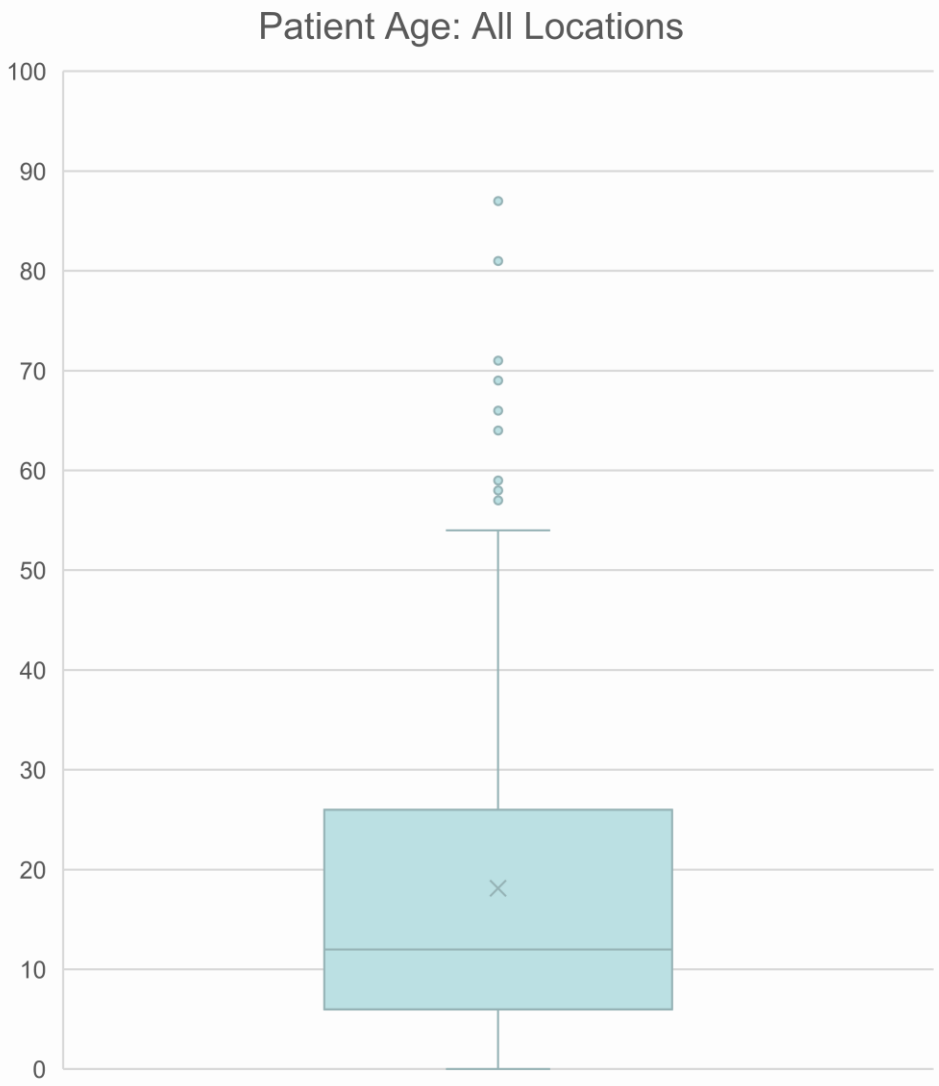
- There were 275 unique patients seen by DHATs at all locations in Quarter 3 2018.
  - DHATs at NARA saw 190 patients in Q3, representing 20% of the total patients seen in clinic (927).
  - DHATs at CTCLUSI saw 85 patients in Q3, representing 19% of the total patients seen in clinic (448).
  - The average patient age was 18 years old, while 60.4% of patients were 15 years of age or younger.
  - American Indian/Alaska Native patients are over-represented in the patient population compared to the general Oregon population. 41.5% of patients were identified as American Indian/Alaska Native (those identifying as AI/AN alone or in combination with another race made up 3.1% of the Oregon population in 2017). However, 39% of patient records did not report Race/Ethnicity.
  - There was an even sex distribution in the patient population: 50.2% of patients were Male.
  - 87.6% of patients had either Public or Tribal Insurance, while only 6.1% of patients were listed with Private Insurance.
  - 55.6% of patients seen in Quarter 3 were identified as new patients.
- In total, all three DHATs completed 636 exams, 2 extractions, 27 restorations and 559 preventive procedures in Quarter 3 2018.
- There were no Complications or Adverse Events reported.


All Locations 2018
160
140
120
100
80
60
40
20
0
Q1 2018
Q2 2018
Q3 2018
Extraction
Miscellaneous Services
Perio
Pulp Therapy
Restorations
Space Maintenance
SSC


All Locations 2018
700
600
500
400
300
200
100
0
Q1 2018
Q2 2018
Q3 2018
Exam
Preventive


NARA Procedures
120
100
80
60
40
20
0
Q1 2018
Q2 2018
Q3 2018
Extraction
Miscellaneous Services
Perio
Pulp Therapy
Restorations
Space Maintenance
SSC


CTCLUSI Procedures
35
30
25
20
15
10
5
0
Q1 2018
Q2 2018
Q3 2018
Extraction
Miscellaneous Services
Perio
Pulp Therapy
Restorations
Space Maintenance
SSC


Patient Age: All Locations
100
90
80
70
60
50
40
30
20
10
0

Dental Pilot Project Program

- Oregon Administrative Rules
  - Rules Advisory Committee (RAC) met June 11, June 25, July 9 & August 20
  - Public Comment Period
  - Public Hearing
  - Hearing Officer Report
  - Final Rules
    - Effective December 1, 2018

Dental Pilot Project Program

- Oregon Administrative Rules
  - Definitions
  - Application Process
  - Authority Responsibilities
  - Advisory Committee
  - Modifications

Dental Pilot Project Program

333-010-0700

Dental Pilot Projects: **Purpose**

(4) A dental pilot project that was approved and was operating before December 1, 2018 has until June 1, 2019 to come into compliance with the minimum standards in OAR 333-010-0760.

Dental Pilot Project Program

333-010-0710

Dental Pilot Projects: **Definitions**

(1) "Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable.

(7) "Complications" means a disease or injury that develops during or after the treatment of an earlier disorder.

(10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to populations that evidence has shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.

Dental Pilot Project Program

333-010-0710

Dental Pilot Projects: **Definitions**

(16) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist or dental hygienist:

(a) Licensed in the State of Oregon; or

(b) A dentist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 679.020 or 679.025; or

(c) A dental hygienist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 680.020.

(21) "Supervisor" means an individual, licensed in the State of Oregon to practice dentistry, designated by the sponsor to oversee trainees at each approved employment/utilization site, with the skills necessary to teach trainees the scope of practice outlined in the approved project.

Dental Pilot Project Program

333-010-0720

Dental Pilot Projects: **Application Procedure**

(3) The Authority will not accept new applications if it determines:

(a) There are a sufficient number of projects to provide a basis for testing the validity of the model as determined by the Authority.

(b) It does not have adequate resources to provide an appropriate level of oversight required by these rules.

Dental Pilot Project Program

333-010-0790

Dental Pilot Projects: **Authority Responsibilities**

(2) Advisory committee. The Authority may convene an advisory committee for each approved dental pilot project.

(a) Individuals eligible to serve on an advisory committee include but are not limited to:

(A) Representatives from:

(i) The Oregon Board of Dentistry;

(ii) Professional dental organizations or societies;

(iii) Educational institutions;

(iv) Health systems; and

(v) Individuals representing the target population served by the pilot project.

(B) Individuals with an interest in public health, oral health or expanding access to medical and dental care.

Dental Pilot Project Program

333-010-0790

Dental Pilot Projects: **Authority Responsibilities**

(b) The purpose of the advisory committee is to gather its members' collective knowledge, experience, expertise, and insight to assist the Authority in meeting its responsibilities.

(c) If the Authority convenes an advisory committee it will solicit members for an advisory committee by public announcement; Individuals interested in serving on the committee are required to complete an application.

(d) From the applications received, the Authority will appoint no more than 15 members who are willing to undertake the duties of an advisory committee member and adhere to the committee charter adopted by the Authority. The Authority will notify each applicant in writing whether they have been appointed to the committee.

Dental Pilot Project Program

333-010-0790

Dental Pilot Projects: **Authority Responsibilities**

(e) An advisory committee member must:

(A) **Attend meetings;**

(B) **Review approved pilot project quarterly reports at the request of the Authority;**

(C) **Attend approved pilot project site visits if invited; and**

(D) **Comply with any confidentiality requirements established by the Authority.**

Dental Pilot Project Program

333-010-0790

Dental Pilot Projects: **Authority Responsibilities**

(g) Following a site visit the Authority will:

(A) Within 60 calendar days, issue a written preliminary report to the sponsor of findings of the site visit, any deficiencies that were found, and provide the sponsor with the opportunity to submit a plan of corrective action;

(i) A signed plan of correction must be received by the Authority within 30 calendar days from the date the preliminary report of findings was provided to the project sponsor;

(ii) The Authority shall determine if the written plan of correction is acceptable no later than 30 calendar days after receipt. If the plan of correction is not acceptable to the Authority, the Authority shall notify the project sponsor in writing and request that the plan of correction be modified and resubmitted no later than 10 business days from the date the letter of non-acceptance was mailed to the project sponsor;

(iii) The project sponsor shall correct all deficiencies within 30 calendar days from the date of correction provided by the Authority, unless an extension of time is requested from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(iv) If the project sponsor does not come into compliance by the date of correction reflected on the approved plan of correction, the Authority may propose to suspend or terminate the project as defined under OAR 333-010-0820, Suspension or Termination of Project.

(B) Within 90 calendar days of receipt of a plan of correction, issue a final report to the sponsor; and

(C) If there are no corrections needed, the Authority will issue a final report within 180 calendar days.

Dental Pilot Project Program

333-010-0800

Dental Pilot Projects: **Modifications**

(1) Any modifications to an approved project shall be submitted in writing to program staff, except as specified in section (4) of this rule. All modifications require Authority approval. Modifications include, but are not limited to the following:

(a) Changes in selection criteria for trainees, supervisors, or employment/utilization sites;

(b) Addition of employment/utilization sites; and

(c) Changes in the scope of practice for trainees.

Dental Pilot Project Program

333-010-0800

Dental Pilot Projects: **Modifications**

(3) If the Authority has convened an advisory committee for an approved project, the Authority may confer with the advisory committee regarding the proposed modification.

(5) The Authority may approve or deny a request for modification. A modification may be denied if:

(a) It does not demonstrate that the project can meet the minimum standards or other provisions in these rules; or

(b) The modification would result in a substantial change to underlying purpose and scope of the pilot project as originally approved.

Dental Pilot Project Program

Current Roster

1. Leon Asseal, DMD
2. Len Barozzini, DDS
3. Jennifer Clemens, DMD, MPH
4. Paula Hendrix, M.Ed, RDH, EPDH
5. Kelli Swanson Jaecks, MA, RDH
6. Kyle Johnstone, MHA, RDH, EPP
7. Jill Jones, MS, RDH, EPP
8. Conor McNulty, CAE
9. Linda Mann, RDH, EPDH
10. Carolyn Muckerheide, DDS
11. Brandon Schwindt, DMD
12. Karen Shimada, MPH
13. Kenneth R Wright DDS, MPH

Dental Pilot Project Program

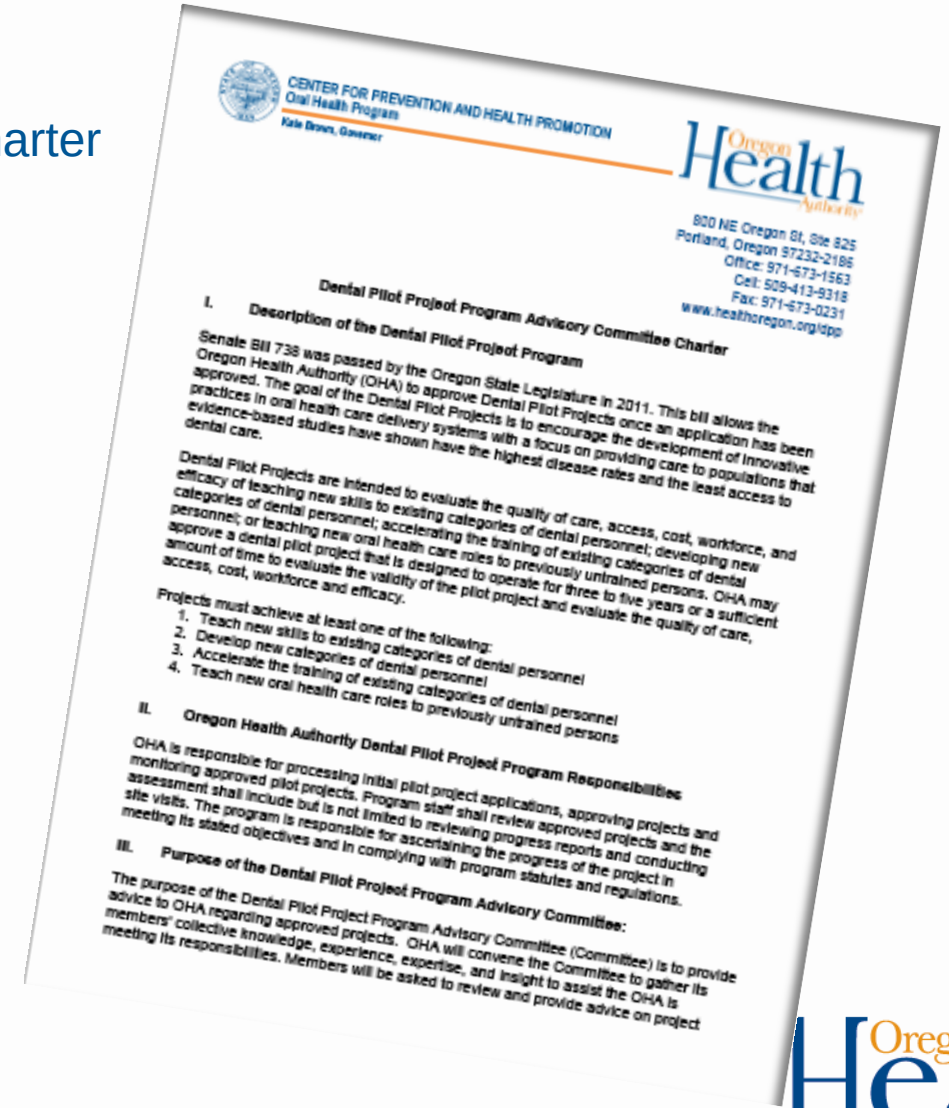
- Call for Applications in early 2019

Call for Applications

Oregon Health Authority

Dental Pilot Project Program

Advisory Committee Charter



CENTER FOR PREVENTION AND HEALTH PROMOTION
Oral Health Program
Kate Brown, Governor

Oregon Health Authority

800 NE Oregon St, Ste 825
Portland, Oregon 97232-2186
Office: 971-673-1563
Cell: 509-413-9318
Fax: 971-673-0231
www.healthoregon.org/dpp

Dental Pilot Project Program Advisory Committee Charter

I. Description of the Dental Pilot Project Program

Senate Bill 738 was passed by the Oregon State Legislature in 2011. This bill allows the Oregon Health Authority (OHA) to approve Dental Pilot Projects once an application has been approved. The goal of the Dental Pilot Projects is to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy of teaching new skills to existing categories of dental personnel; developing new categories of dental personnel; accelerating the training of existing categories of dental personnel; or teaching new oral health care roles to previously untrained persons. OHA may approve a dental pilot project that is designed to operate for three to five years or a sufficient amount of time to evaluate the validity of the pilot project and evaluate the quality of care, access, cost, workforce and efficacy.

Projects must achieve at least one of the following:

1. Teach new skills to existing categories of dental personnel
2. Develop new categories of dental personnel
3. Accelerate the training of existing categories of dental personnel
4. Teach new oral health care roles to previously untrained persons

II. Oregon Health Authority Dental Pilot Project Program Responsibilities

OHA is responsible for processing initial pilot project applications, approving projects and monitoring approved pilot projects. Program staff shall review approved projects and the assessment shall include but is not limited to reviewing progress reports and conducting site visits. The program is responsible for ascertaining the progress of the project in meeting its stated objectives and in complying with program statutes and regulations.

III. Purpose of the Dental Pilot Project Program Advisory Committee:

The purpose of the Dental Pilot Project Program Advisory Committee (Committee) is to provide advice to OHA regarding approved projects. OHA will convene the Committee to gather its members' collective knowledge, experience, expertise, and insight to assist the OHA in meeting its responsibilities. Members will be asked to review and provide advice on project

Dental Pilot Project Program

Chart Calibration Training

Reviewers Asked Question: Overall Impression of the Procedure

Ranked Score 1(worst)...2...3...4...5 (best)

Example:

	A	B	C	D	E	F	Average
Composite Restoration #26	5		4	2	1	4	2.75
Pulp Therapy #S	4	4		1		3	3
Extraction #D	2			3	2	5	3.00
Restoration #30	4		3	2	2	5	3
Restoration #3	4	3		1			2.7
A, B, C, D, E, F = Individual Chart Reviewers							

Nitrous Oxide Modification

Pilot Project #100

Current Nitrous Oxide Pilot Project Guidelines

- Presently, DHAT trainees are not allowed to administer or treat patients who are on nitrous oxide.
- At both CTCLUSI and NARA, there is a need to manage patients who may have dental anxiety

Current State Guidelines

- Arizona, Minnesota, and Vermont all have Nitrous Oxide as part of their dental therapy practice plan

Nitrous Oxide Modification

- NPAIHB requests the addition of Nitrous Oxide to the practice plan
  - Trainees must complete a training course of at least 14 hours of instruction in the use of nitrous oxide from a dental school or dental hygiene program in accordance with OAR 818-026-0040
  - Trainees must submit a completed nitrous oxide application to the Oregon Health Authority Dental Director
  - Trainees' supervising dentist must hold a valid (unexpired) nitrous oxide OBD permit

Nitrous Oxide Modification

- NPAIHB requests the addition of Nitrous Oxide to the practice plan
  - Nitrous Oxide will only be permitted under indirect supervision
  - Upon approval by OHA, DHATs may begin administering nitrous oxide or working on patients who are on nitrous oxide administered by a permitted provider
  - Patients will sign a DHAT treatment consent form and a nitrous oxide consent form for each visit

Thank you

Internal Dental Advisory Committee Introduction

Dr. Rachael Hogan

Background

- Chief Dentist, Swinomish Indian Tribal Community
- Member of Swinomish Dental Provider Licensing Board
- Supervising dentist for a Dental Health Aide Therapist for three years
- Member of Washington State Dental Association
- Arcora Foundation Board of Trustees
- Member of Internal Advisory Committee for Pilot Project #100

Purpose

Internal advisory committee meets quarterly and provides expertise and review of project components including:

- Clinical procedure protocols
- Data collection and use
- Policies that impact pilot success
- Modifications
- Overall project implementation

Members

- **Indian Health Service representative:**

Christopher G. Halliday, D.D.S., M.P.H. RADM (ret.), USPHS
Deputy Director, Division Of Oral Health, Indian Health Service HQ

- **NPAIHB EpiCenter representative**:

Victoria Warren-Mears, PhD, RDN, FAND
Director, Northwest Tribal Epidemiology Center

- **ANTHC representative:**

Mary Williard, DDS
Director, Alaska Dental Therapy Education Program
Alaska Native Tribal Health Consortium

- **Representative from institution currently educating other types of dental providers:**

Frank Catalanotto, DMD
Professor, Department of Community Dentistry and Behavioral Science, University of Florida College of Dentistry
Pediatric Dentist

- **Representative from each pilot site's health department:**

Kelle Little, RDN
Health and Human Services Administrator
Coquille Indian Tribe Community Health Center

Vicki Faciane
Health and Human Services Administrator,
Conf. Tribes of Coos, Lower Umpqua and Siuslaw Indians

Allyson Lacatsas
Director of Health Services, NARA

- **Community member from pilot sites:**

Chief Warren Brainard
Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians

- **Representative of a dental organization outside of pilot project:**

Rachael Hogan, DDS
Dental Director, Swinomish Indian Tribal Community
Arcora Foundation Board of Trustees

Current Issues

- Reviewed and provided comments to state on recent Pilot Rule Amendments
- Yearly review of data –CTCLUSI in August, NARA at next mtg.
- Review of Nitrous Oxide sedation modification request
- Primary teeth extraction criteria

NITROUS OXIDE APPLICATION FORM Pilot Project 100 (Adapted from the form used for Nitrous Oxide Permits by the State of Oregon)

Name_____

Mailing Address_____Business Phone _____

Business Address _____

City_____State_____Zip _____

Please note:

Any of the following will result in automatic rejection of the application and delay the application process:

- **Application must be completed on a typewriter or a computer.**
- **Copying or duplicating another's application in part or in total.**
- **Questions are not answered completely.**
- **Missing forms, certificates, or proof of training.**
- **Copying, cutting and/or pasting from other written material into the application or listing "see attached". (i.e., literature, DPA, publications). Applications must be completed using your own protocols.**

I have read and understand the above information: _____

SIGNATURE

I. TRAINING

1) Describe and **provide evidence of your formal training in nitrous oxide** (use additional sheets if necessary)
Use additional sheets if necessary

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

2) Describe the formal education and in-office training your anesthesia assistant(s) has/have:

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

3) Provide copies of your anesthesia assistant's (s') valid and current Health Care Provider BLS/CPR level, or its equivalent, course completion documentation.

4) Briefly describe your minimum training standards for personnel who assist you with anesthesia.

II. PREOPERATIVE

1) Briefly describe your preoperative evaluation procedures.

2) Describe your minimum health standards for nitrous oxide administration, how you document your preoperative evaluation.

3) List contraindications for nitrous oxide administration.

4) What pre-induction instructions do you give patients? Do you have an instruction sheet which you give the patient? (Attach a copy.)

5) Attach a copy of your informed consent form if you have one.

6) Attach a copy of your health history form.

III. OPERATIVE

Describe your nitrous oxide administration procedures, listing dosages used, and documentation of monitoring.

IV. POSTOPERATIVE

Describe your standards for discharge.

V. EMERGENCY

1) Describe your emergency protocol (i.e., time line or algorithm) and explain what responsibilities your staff members have.

2) Do you have regularly scheduled emergency drills? ☐ yes ☐ no If yes, how often? _____
Date of most recent drill. _____

3) Describe your emergency kit.

a) List the drugs it contains and what each drug is used for.

b) What airway emergency equipment is available?

c) How do you ensure emergency kit contents are kept current?

I certify that the above statements are true. I acknowledge that by applying to the OHA as part of Pilot Project #100 for the ability to use nitrous oxide, I consent to the conduct of office evaluations.

Signature_____ Date _____

Curriculum

The level of competence the trainee shall have before entering the employment/utilization phase of the project:

Trainees must successfully complete the *ADTEP* *program in order to begin the preceptorship at their home clinic with their supervising dentist.

The evaluation process used to determine when trainees have achieved the level of competence:

Once trainees *graduate from* training with the *ADTEP*, *meeting the requirements of CHPACB Section 2.30.610 (b) Competencies,* they will enter a supervised preceptorship with their supervising dentist at the pilot site clinic*, as defined by an Evaluation and Monitoring Plan approved by OHA:*

1. Supervising dentist monitoring during preceptorship.

During the 400-hour preceptorship, in which the dentist must directly supervise the DHAT, the web-based tracking form in Appendix D, will be filled out in order to evaluate the quality of each procedure. The DHAT is expected to perform the procedures eight times (unless otherwise noted on list), work independently each time, and in compliance with the established standards for review of each aspect of the procedure. If the DHAT has been recertified at least once by the AK CHAP Certification Board, they are only required to perform each procedure 4 times (unless otherwise noted on list) and complete an 80-hour preceptorship to demonstrate competency. DHATs in AK are recertified by the AK CHAP Certification Board every two years, and have to demonstrate competency in each procedure either 8 times or 80 hours under direct supervision of their dentist. There is also precedence of an 80-hour expedited preceptorship for recertified DHATs under the authority of the Swinomish Indian Tribal Community's Dental Health Provider Licensing Code.

The tracking form will allow the supervising dentist to rate the DHAT's work as acceptable, or unacceptable. For procedures marked "unacceptable" the supervising dentist will be required to fill out the notes section of the form indicating the relevant issues and a plan for correction.

At the end of the preceptorship, procedures that are rated acceptable on the final evaluation will be included in the practice plan agreement or "standing orders,"(Appendix G) allowing the DHAT to perform them under the supervision levels prescribed.

Below is a list of procedures that the DHAT has been trained to perform. Dental codes associated with these procedures are attached in Appendix E. DHATs should be able to

perform these procedures independently, with clinical competency. If any of the procedures are not performed at the clinic, or will not be a part of the DHAT practice agreement, it will be noted that in the final practice plan agreement. Experiences may be simulated if applicable and no appropriate patients are available.

In order to show maintenance of competencies, standing orders will be reviewed and signed every two years by the DHAT and the supervising dentist.*

The hours and months of the time required to complete the didactic and clinical phases:

The program is 22 months + supervised preceptorship.

Please see Appendix C for full curriculum descriptions and competencies required for graduation

Training and approval process for Nitrous Oxide sedation

ADTEP does not include Nitrous Oxide (NO) sedation in its curriculum. Pilot Project #100 sites currently use NO as standard of care, especially with pediatric patients, and it is in the best interest of the clinic and the patients they serve for trainees to able to also administer NO. Trainees must complete additional training in Oregon and receive approval from the Oregon Health Authority before NO can be added to their scope of practice and Practice Plan. Nitrous Oxide sedation will be limited to indirect supervision in the Practice Plan:

1. Trainees must have completed a training course of at least 14 hours of instruction in the use of nitrous oxide from a dental school or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association in accordance with OAR 818-026-0040 (1)(c).

2. Trainees' supervising dentist(s) must hold a valid Oregon Board of Dentistry Nitrous Oxide permit.

3. If trainees work on a patient who has been administered NO by another provider, that provider must hold a valid Oregon Board of Dentistry Nitrous Oxide Permit.

4. Trainees must submit a completed Nitrous Oxide Application Form (PN9a) and all accompanying materials to the Oregon Health Authority Dental Director. OHA will have 14 days upon receipt to approve or deny the application.

6. Upon approval, DHAT may start administering and/or working on patients who have been administered NO. DHAT Practice Plans will reflect OHA approval and specify indirect supervision required.

EDUCATIONAL REQUIREMENTS FOR NITROUS OXIDE DHAT ADMINISTRATION IN APPROVED PILOT PROJECT CLINICS

DHAT Trainees as part of pilot project 100 are not permitted to administer nitrous oxide **without documentation** of current training/education and/or competency in the category for which the applicant is applying.

The applicant may demonstrate current training/education or competency by any one of the following:

1. Initial training/education was completed within the **immediate two (2) years prior** to applying to use nitrous oxide within pilot project #100.
   - Provide documentation that training/education or competency in this area meets requirements of OAR 818-026-0040 (1)(c)

2. Initial training/education was completed within **the immediate five (5) years prior** to applying to administer nitrous oxide within pilot project #100
   - Provide documentation of all continuing education that would have been required for approved nitrous oxide use in Oregon during the five year period following initial training.
     - Nitrous Oxide 10 hours – OAR 818-026-0040(9)

   or

   - Provide documentation of completion of a comprehensive review course approved by the OHA Dental Director for Pilot Project #100 for the use of nitrous oxide to which the applicant is applying and must consist of at least one-half (50)% of the hours required by rule for Nitrous Oxide Administration (7 hours).

3. Initial training/education that was completed **greater than five (5) years immediately prior** to completing this form.

   - Provide documentation from another state that the applicant is licensed in that state and that the applicant holds the same permission to administer nitrous oxide being applied for in Oregon and provides documentation of the completion of at least 25 cases in the requested level of nitrous oxide administration.

   or

   - Demonstration of competency to the satisfaction of the OHA that the applicant possesses adequate nitrous oxide skill to safely deliver services to the public.

NITROUS OXIDE APPLICATION FORM Pilot Project 100 (Adapted from the form used for Nitrous Oxide Permits by the State of Oregon)

Name_____

Mailing Address_____Business Phone _____

Business Address _____

City_____State_____Zip _____

Please note:

Any of the following will result in automatic rejection of the application and delay the application process:

- **Application must be completed on a typewriter or a computer.**
- **Copying or duplicating another's application in part or in total.**
- **Questions are not answered completely.**
- **Missing forms, certificates, or proof of training.**
- **Copying, cutting and/or pasting from other written material into the application or listing "see attached". (i.e., literature, DPA, publications). Applications must be completed using your own protocols.**

I have read and understand the above information: _____

SIGNATURE

I. TRAINING

1) Describe and **provide evidence of your formal training in nitrous oxide** (use additional sheets if necessary)
Use additional sheets if necessary

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

2) Describe the formal education and in-office training your anesthesia assistant(s) has/have:

TITLE OF COURSE	DATE	HOURS (CLINIC)	HOURS (CLASSROOM)	SPONSORING INSTITUTION OR LOCATION

3) Provide copies of your anesthesia assistant's (s') valid and current Health Care Provider BLS/CPR level, or its equivalent, course completion documentation.

4) Briefly describe your minimum training standards for personnel who assist you with anesthesia.

II. PREOPERATIVE

1) Briefly describe your preoperative evaluation procedures.

2) Describe your minimum health standards for nitrous oxide administration, how you document your preoperative evaluation.

3) List contraindications for nitrous oxide administration.

4) What pre-induction instructions do you give patients? Do you have an instruction sheet which you give the patient? (Attach a copy.)

5) Attach a copy of your informed consent form if you have one.

6) Attach a copy of your health history form.

III. OPERATIVE

Describe your nitrous oxide administration procedures, listing dosages used, and documentation of monitoring.

IV. POSTOPERATIVE

Describe your standards for discharge.

V. EMERGENCY

1) Describe your emergency protocol (i.e., time line or algorithm) and explain what responsibilities your staff members have.

2) Do you have regularly scheduled emergency drills? ☐ yes ☐ no If yes, how often? _____
Date of most recent drill. _____

3) Describe your emergency kit.

a) List the drugs it contains and what each drug is used for.

b) What airway emergency equipment is available?

c) How do you ensure emergency kit contents are kept current?

I certify that the above statements are true. I acknowledge that by applying to the OHA as part of Pilot Project #100 for the ability to use nitrous oxide, I consent to the conduct of office evaluations.

Signature_____ Date _____

INFORMED CONSENT PLAN:

Our mission is to connect tribal communities with innovative approaches to address AI/AN oral health inequities, to remove barriers currently impeding tribal communities from creating efficient, high quality, modern dental teams and to provide opportunities for AI/AN people to become oral health providers.

In order to be successful, we need both strong support from tribal leadership and communities and from the broader community/state where tribes are located. Due to the intense and constant nature of the opposition from the American Dental Association and State Dental Association and the vast resources of these associations, it is necessary to stay vigilant ensure that accurate information is being shared on a regular basis with communities where pilot projects will be operating.

The goals of our informed consent plan is to educate communities, stakeholders and the general public in order to assuage fears, ensure that clients have the information they need and are notified before receiving services, and create a supportive environment in Oregon for our pilot projects**. Before services are ever provided by a DHAT we plan to educate and build awareness in our pilot communities about what DHATs are, their benefits, what services they can provide, their training, and information about the documented quality and safety of services provided by DHATs.**

Additionally, during scheduling, patients will be informed that they will be seen by a DHAT or DHAT Trainee. At that point they will have the ability to request to be seen by a dentist. Additionally, any patient who comes to the clinic and wishes to be seen by a dentist and not a DHAT or DHAT trainee will be able to make that request

- *Written informed consent will be obtained by each pilot project site for treatment performed by the Dental Health Aide Therapist (DHAT) trainee in the pilot project. A copy of the signed and dated form will be stored in the patient record.**

- *Written informed consent will be obtained by each pilot project site for the following procedures: nitrous oxide sedation, silver diamine fluoride and oral surgery procedures. A copy of the signed and dated form will be stored in the patient record.*

- *Verbal informed consent will be obtained and documented in the chart for all other procedures the trainee is authorized to complete as part of the approved pilot project application and evaluation & monitoring plans. Verbal consent will follow the process documented in the submitted PARQ Informed Consent document submitted by the project.*

***Appendix D** includes written informed consent templates for DHAT providing services (both during and after preceptorship), the informed consent forms for Nitrous Oxide sedation, SDF, and oral surgery for each clinic, and the PARQ document that is to be used as a guide to receive verbal consent for all other procedures.*

*Italicized language from August 2018 amended application

Confederated Tribes of the Coos, Lower Umpqua, and Siuslaw Indians Dental Clinic

1245 Fulton Ave. Coos Bay, OR 97420 (541)888-6433

Nitrous Oxide Sedation Consent Form

Patient Name: _____

Introduction: Nitrous oxide is a colorless, slightly sweet gas that is used during dental treatment for relaxation and anxiety relief. When inhaled, it can induce feelings of euphoria and sedation. It also can produce sensations of drowsiness, warmth, and tingling in the hands, feet and/or the mouth. In the dental setting, it will not induce unconsciousness. You will be able to swallow, talk, and cough as needed.

Contraindications: Please let us know if you have any of the following medical conditions because we may not be able to safely use nitrous oxide: congestive heart failure, chronic obstructive pulmonary disease (COPD), chronic bronchitis, emphysema, bronchiectasis, pregnancy, tuberculosis, macrocytic anemia, immune diseases, respiratory diseases, middle-ear infections, history of substance abuse, multiple sclerosis, epilepsy, or are taking medication for erectile dysfunction. Also, if you suffer from claustrophobia, you may choose not to use nitrous oxide.

Preoperative Guidelines: Nitrous oxide is administered through a nasal mask. You must be able to breathe through the nose (blocked nasal passages, colds, etc., defeat the idea of using nitrous oxide for relaxation). Nitrous oxide may cause "stomach butterflies" (nausea) which may result in vomiting. On the day of your appointment do not take any other sedatives unless prescribed by your dentist.

Instructions During Nitrous Use: Your mask must remain firmly in place during the entire period. Do not breathe through your mouth. Breathe through the nose only. Notify the doctor or hygienist if you are experiencing difficulty breathing through your nose. You cannot talk while nitrous oxide is being used. Talking blows nitrous oxide into the room air, lessening the desired effect for you and exposing the dental staff to the nitrous effects.

Postoperative Guidelines: Recovery from nitrous oxide sedation is rapid. The gas will be flushed from your system with oxygen. If you feel dizzy after the sedation, remain seated. The sensation usually passes in a few minutes. Do not leave the office until your head feels clear and you are able to function (i.e., walk and drive) safely.

Risks of nitrous oxide: You may feel nauseated, dizzy, drowsy, or claustrophobic during and after sedation.

Alternatives to Nitrous Oxide: You may choose not to use nitrous oxide and complete your dental treatment without addressing your anxiety. Or if your dentist feels it is an option for you, you may choose to take an oral sedative or pill that will relieve your anxiety. You may withdraw your consent to nitrous oxide at any time.

I understand the above statements and have had my questions answered. Plans for use, alternatives for use, and risks associated with use have all been addressed. I hereby give consent to be administered nitrous oxide.

Patient Signature: _____ Date: _____

Informed Consent for Nitrous Oxide

Indication for use of Nitrous Oxide or “laughing gas” is being administered to help control the anxiety of the patient during dental treatment.

- It is the intent of this procedure to relax the patient only, not to put them to sleep
- Gagging may be reduced
- Patient may cry during treatment, but they will be given a local anesthetic to block pain

I understand that the administration of nitrous oxide has hazards, risks, and potential side effects. They include but are not limited to:

- Excessive perspiration, sweating, and/or feeling flush
- Excessive talking, laughing, nervousness, anxiousness, disassociation, and/or hallucinations
- Shivering/chills, tingling, lightheadedness, and/or heavy feeling followed by feeling of floating
- Nausea and vomiting
- Impaired speech, mental performance, and motor reflexes
- Medical conditions including: hypotension (decrease in blood pressure), apeana, (occasional pause in breathing), respiratory suppression, diffusion hypoxia (short-term reduction in oxygen supply to lungs immediately following Nitrous Oxide use), and adverse reproductive effects.

The dentist/hygienist discussed with me and I understand that nitrous oxide is optional and is not required for dental treatment. The benefits of nitrous oxide include, but are not limited to, reducing or preventing fears and anxieties that may precipitate other medical problems including fainting, racing heartbeat, panic attacks, hyperventilation, or other heart related disorders.

The consent is valid: ( ) Today only ( ) for current treatment plan

Please mark any of the following conditions you have:

( ) Pregnancy
( ) B12 deficiency
( ) Acute otitis media
( ) Inadequate hemoglobin Levels
( ) Cystic fibrosis
( ) Medication sensitivities
( ) Chronic Obstructive Pulmonary Disease
( ) Emphysema
( ) Chronic bronchitis
( ) Recent Alcohol use, narcotics or street drugs

I consent and understand the above procedure and agree to cooperate with my dental team. I will follow post-operative instructions to the best of my ability for my own comfort and safety. I have had an opportunity to ask questions about the above treatment.

Patient/Parent or Legal Guardian Date Provider Date

Dental Therapist CDT Billing Codes: DPP #100 Scope of Practice

Red = new to list March 2018 (accepted) Highlighted = not on NPAIHB submitted list Blue= Strike Through/Denied(Not Accepted) Highlighted Green=proposed NO modification

Prophylaxis	
D1110	Prophylaxis adult
D1120	Prophylaxis child
Fluoride	
~~D1203~~	~~NOT IN 2018 CODES~~
~~D1204~~	~~NOT IN 2018 CODES~~
D1206	Topical fluoride varnish; therapeutic application for moderate to high caries risk patients
D1208	Topical application of fluoride - excluding varnish
Other Preventative Services	
D1310	Nutritional counseling for control of dental disease
D1320	Tobacco counseling for the control and prevention of oral disease
D1330	Oral hygiene instructions
Sealants	
D1351	Sealant per tooth
D1352	Preventive resin restoration in a moderate to high caries risk patient – permanent tooth
D1353	Sealant repair - per tooth
D1354	Interim caries arresting medicament application
Spacers	
D1510	Space maintainer - fixed - unilateral
D1515	Space maintainer fixed bilateral
D1550	Re-cement or re-bond space maintainer
D1555	Removal of fixed space maintainer – procedure performed by dentist or practice that did not originally place the appliance
Radiology	
D0210	Intraoral complete series (including bitewings)
D0220	Intraoral periapical; first film
D0230	Intraoral periapical; each additional film
D0240	Intraoral occlusal film
D0250	Extra-oral - 2d projection radiographic image created using a stationary radiation source, and detector.
D0260	Extraoral; each additional film
D0270	Bitewing; single film
D0272	Bitewings; two films
D0273	Bitewings; three radiographic images
D0274	Bitewings; four films
D0277	Vertical bitewings; 7 to 8 films

D0290	Posterior, anterior or lateral skull and facial bone survey film
D0330	Panoramic film
D0350	2D oral/facial photographic image obtained intra-orally or extra-orally
Tests and Laboratory Examinations	
D0460	Pulp vitality tests
D0601	Caries risk assessment and documentation, with a finding of low risk
D0602	Caries risk assessment and documentation, with a finding of moderate risk
D0603	Caries risk assessment and documentation, with a finding of high risk
ART	
D2940	Protective restoration
D2941	Interim therapeutic restoration – primary dentition
Perio	
~~D4341~~	~~Periodontal scaling and root planning – four or more teeth per quadrant~~
D4355	Full mouth debridement to enable comprehensive evaluation and diagnosis
D4381	Localized delivery of antimicrobial agents via a controlled release vehicle into diseased crevicular tissue, per tooth
Evaluation	
D0120	Periodic oral evaluation established patient
D0140	Limited oral evaluation problem focused.
D0145	Oral evaluation for a patient under three years of age and counseling with primary caregiver
D0150	Comprehensive oral evaluation new or established patient
D0170	Re-evaluation limited, problem focused (established patient; not postoperative visit)
D0171	Re-evaluation – post-operative office visit
D0190	Screening of a patient
D0191	Assessment of a patient
Amalgam Restorations	
D2140	Amalgam; one surface, primary or permanent
D2150	Amalgam; two surfaces, primary or permanent
D2160	Amalgam; three surfaces, primary or permanent
D2161	Amalgam; four or more surfaces, primary or permanent
Resin Restorations	
D2330	Resin; one surface, anterior
D2331	Resin; two surfaces, anterior
D2332	Resin; three surfaces, anterior
D2335	Resin; four or more surfaces or involving incisal angle (interior)
D2390	Resin based composite crown, anterior
D2391	Resin based composite; one surface, posterior
D2392	Resin based composite; two surfaces, posterior
D2393	Resin based composite; three surfaces, posterior
D2394	Resin based composite; four or more surfaces, posterior
	Stainless Steel Crowns

D2930	Prefabricated stainless steel crown primary tooth
D2931	Prefabricated stainless steel crown permanent tooth
D2932	Prefabricated resin crown
D2933	Prefabricated stainless steel crown with resin window
D2934	Prefabricated esthetic coated stainless steel crown – primary tooth
	Pulpotomy
D3110	Pulp cap; direct (excluding final restoration)
D3120	Pulp cap; indirect (excluding final restoration)
D3220	Therapeutic pulpotomy (excluding final restoration) – removal of pulp coronal to the dentinocemental junction and application of medicament
D3221	Pulpal debridement; primary and permanent teeth
D3230	Pulpal therapy (resorbable filling) – anterior, primary tooth (excluding final restoration) – Primary incisors and cuspids
D3240	Pulpal therapy (resorbable filling) – posterior, primary tooth (excluding final restoration) – Primary first and second molars
	Extractions
D7111	Extraction, coronal remnants deciduous tooth
D7140	Extraction, erupted tooth or exposed root (elevation and/or forceps removal)
	Emergency Tx Pain
D9110	Palliative (emergency) treatment of dental pain minor procedures
	Telemedicine Presentation
D0140	Limited oral evaluation problem focused.
	Miscellaneous Services
D9991	Dental case management - addressing appointment compliance barriers
D9992	Dental case management – care coordination
D9993	Dental case management – motivational interviewing
D9994	Dental case management – patient education to improve oral health literacy
D2920	Re-cement or re-bond crown
D9230	Inhalation of nitrous oxide

Dental Therapist Chart Review Form

This form is designed to help support the evaluation of dental therapists with the NPAIHB after completion of the preceptorship. Please only fill out the relevant sections of this form.

Each section has a scoring criteria of "Acceptable" and "Unacceptable." Within each section, a short description of what that means is included. This form is specifically for CHART REVIEWS.

Score of <70% are considered a fail. The dental program may use this tool for education and training of their staff members.

Adapted from:
APPENDIX III
INDIRECT REVIEW OF CLINICAL QUALITY
CHART REVIEW
United States Indian Health Service

AND
Nitrous oxide requirements for the State of Oregon

* Required

Email address *

Your email

Dental Therapist Name *

This is the dental therapist who provided the treatment that is being reviewed.

Choose

Evaluating Provider's Name *

This is the name of the person completing the chart review.

Choose

Organization *

Choose

Date of Service *

Date of service must be recorded for auditing purposes.

MM DD YYYY

/ / 2018

Date of patient's last comprehensive exam

Required if patient has had an exam. If patient does not have an exam on file (eg, emergency) leave blank."

MM DD YYYY

/ / 2018

Unique ID *

Defined by NPAIHB - Ideally should be to pair an ID that can be crosswalked into Dentrix

Your answer

Every Visit

1) Completed and Signed Medical History Updated
A health questionnaire completed by the patient and signed by the provider within the past 12 months is present and documentation exists that it was reviewed at each visit with the changes or the phrase “no changes” recorded. Medical alerts are highlighted.

2)Precautions appropriate for Physical Status
For patients with American Society of Anesthesiologists (ASA) Physical Status (PS) classifications 2-5, appropriate measures have been taken to ensure patient safety and appropriate treatment. (e.g.- blood pressure, blood sugar, consultations when necessary) See ASA website for PS definitions: http://www.asahq.org/clinical/physicalstatus.htm

3) Appropriate Codes
Appropriate ADA codes are recorded (including tooth number and surface when appropriate) and documentation exists in the progress note to justify all codes.

4) Complete Progress notes (paper or digital)
Dental Progress Notes include:
a. date of treatment
b. signature of the provider(s)
c. printed or stamped name of provider(s)
d. degree of the provider(s)

5) Auxillary Initials
Progress notes indicate that dental auxiliaries initial the direct patient care procedures performed.

6) Disposition (NV)
Dental progress notes include a disposition at the end of each visit. Next appointment, further dental needs - the purpose is to demonstrate continuity of care.

7) Informed Consent
Documentation of informed consent is present for appropriate procedures as defined by the facility. Informed consent includes documentation of discussion of risks, benefits, and alternatives to treatment.

8) Pain Documentation
Patient’s pain has been assessed, documented, and adequately addressed and/or managed.

9) Appropriate images made -- per NPAIHB plan. See link: <url here>

Every Visit

	Acceptable	Unacceptable	NA
Completed and Signed Medical History Updated	○	○	○
Precautions appropriate for Physical Status	○	○	○
Appropriate Codes	○	○	○
Complete Progress notes	○	○	○
Disposition (NV)	○	○	○
Auxillary Initials or Name Recorded	○	○	○
Informed Consent	○	○	○
Pain Documentation	○	○	○
Appropriate images made of irreversible procedures	○	○	○

Every Visit Comments

This field is REQUIRED to be filled out in the event that any areas in the above section do not receive acceptable scores to better monitor performance.

Your answer

Exam and Radiography

1) Radiographs: Type and Frequency Meet Guidelines
The types and frequency of radiographs meet clinic policies and are consistent with ADA/FDA guidelines. Copies of the guidelines can be obtained at:
http://www.ada.org/prof/resources/topics/topics_radiography_chart.pdf and
http://www.ada.org/prof/resources/topics/topics_radiography_examinations.pdf

2) X-rays read
Documentation that radiographs have been read exists in the patient record.

3) Hard tissue findings recorded
All hard tissue findings (pathology, abnormalities) are recorded in the dental record.

4) Soft tissue findings recorded
Evidence of soft tissue exam is present, either by listing of abnormalities or designation of "STN" (Soft Tissues Normal) or "WNL" (Within Normal Limits).

5) Periodontal status
The record of patients receiving a complete dental exam contains CPITN/PSR scores and a written diagnosis by ADA-Case Type (Gingivitis, Early Periodontitis, Moderate Periodontitis, or Advanced Periodontitis), based on probing and radiographic evidence.

5) Orthodontic status (age 6-20)
Orthodontic status (for patients ages 6 to 20) is noted on the dental exam sheet.

6) Treatment Plan created
Written treatment plan exists for all patients receiving initial or recall dental exams.
a. Treatment plan is easily understood
b. Follows a logical sequence
c. Is revised as needed, revisions are dated and initialed

7) Notation of needed, unavailable services
If a full scope of services is not available at the facility, a chart notation is made that the patient has been informed of his/her need for treatment at another facility.

8) Follow up / recall consistent with need
The patient is placed in a recall program based on his/her individual risks and clinic resources, rather than arbitrary time intervals.

Exam and Radiography *

	Acceptable	Unacceptable	NA
Radiographs: Type and Frequency Meet Guidelines	○	○	○
X-rays read	○	○	○
Hard tissue findings recorded	○	○	○
Soft tissue findings recorded	○	○	○
Periodontal status and diagnosis	○	○	○
Orthodontic status (age 6-20)	○	○	○
Treatment Plan created	○	○	○
Notation of needed, unavailable services	○	○	○
Follow up / recall consistent with need	○	○	○

Exam / Radiography Comments

This field is REQUIRED to be filled out in the event that any areas in the above section do not receive acceptable scores to better monitor performance.

Your answer

Emergency Services

1) Emergency Treatment: Soap Used
“SOAP” or similar format is used for each dental emergency patient to document chief complaint, objective findings, diagnosis, and treatment plan in the patient record.

2) Emergency Treatment: Diagnosis consistent with findings
Diagnosis is consistent with subjective and objective findings.

3)Emergency Treatment: Tx consistent with Dx & appropriate.
Treatment is consistent with and appropriate for the diagnosis.

4) Emergency Treatment: Screening Exam (as part of limited exam)
Evidence of an intraoral screening exam is present for emergency patients, either by listing of abnormalities (e.g., gross caries, periodontal disease, soft tissue lesions) or “WNL” (within normal limits).

Emergency Services *

	Acceptable	Unacceptable	NA
SOAP Used	○	○	○
Diagnosis consistent with findings	○	○	○
Treatment consistent with diagnosis and appropriate	○	○	○
Screening exam (as part of a limited exam)	○	○	○

Emergency Services Comments

This field is REQUIRED to be filled out in the event that any areas in the above section do not receive acceptable scores to better monitor performance.

Your answer

Endodontic Services within DHAT Scope

1) Radiographs available
Preoperative and postoperative radiographs are available for each tooth receiving endodontic treatment.

2) Findings support diagnosis
Findings support the diagnosis and ruling out competing diagnoses are entered in the dental record.

3) Adequate documentation
Chart entries document the following
a. Relevant documentation such as medicament and restorative materials

4) Post-Op Instructions
Postoperative instructions and recommended follow-up care are documented appropriately.

Endodontic Services *

	Acceptable	Unacceptable	NA
Radiographs available	○	○	○
Findings support diagnosis	○	○	○
Adequate documentation	○	○	○
Post-Op Instructions	○	○	○

Endodontic comments

This field is REQUIRED to be filled out in the event that any areas in the above section do not receive acceptable scores to better monitor performance.

Your answer

Oral Surgery Services

1) Appropriate pre-op xrays
A preoperative radiograph showing the apex of each root is available for all teeth extracted.

2)Appropriate follow up for difficult procedures
Any documented difficult surgical procedure or untoward outcome has appropriate follow-up arranged.

Oral Surgery Services *

	Acceptable	Unacceptable	NA
Appropriate pre-op x-rays	○	○	○
Appropriate follow up for difficult procedures	○	○	○

Oral Surgery Comments

Your answer

Restorative and Pediatric Care

Restorative Care:
1) Materials used appropriately
Restorative materials are used appropriately for satisfactory esthetic results and as accepted for use by the ADA.

2) No Overhangs/Open Margins
Recent bitewing radiographs (no older than two years) show absence of obvious overhangs, open margins, or open contacts on restorations previously placed by the dental staff being evaluated.

3) Isolation Documentation
In cases where rubber dam is not used, the reason for non-use is documented. In clinics where there is no evidence of documentation of non-use of the rubber dam, the provider(s) should be questioned as to whether the rubber dam is used for all restorations.

Pediatric Care:
1) SSC's used appropriately
An SSC is provided or planned for each primary molar with three or more carious surfaces or pulp therapy, unless contraindications are documented.

2) Space Maintenance
The dental record indicates that space maintenance is provided or planned for each prematurely lost primary molar, or reason for non-provision is documented, and there is provision for appropriate recall (6 months or less).

3) Behavior and management documented (<6)
Documentation of the behavior for all children under the age of 6 is documented.
a. Behavior management techniques used and their level of effectiveness are documented.

Pediatric and Restorative Care *

	Acceptable	Unacceptable	NA
Materials used appropriately	○	○	○
No Overhangs/Open Margins	○	○	○
Isoluation Documentation	○	○	○
SSC's used appropriately	○	○	○
Space maintenance	○	○	○
Behavior and management documented (under 6)	○	○	○

Pediatric and Restorative Comments

Your answer

DRAFT CONTENT BELOW THIS LINE

All changes were made below this line

Nitrous Oxide

1) Nitrous Oxide consent obtained
Nitrous Oxide consent is completed and included in the patient record

2) Indication for nitrous documented
Indication for nitrous recorded in patient chart.

3) Pre op condition / vitals documented
Pre op condition consistent with patient that would benefit from nitrous oxide treatment.

4) Nitrous readings included in chart
As described.

5) Post operative vitals documented
Post operative blood pressure recorded in patient record

6) Post operative condition documented
As described

Nitrous Oxide

	Acceptable	Unacceptable	NA
Nitrous Oxide consent obtained	○	○	○
Indication for nitrous documented	○	○	○
Pre op condition / vitals documented	○	○	○
Nitrous readings included in chart	○	○	○
Post operative vitals documented	○	○	○
Post Op condition documented the same as pre-operative condition	○	○	○

Nitrious Oxide Comments

Your answer

A copy of your responses will be emailed to the address you provided.

SUBMIT

Never submit passwords through Google Forms.

Appendix G:
Dental Health Aide Therapist
Practice Agreement Template

In recognition of your completed education and demonstrated proficiency, as proscribed by the Community Health Aide Program Certification Board- Standards and Procedures, as amended, Section 2.30.600 (1) and (2) [Dental Health Aide Therapist Training and Education Requirements], achieved by graduating from:

_____ on_____

and by entering a clinical preceptorship under the direct supervision of a dentist as directed in Revised Appendix B of the Pilot Project #100 Evaluation and Monitoring Plan and updated in this Practice Agreement on _____

NPI number: _____

You are entering into this practice agreement, in accordance with the attached individualized instructions, to provide the services, treatments, disease prevention, and education outlined in the Community Health Aide Program Certification Board- Standards and Procedures, as amended, Section 2.30.610 (b)(3) [Dental Health Aide Therapist Training Supervision and Competencies; Competencies], performed to the standards set forth in your training and preceptorship.

This Practice Agreement allows for general or indirect supervision, as noted, in accordance with the attached individualized instructions, for every procedure listed, signed, and dated by both the supervising dentist and dental therapist. All procedures in the dental therapist scope that are not listed on this practice agreement require direct supervision.

Procedures that have been successfully demonstrated in accordance with Appendices B and D of the Pilot Project #100 Evaluation and Monitoring Plan can be added as they are completed, and performed under the supervision indicated in this practice plan during the preceptorship.

If in the event a new supervising dentist is assigned, each procedure listed in this Practice Agreement must be successfully demonstrated once to the new supervising dentist under direct supervision for a minimum of 80 hours.

Every two years this Practice Agreement must be reviewed, and each procedure listed in the Practice Agreement successfully demonstrated at least once to your supervising dentist for a minimum of 80 hours.

ALWAYS report to your referral doctor (or dentist) any variation from the typical presentation. If you are unsure of your assessment, report prior to providing treatment.

ALWAYS refer any conditions outside the scope of your training or practice agreement.

Appendix G:
Dental Health Aide Therapist
Practice Agreement Template

I understand my individualized Practice Agreement, and that it is limited by the above statements, and limited by the attached instructions. I understand these orders must be reviewed and re-signed by myself and my supervising dentist according to above instructions every 2 years after completion of my preceptorship and in the event a new supervising dentist is assigned.

_____ _____

Dental Health Aide Therapist signature Date signed

_____ _____

Supervising Dentist signature Date signed

- ☐ _____ has successfully completed his/her preceptorship achieving the minimum required hours (circle 80 or 400) and successfully demonstrated competency in each of the procedures listed in this practice agreement under direct supervision.
- ☐ _____ has successfully completed his/her 80 hour period of direct supervision with a new supervising dentist, successfully demonstrated competency in each of the procedures listed in this practice agreement under direct supervision.
- ☐ _____ has successfully completed his/her biennial review achieving the minimum required 80 hours of direct supervision and successfully demonstrated competency in each procedure listed in this practice agreement.

Supervising Dentist signature Date signed

_____

Supervising Dentist printed name

_____

Appendix G:
Dental Health Aide Therapist
Practice Agreement Template

Individual instructions:

Service	**Supervision: Instructions**	**CHAP-CB Standard**	**Dentist Initial and Date**	**DHAT Initial and Date**
Topical fluoride application	General: Providing topical fluorides, including gels, foam, varnish and rinses.	2.30.110		
Diet education	General: As it relates to oral health	2.30.110		
OHI	General: Oral hygiene instructions	2.30.110		
Taking medical and dental history	General: Problem- specific medical and dental history taking as it relates to oral health	2.30.210		
Charting	General: Dental charting and patient record documentation	2.30.210		
Sterilization	General: Instrument handling and sterilization procedures, maintain validation tests and logs	2.30.210		
Photographs	General: Intraoral and extraoral	2.30.210		
Sealants	General: Placement and maintenance using appropriate material, technique and occlusion	2.30.220		
Prophy	General: Toothbrush, hand scaling, ultrasonic or piezoelectric cleaning and rubber cup polishing of the coronal/ exposed surfaces of teeth **Report prior to treatment if:** • If pocketing is greater than 4 mm • If subgingival calculus is clinically or radiographically evident • If teeth have more than class I mobility • If bone loss is more than 10%	2.30.230		
Radiographs	General: Panoramic, extraoral, and intraoral	2.30.240		
ART	General: Use of hand instruments for excavation of gross caries. Mixing, placing and contouring appropriate restorative material • For teeth with asymptomatic decay	2.30.260		

	or clearly reversible pulpitis and patient behavior or equipment availability indicates • Or as initial caries control as part of a sequenced treatment plan			
SSC	General: Stainless Steel Crown prep, fit and placement • Deciduous teeth • Permanent teeth	2.30.550		
Restorations	General: Excavate and place restorations using material appropriate for patient and the tooth, with appropriate bonding agents when indicated: • Composites(Resin, RMGI and GI) • Amalgams Cusp protected amalgams	2.30.610		
Diagnosis and treatment of caries	General: Observations must be documented that support the assessment and a plan for treatment, not just restoration, must be written	2.30.610		
Pulpotomies	General: On deciduous teeth	2.30.610		
Uncomplicated extractions	Indirect: 1) All extractions will be performed under the indirect supervision of the trainee's dentist. Indirect supervision is defined under ORS 679.010 as supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed. 2) For primary and permanent tooth extractions, the DHAT will first receive and document authorization from the supervising dentist. 3) For primary teeth, the trainee may perform non-surgical extractions on teeth that exhibit some degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gumline, or needs to be sectioned for removal. 4) For permanent teeth, the trainee may perform non-surgical extractions of periodontally diseased teeth with evidence of bone loss and +2 degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gumline, or needs to be			

	sectioned for removal.			
Emergency services	General: To alleviate pain and infection	2.30.610		
Local anesthesia	General: For intraoral procedures	2.30.610		
Space maintenance	General: Recognize and treat conditions needing space maintenance	2.30.610		
Maintain dental equipment	General: Maintain and repair user-serviceable parts to typical fixed and portable dental equipment	2.30.610		
Community program development	General: Development and carrying out a community oral health education and disease prevention program	2.30.610		
Nitrous Oxide sedation	Indirect: Must have completed training in accordance with OAR 818-026-0040 (1)(c) and receive approval from OHA Dental Director	N/A		

NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD

Burns-Paiute Tribe
Chehalis Tribe
Coeur d' Alene Tribe
Colville Tribe
Coos, Suislaw & Lower Umpqua Tribe
Coquille Tribe
Cow Creek Tribe
Cowlitz Tribe
Grand Ronde Tribe
Hoh Tribe
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Muckleshoot Tribe
Nez Perce Tribe
Nisqually Tribe
Nooksack Tribe
NW Band of Shoshone Tribe
Port Gamble S'Klallam Tribe
Puyallup Tribe
Quileute Tribe
Quinault Tribe
Samish Indian Nation
Sauk-Suiattle Tribe
Shoalwater Bay Tribe
Shoshone-Bannock Tribe
Siletz Tribe
Skokomish Tribe
Snoqualmie Tribe
Spokane Tribe
Squaxin Island Tribe
Stillaguamish Tribe
Suquamish Tribe
Swinomish Tribe
Tulalip Tribe
Umatilla Tribe
Upper Skagit Tribe
Warm Springs Tribe
Yakama Nation

November 8, 2018

Dr. Bruce Austin, Dental Director
Oregon Health Authority
800 NE Oregon St.
Portland, OR 97232

Dear Dr. Austin,

Pilot Project #100 is requesting to modify our Dental Pilot Project Application and Evaluation and Monitoring Plan, to allow DHAT trainees to administer and treat patients on nitrous oxide (NO) under indirect supervision.

Justification: The Alaska Dental Therapy Education Program does not teach the use of NO as it is not a practical sedation method when DHATs are travelling to villages, and temperature control is unstable. The OHA Pilot Project #100 Advisory Committee has asserted that the use of nitrous oxide is best practice and that patients, especially pediatrics, in Oregon are best served if this form of sedation is an option. The pilot project sites currently use NO in their clinics, and we agree that it would be beneficial to patient and providers to enable this addition to the scope with the appropriate training, supervision and monitoring.

"The American Academy of Pediatric Dentistry (AAPD) recognizes nitrous oxide/oxygen analgesia/anxiolysis inhalation (minimal sedation) as a safe and effective technique to reduce anxiety, produce analgesia and enhance effective communication between a patient and the health care provider. Almost 90% of pediatric dentists administer nitrous oxide to their patients to reduce or eliminate anxiety and pain during dental procedures. Nitrous oxide/oxygen administration provides multiple benefits to both patient and dentist. For the patient, nitrous oxide/oxygen provides anxiety relief and analgesia (pain control) that is safe and quickly reversed with minimal side effects."[1]

We also believe adding this to the scope of practice is consistent with other states utilizing dental therapists. According to Minnesota 2009 Session Laws, Chapter 95, Article 3, Subd. 4, the scope of practice for a Dental Therapist includes the administration of nitrous oxide under general supervision.

Impact on the project: The goal of this modification is to expand the patient population the DHATs are able to treat including anxious adults, children, or those with special needs.

In order to ensure safety and trainee competence, the following summary of modifications are proposed to our Evaluation and Monitoring Plan. Explicit changes are attached with proposed modifications indicated in yellow highlight:

(Over)

2121 SW Broadway, Suite 300 · Portland, OR 97201
19201 L Street NW, Suite 420 · Washington, DC 20036
Main Office: (503) 228-4185 · Fax: (228) 228-8182 · www.npaihb.org

1. PN9 Training: Add requirement of OHA approval of NO sedation application, which includes completion of a 14-hour Nitrous Oxide Training course in compliance with OAR 818-026-0040.
2. IC1 Informed Consent: Add reference to NO consent forms
3. NO consent forms from both clinics (to be added to Appendix D)
4. Evaluation and Monitoring Plan Appendix E: Add NO sedation code to approved CDT code list
5. Evaluation and Monitoring Plan Appendix F: Add NO to chart review
6. Evaluation and Monitoring Plan Appendix G: Add NO to practice plan, stipulating only under indirect supervision, and only after completing training course in compliance with OAR 818-026-0040.

If you have any further questions or concerns, please contact Christina Peters, Native Dental Therapy Initiative Project Director or Dr. Gita Yitta, Pilot Project #100 Dental Director.

Sincerely,

Joe Finkbonner, RPh, MHA
Executive Director, Northwest Portland Area Indian Health Board

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[1] Use of Nitrous Oxide for Pediatric Dental Patients. Pediatr Dent. 2017 Sep 15;39(6):273-277.