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

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March 12, 2018

Eli Schwarz, DDS, MPH, PhD
Department of Community Dentistry
Oregon Health & Science University
3030 SW Moody Ave, Suite 135B
Portland, OR 97201

RE: Final Report for April 5, 2017 Site Visit

Dear Dr. Schwarz,

The Oregon Health Authority (OHA) conducted the first required site visit for Dental Pilot Project #200, "Training Dental Hygienists to Place Interim Therapeutic Restorations", on April 5, 2017 in Independence, Oregon.

The OHA Dental Pilot Project Program is responsible for monitoring approved pilot projects and ascertaining the progress of each project in meeting its stated objectives and complying with program statutes and regulations. The primary role of the Oregon Health Authority is monitoring for patient safety. Secondarily, OHA staff shall evaluate approved projects and the evaluation shall include, but is not limited to, reviewing progress reports and conducting site visits.

The OHA has determined that Dental Pilot Project #200 is in compliance with the requirements set forth in the Oregon Administrative Rules (OARs) 333-010-0400 through 333-010-0470 and therefore has **passed** the site visit. Below is an overview of the results from the site visit.

Dental Pilot Project (DPP) #200 Site Visit One: April 5, 2017

Materials and Methods

On April 5, 2017, OHA Dental Pilot Project Program staff and members of the Advisory Committee for DPP #200 visited one clinical site related to the utilization/employment phase of DPP #200: Independence Elementary School. This was the first site visit for DPP #200. Please see appendix A for site visit materials utilized and an abstraction of the project.

The site visit process was divided into two separate components: interviews with project participants and clinical record reviews. OHA program staff and participating Advisory Committee members were provided with evaluation tools to record their observations during the interview components. Please see appendix B for the evaluation tool templates.

Observations and Results
Below are the summarized results from interviews with project participants, the supervising dentist and expanded practice dental hygienist (EPDH) trainee.

Curriculum and Clinical Protocols: The training curriculum being used for the pilot project, "Guidelines for Placement of Interim Therapeutic Restorations" (ITRs), consists of a didactic online module developed by Paul Glassman DDS, MA, MBA, followed by lab in a clinical setting. In the clinical laboratory, dentists watch and oversee both radiographs and ITR placement. EPDH trainees were given three weeks to complete the online didactic portion of the training program. Webinars were developed and made available to answer specific questions. In the laboratory portion of training, EPDH trainees were required to complete five ITRs on a typodont with observation and five ITRs independently before being allowed to move on. Training materials are available online for future use of the EPDH trainee and supervising dentist(s), although project staff indicate that materials are rarely needed. Clinical protocols are freely available to EPDH trainees in electronic form and are included in appendix C.

EPDH Trainee(s): As of the site visit date, DPP #200 has included three participant EPDH trainees. Trainees are EPDHs that are hand-selected by Capitol Dental Care and project staff based on a history of quality performance, personal interest and location in the project areas. Two EPDH trainees have completed all required clinical and didactic training materials. Out of these two EPDHs, one trainee has been promoted to the utilization phase and is actively placing ITRs in the field. The other EPDH is awaiting future modifications to the project and plans to work in the project once it expands to sites closer to her home. The third EPDH trainee has yet to complete the training course and needs to present one final acceptable ITR to complete the clinical laboratory section of the training. This trainee plans to finish this requirement when she returns from maternity leave.

Meagan Newton, EPDH, is currently the only active trainee in the utilization phase of the project. She has been a licensed EPDH/RDH for three years with an initial licensure date of May 7, 2014. She reports that she generally works in school settings four days per week. Licensing information for each trainee is located at Capitol Dental offices. The overall scope of DPP #200 is relatively small, with trainees implementing a single procedure outside of the authorized scope of practice for an EPDH. She described the ITR as "easier than a sealant, the only new skill is scooping". She describes the procedure as easy to learn and felt that the training program prepared her to perform the ITR procedure with a high level of confidence. Ms. Newton reports that she has a good working relationship with the supervising dentist.

Supervising Dentist: Jennifer Clemens, DMD, is the current supervising dentist for the project, and she works as a general dentist at Smile Keepers Dental in Salem, OR. Dr. Clemens reports spending two days in clinic and one day in surgical centers per week. She indicated that she currently has a six-month waiting list for surgical restorative procedures. Her inspiration for participating in this pilot project is her desire to look at alternate ways to reach populations that are not currently accessing care – fixing the population health needs to start upstream. Dr. Clemens describes her duties as reviewing patient charts to identify patients qualifying for an ITR and being a support for the EPDH trainee and oral health in the community. Previous work experience in direct supervision with the trainee has been invaluable for their current working relationship. Dr. Clemens reports that the EPDH trainee's evaluations are accurate and comprehensive. She reports that, based upon charting and images, there is a high level of

confidence in the quality of patient care and ITR placement.
Process of Care: The approved Dental Pilot Project site in Polk County involves multiple school locations. The EPDH attempts to see as many patients in kindergarten through second grade at each school before moving on to the next location.

Patients are treated in a private area designated by the school using mobile dental equipment. Infection control procedures, found in appendix D, follow necessary requirements under OAR 818-012-0040. Dental instruments are sterilized offsite at the school-based health center.

Each patient with a positive informed consent form receives an evaluation and preventive services by the EPDH trainee who works under general supervision of the supervising dentist. The consent form template can be found in appendix E. The EPDH trainee makes recommendations based on an oral examination, radiographs and intraoral images that are then stored and forwarded to the supervising dentist who is located offsite. The supervising dentist is available by phone, text messaging and secure electronic communication through Denticon EHR software that is housed on an encrypted laptop.

After initial evaluation, diagnosis and approval from the supervising dentist, the patient is seen for the necessary procedures once the appropriate consent form is returned. A separate Consent to Perform Specific Procedures is sent to the parents if an ITR is required, and the child is treated later upon receipt of the signed consent form. This process may require two or three visits by the patient to receive the ITR procedure under the pilot project.

Patients receive a follow-up visit 3 to 6 months after treatment when the EPDH trainee returns to their particular school location. The follow-up visit evaluates the retention of the ITR and whether additional treatment or referrals are required. A retention check intra-oral photograph is taken and sent to the supervising dentist for assessment of the ITR as to whether it is still clinically acceptable based on ITR clinical protocols.

It was reported that most patients who need treatment receive one or two ITRs, although sometimes up to three are required on a single child. Both the EPDH trainee and the supervising dentist feel that the EPDH trainee is more conservative (or “gun shy”) than the supervising dentist in recommending an ITR, although they have a 95% agreement rate.

Competency: Competency assessment records are available for all EPDH trainees from the lab and clinical training. Comments and records of all procedures are adequately documented in patient records. Any complications or difficulties in procedure would be documented in electronic health records.

Complications: Complications from the ITR procedure would be seen over time for a variety of reasons. Examples include if there was accidental exposure of the pulp and subsequent pain and/or infection occurred. ITRs can also fracture and may require removal and/or repair using a dental drill by a dentist. Dental caries can also develop around the margins of the ITR over time. The project officials report no complications have occurred to date.

Clinical Records Review: Due to the small overall number of procedures completed thus far, OHA program staff reviewed a random convenience sample of 10 patient charts based upon summary data of all procedures completed so far. From these, full de-identified records for each chart number were provided by project administrators in advance of the site visit date and were

shared with members of the DPP #200 Advisory Committee for review. Between the beginning of the utilization phase and the time of the first site visit, 23 patients received a total of 33 ITRs by EPDH trainee Meagan Newton. The 10 randomly selected charts for review represented 10 patients (43.5 percent of all patients receiving ITRs) and 14 ITRs (42 percent of all ITRs placed). Within the chart review sample, 50% of patients were female and 50% were male. Patients' average age was 6 years. Of the 10 patients reviewed, five patients were on Medicaid insurance, two were uninsured, two were privately insured and one was unknown. 70% of charts reviewed were Hispanic/Latino.

Charts were reviewed by DPP #200 Advisory Committee members as subject matter experts and by the OHA Statewide Dental Director for signs of EPDH trainee competency and patient safety. All charts were reviewed for documentation of informed consent, basic patient encounter notes, radiograph and intraoral photograph quality, ITR placement, quality and retention. All charts reviewed were deemed acceptable according to criteria developed for assessment of the records, which can be found in appendix F. All charts adequately documented required processes, although it is recommended that the supervising dentist always sign recommendations in the chart notes.

External Evaluator: Dr. John Engle, a pediatric dentist at OHSU, currently fills the role of the external evaluating dentist. Dr. Engle works in the Department of Pediatric Dentistry at OHSU where his "responsibilities include both clinical and didactic oversight of predoctoral dental students as well as residents in [the] pediatric dental residency program at both the School of Dentistry as well as at Doernbecher Children's Hospital." After attending the clinical training, Dr. Engle now reviews both radiographs and pre-operative and post-operative clinical photos of selected patients. He refers to the clinical training as "a well-designed program [that] was structured to allow for ample discussion and reflection. All aspects of the training allowed for integration and input of dentists, hygienists and support staff."

In describing EPDH trainee quality of care (OAR 333-010-0410), Dr. Engle says, "While there were a couple of films that I would describe as 'fuzzy' due to patient movement, they all fell within the range of clinically acceptable based on criteria that we would normally use in our school clinics. [Post-operative intraoral digital images] were all excellent. I work with residents that take clinical photos, and I was impressed that the provided photos would rank alongside those of our residents." In evaluating criteria for successful completion of an ITR, "I look at the extent of changes in the enamel in the preoperative photo which will determine the expected outline form of the completed restoration. Once the ITR is placed, I judge its outline form and compare that with the expected form. I judge contours of the ITR to ascertain that the form of the material approximates that of the morphology of the tooth. Finally, I look at the surface characteristics of the ITR. Currently, I have reviewed 24 records. All of the reviewed photos demonstrated acceptable results. I had listed comments on the provided spreadsheet. Two or three of the restorations were seen to have some surface roughness which would not impact clinical performance." From these observations, Dr. Engle has not identified any performance weaknesses.

Alternate external evaluating dentists from the Department of Pediatric Dentistry at OHSU will continue to consult and provide evaluation on the project, as Dr. Engle is expected to retire in the near future. Please see appendix G for Dr. Engle's full remarks and a statement declaring any conflict of interest.

Identified Issues: The project reports that they have come across a few issues during the course of the project so far. Both the EPDH trainee and supervising dentist report encounters with patients who have rampant caries and question whether it is worth placing a single small ITR on eligible caries when the patient will likely require a much more intensive treatment plan, potentially including general anesthesia.

A second issue identified concerns barriers to contacting parents when they do not return consent to treat forms. The school secretary is an important factor in parent communication, as parents have a high degree of trust in familiar school staff. The school secretary works to assist the EPDH in obtaining consent. Unfortunately if parents do not respond to requests for consent to treat, the EPDH trainee and the school do not have the capacity to continue communication attempts after a third phone call.

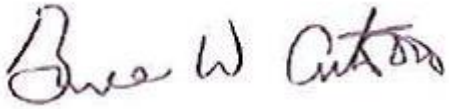
Site visit findings that need further clarification, require implementation in the pilot project, or require other follow-up:

- Signature of the provider or provider initials should be entered with each chart note to clarify who has entered the note into the EHR.
- Clarification on the procedures and sequence of steps for the process of communicating with the Supervising Dentist and EPDH should be written out in a procedure format and available for review by the OHA and the Advisory Committee.
- Emergency procedures should be clarified as to the sequence of steps taken when a child presents to the EPDH trainee with a dental emergency that requires immediate dental attention.
- OHA will work collaboratively with the project managers to provide a framework for reporting out adverse events. Per OAR 333-010-0435: Dental Pilot Projects: Evaluation and Monitoring, “A sponsor must report adverse events to the program the day they occur.” OHA will collaborate with the project managers to define adverse events under the approved project and what will necessitates the completion of an Adverse Event form (Appendix G).

Conclusion
The Oregon Health Authority has determined that Dental Pilot Project (DPP) #200 is in compliance with the requirements set forth in the Oregon Administrative Rules 333-010-0400 through 333-010-0470, and therefore has **passed** the site visit. (Appendix H)

While DPP #200 has passed the site visit, the project must respond to and follow-up with any site visit findings.

Sincerely,



Bruce Austin
Statewide Dental Director