



**Oregon Health Authority  
Dental Pilot Project Program  
Rules Advisory Committee**

**Date:** June 11, 2018

**Time:** 9:00 am - 11:00 am

**Location:** Portland State Office Building, 800 NE Oregon St., Room 1 A, Portland, OR 97232

**Attendees:**

**Committee Attendees:** Quanita Anwar (phone), Todd Beck, Jennifer Clemens, Shannon English, Christina Peters (phone), Hai Pham, Laura McKeane, James McMahan, Conor McNulty, Eli Schwarz, Heather Simmons (phone), Emily Wineland (phone)

**OHA Staff:** Bruce Austin, Kelly Hansen, Sarah Kowalski, Mauri Mohler, Amy Umphlett, Cate Wilcox

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All meetings are recorded and transcribed. \*\*\*\*\* indicate portions of the meeting that were not audible in the recording.

**Agenda Topic: Welcome and Introductions**

Meeting began at 9:04am. Committee Members and OHA Staff introduced themselves.

**Agenda Topic: Background Information; Brief Overview of the Rulemaking Process**

Ms. Kowalski provided background information on the Dental Pilot Project Program. The legislation in 2011, SB738 and 2016, SB606, which extended the sunset date of the program.

**Agenda Topic: Review Draft Amended Rules**

*Recording began under proposed text changes under Dental Pilot Projects: Purpose. The context of the beginning of this section relates to a question from a committee member regarding how long a currently approved and operating dental pilot project has to come into compliance with the amended rules.*

*Beginning of Transcription:*

Next Speaker Yeah. I mean that, that, so, so I think that, uh, \*\*\*\*. Well let me just say I mean, I, I would be mindful for 6 months to –

Next Speaker Or they could put a placeholder for now and then after \*\*\*\* the rules see how much needs to be changed \*\*\*\* –

Next Speaker Yeah.

Next Speaker – projects and we can always go back to that. Um, we'll just mark it up and \*\*\*\* 6 months \*\*\*\* right now.

Next Speaker Yeah. I can that would help \*\*\*\*.

Next Speaker I think it's a great plan.

Next Speaker So, so the thing is that, you know, the existing \*\*\*\* I hope that makes sense. I, \*\*\*\*. What we had decided is, is, is two dates –

Next Speaker Mm hmm.

Next Speaker – and then the next one would be in probably half a year from now. So I'm kinda, so let me be up front \*\*\*\* we would know that \*\*\*\*. So I would, I would suggest then that, that the, uh, at least the existing projects get their stuff from \*\*\*\* so that, that, the, we then have from that time within that 6 months to actually comply with \*\*\*\*.

Next Speaker Well and that sounds, the timing sounds about right. \*\*\*\* and then, then an additional 6 months or whatever.

Next Speaker For the, yeah, a year from now. \*\*\*\*. I think that would be –

Next Speaker \*\*\*\*.

Next Speaker \*\*\*\* as to the point, let's just keep going –

Next Speaker Yeah.

Next Speaker – 'cause there, there may not be as many changes as, uh, maybe \*\*\*\* –

Next Speaker: Yeah.

Next Speaker: – \*\*\*\*.

Next Speaker: Okay. Um, so we went down to \*\*\*\* definitions and we did not have a definition for adverse events in the, uh, original rules. So we did, uh, put this in here. Uh, this is No. 1, adverse event means \*\*\*\* plus a dental treatment regardless of whether it is associated with care or considered preventable.

Next Speaker: \*\*\*\*.

Next Speaker: When did you come up with that definition?

Next Speaker: \*\*\*\*.

Next Speaker: But the, if we could, uh, just walk down to five at the same time because it's –

Next Speaker: Yeah.

Next Speaker: – \*\*\*\* comes from the same body of thinking.

Next Speaker: Yeah. Yeah.

Next Speaker: And, and I was kinda wondering if we actually need a definition of complications.

Next Speaker: That is a question?

Next Speaker: Yes.

Next Speaker: Do you wanna expand on it?

Next Speaker: Yeah. Um, and how it's different than adverse events.

Next Speaker: Sure.

Next Speaker: Complications can vary from, you know, an abscess \*\*\*\*. You know, adverse outcomes to treatment and so if you've been a, you've always, I mean, when we have standards, we measure those, um, whether, you know, \*\*\*\* 6 months \*\*\*\* have, um, \*\*\*\* and so, yes, I think it does mean \*\*\*\*.

Next Speaker: And I don't think a complication is the same as an adverse outcome. I mean a complication is somethin' that you'd have to \*\*\*\* it doesn't necessarily mean \*\*\*\*.

Next Speaker: Mm hmm.

Next Speaker: So I think they need separating.

Next Speaker: Yes.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* adverse outcome is \*\*\*\* complication?

Next Speaker: Well, I think an adverse outcome can come from a complication. Um, but if there is unwanted outcome – and we have all kinds of flowery names to make them sound not so bad –

Next Speaker: Yeah.

Next Speaker: – but I do a root canal and I hurt \*\*\*\* that is a complication. Now, does that lead to an adverse outcome? \*\*\*\*.

Next Speaker: Right.

Next Speaker: What is considered an adverse outcome?

Next Speaker: The adverse outcome \*\*\*\*.

Next Speaker: Say that again.

Next Speaker: Adverse event would be different than adverse outcome.

Next Speaker: I would think that adverse event would \*\*\*\* like to an, a complication.

Next Speaker: Right.

Next Speaker: It's something that happens. But the result of what happens is the outcome and I think that's what we're and \*\*\*\* speak for it, but –

Next Speaker: Well, one is adverse event and \*\*\*\* complications. So I think that there's \*\*\*\*. Maybe it still needs to get \*\*\*\*.

Next Speaker: Well, would adverse be \*\*\*\*?

Next Speaker: Ad, ad, adverse outcome.

Next Speaker: Would that be \*\*\*\*?

Next Speaker: I think so because an adverse complication is that sort of \*\*\*\* like a, the bad horrible?

Next Speaker: Yeah.

Next Speaker: Okay. So, if you change the language from adverse event to adverse \*\*\*\* –

Next Speaker: It would be –

Next Speaker: It would be the difference in the \*\*\*\*.

Next Speaker: – and making sure that you have the word complication \*\*\*\*.

Next Speaker: Okay. So, I think we're gonna find that later throughout \*\*\*\* you do refer to adverse event. So, so, \*\*\*\*.

Next Speaker: And that's one of the things with, where I guess, \*\*\*\* –

Next Speaker: Yeah.

Next Speaker: – time in that document right there is we make a change and then we spend the next, you know, 10 hours talking about where it, you know, –

Next Speaker: Yeah.

Next Speaker: – every place it's noted we have to change that as well and yeah, \*\*\*\* yes.

Next Speaker: \*\*\*\*.

Next Speaker: Well, I, I think \*\*\*\* two questions about \*\*\*\* adverse events and, and, \*\*\*\* whatever we're gonna call any complications. The language regardless of whether it's associated with errors, does this

mean that dental, that the dental providers in the project will be held responsible for adverse events that are not of their causing?

Next Speaker: \*\*\*\*.

Next Speaker: No. I still think this would be \*\*\*\* liability. It just defines adverse outcome and, and it points out that it's not because of a shortcoming of providers and \*\*\*\* that sometimes it's a provider's fault and sometimes things happen.

Next Speaker: Well, and I just asked because it is also my understanding that sometimes complications are not the result of treatment either and I would ask the clinicians in the room if all, I mean, is it, is, is it possible that there could be, you know, patient behavior and other things like that, that could lead to complications or, you know, I just, I, I think it's important to have these things defined but I wonder, um, I, I wanna make sure that the providers in the dental pilot projects are not held to a standard that is impossible to meet. Like, if they, if, if none of their patients can have complications without having ramifications on the project or ramifications on them as providers but I mean, they, they shouldn't be practicing healthcare because complications and other things like that happen.

Next Speaker: Hi. This is Todd Beck. Um, and yes, I am in private practice. 22 years in, uh, Board of Dentistry and \*\*\*\* does not in any way indict a practitioner. It's something that's noted in the chart as an event or an outcome. Most of the complaints that we get at the Board of Dentistry, where someone has alleged poor treatment, we find that there is no poor treatment. That it's not the fault of the practitioner. It's poor \*\*\*\* which is just sort of the way the patient is or patient complaints, patient behavior. It was a bad day. People make mistakes. We're not, I have no desire personally and I don't think anyone on this committee or our Board of Dentistry does, to hold these practitioners at a higher standard than me, but I do expect to hold them to the same standard as me and I think these words, these definitions need to be in place so that we can set those standards.

Next Speaker: Right. This is Bruce Austin, I do have the \*\*\*\*, I this, this is basically \*\*\*\* but it's tracking health notes especially with the \*\*\*\* of consent.

Next Speaker: Okay, so, next, um, number three says clinical evaluator; it means the dentist licensed in Oregon or another state who is responsible for conducting a clinical evaluation of an improved dental pilot project who's unaffiliated with the project and has no financial or commercial interest in the project's \*\*\*\*. And this came, um, it was not \*\*\*\* in the rules, the original rules, and there was some, we found that part of the purpose of the pilot \*\*\*\* evaluating the clinical efficacy, patient safety, quality and not just looking at, um, patient's \*\*\*\*. There's \*\*\*\* areas to \*\*\*\* and would have the \*\*\*\* in my \*\*\*\*.

Next Speaker: All right. This is how \*\*\*\*, um, I personally appreciate the evaluation and the \*\*\*\* reports. I think you understand that a clinical evaluator may be effective \*\*\*\*. But, what about \*\*\*\*? \*\*\*\*?

Next Speaker: Um, so the, can I, uh, respond to that briefly?

Next Speaker: Uh, this is Kelly Hansen, \*\*\*\* who's a dentist and he, there are some things that \*\*\*\* in the past about using the word "evaluator" multiple times. They're still a separate program evaluation content \*\*\*\*.

Next Speaker: Maybe you'll get \*\*\*\* definitions. \*\*\*\* and we'll talk about that. But I do agree that there is \*\*\*\*, that \*\*\*\* this program evaluator, evaluate the discussions, um, \*\*\*\*, not evaluation plan.

Next Speaker: \*\*\*\* to were \*\*\*\* away. It's a clinical piece in the overall \*\*\*\*.

Next Speaker: This is Christian Peters. I had a question. Uh, if a project doesn't \*\*\*\* language, I mean I, obviously, his strength has that \*\*\*\* clinical evaluations, but what about \*\*\*\*, what if those projects are found highly within like the \*\*\*\* practice of an \*\*\*\*. Or, I mean, do you think that there could be found room for having credible evaluators for \*\*\*\* within their scope just because after they do a higher \*\*\*\* stuff like this would, I mean, I \*\*\*\* an independent evaluator, but, dentists are pretty expensive and they're very busy and if you're a chiropractor \*\*\*\* scope of \*\*\*\* could be or some \*\*\*\* future, um, it might be \*\*\*\* for them to have that option of having another clinical evaluator.

Next Speaker: So, this is Sarah Kowalski, the reason that I would say no to that is that the purpose is very spanning in scope into an area as a person is being in practice on a hygienist work \*\*\*\*. So, first we have the \*\*\*\* scope would be the dentist. So they're –

Next Speaker: The \*\*\*\* expanding the practice of a dental, of a dental assistant.

Next Speaker: \*\*\*\*.

Next Speaker: That was just, I have information \*\*\*\*. Yeah.

Next Speaker: I'm not understanding. So what you're asking is rather than having a dentist be an eval – this is \*\*\*\* – rather than having a dentist be an evaluator, a clinical evaluator having an expanded function, hygienist support assistant be an evaluator?

Next Speaker: No, I'm saying, I'm saying it doesn't absolutely for, for \*\*\*\* projects, the dentist will be probably be the appropriate evaluator. But whether your project is teaching a couple of skills to a dental assistant and all of that project also \*\*\*\* dental hygienist or the standard prac, practice dental hygienist, I'm saying why not expand the – the group can be a clinical evaluator based on the scope of the project, not just a happy dentist be, because it's a much smaller project, and it's within the scope of practice of the dental hygienist. I think it would be reasonable to have a dental hygienist for that project as an evaluator; not every project, but I mean that –

Next Speaker: Can you, can you –

Next Speaker: – specific project.

Next Speaker: – yeah, yeah, this is, this is Todd Beck Can you –

Next Speaker: \*\*\*\* so that \*\*\*\*?

Next Speaker: – can you give an example of what you're talking of project? I mean, just a rough example, broad strokes of a project that you would think that a dentist should not be involved in. It should be either the expanded function, hygienist support assistant so I can better understand what you're asking.

Next Speaker: Well, I'm not saying should not be involved in \*\*\*\* giving options to the project themselves. But, you know, let's say there's some type of scalings that a dental assistant could be trained to do, and maybe that's one procedure they're going to teach to the dental assistant. I mean, I think that, that a dental hygienist could oversee that project and could very well evaluate that project.

Next Speaker: Okay. All right, well, we've made some notes. Let's move on.

Next Speaker: And I think we also need to keep in mind overall for these rules, they need to be able to \*\*\*\* project and \*\*\*\*.

Next Speaker: I think that's a very good point, yes. So \*\*\*\* it, it sounds like we do want to have \*\*\*\*. Some people want \*\*\*\* discuss that in the next meeting.

Next Speaker: For the \*\*\*\* –

Next Speaker: Probably, 'cause the evolution of an adverse outcome kinda –

Next Speaker: So I, I, I'm adverse \*\*\*\*, I'm adverse \*\*\*\*.

Next Speaker: I would like \*\*\*\* –

Next Speaker: \*\*\*\*.

Next Speaker: – \*\*\*\*.

Next Speaker: Okay.

Next Speaker: Yeah, it sounds like we're using all these \*\*\*\*, so it'd be nice \*\*\*\*.

Next Speaker: Yeah, \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: So moving on to, um, the next page. Um, \*\*\*\*. No. 7, this is a, a \*\*\*\* for dental project manager. Uh, \*\*\*\* individual who is actively responsible for oversight of the dental \*\*\*\* project for the dentist license \*\*\*\*. Anybody have any questions about that?

Next Speaker: Uh, \*\*\*\*. Do we, do we have \*\*\*\*? Do we have time to \*\*\*\* project managers?

Next Speaker: My, –

Next Speaker: I think –

Next Speaker: – my guess is \*\*\*\*. Given the number of projects that we have, it's not like we're doing 100 projects.

Next Speaker: But, but I, I \*\*\*\*, uh, I just don't like this simply because, um, the project manager \*\*\*\* in general are not actually educated pe, project managers. And, uh, –

Next Speaker: \*\*\*\*.

Next Speaker: – we have several examples of that not doing well. Uh, but, um, uh, what I actually \*\*\*\* is that \*\*\*\* in a lot of \*\*\*\* structure and so on and so forth. And I'm not sure that the project manager needs to be \*\*\*\*. The project manager who supervises that the project runs on time, that the, uh, reports go back to the, to the state, that, uh, all these things happen. Uh, um, I would not choose \*\*\*\* for this purpose for sure.

Next Speaker: Okay.

Next Speaker: So there needs to be a project manager that could be a project manager, but that person does not \*\*\*\* system. I don't see what the \*\*\*\* is going to do in this, in this \*\*\*\*.

Next Speaker: Maybe \*\*\*\* requirement \*\*\*\* consultant, and they don't \*\*\*\*.

Next Speaker: So from looking \*\*\*\*, I think we need to look at seven and 15 together and maybe draw some different lines. I think the intent of \*\*\*\* the dental project manager is assure them that the project has a practicing dentist \*\*\*\* with the project. But I appreciate what you're saying to me about the day-to-day running and supervising and doing the reports is probably not the best of the templates. So maybe we can look at that together with the project director and maybe redefine them a little bit.

Next Speaker: So where do these things \*\*\*\*? 'Cause I haven't \*\*\*\*. Uh, can you point me to where these things actually appear in the rules \*\*\*\* different project \*\*\*\*? Uh, –

Next Speaker: It's probably in the \*\*\*\*.

Next Speaker: – project \*\*\*\*.

Next Speaker: The application \*\*\*\*.

Next Speaker: In the application part. Yeah.

Next Speaker: Um, and we need to get \*\*\*\*.

Next Speaker: Yeah. Because I'm, I'm aware that this is the, the \*\*\*\*. You know, sometimes when you \*\*\*\* this information, \*\*\*\* the whole \*\*\*\* that would define the rule \*\*\*\*. But \*\*\*\* have any meaning when you actually get to the actual rules. And I just feel that, that the, this becomes very kind of \*\*\*\*. Um, the, and we need to consider whether it actually \*\*\*\*.

Next Speaker: I think there's many non-clinician dental people that could be excellent project managers that don't have to be dentists.

Next Speaker: \*\*\*\*.

Next Speaker: I mean, it's \*\*\*\* here because there is, um, –

Next Speaker: \*\*\*\*.

Next Speaker: There needs to be a dentist as well.

Next Speaker: Right.

Next Speaker: That's, that's –

Next Speaker: For the safety of the project, I think that there needs to be dentist onboard. And, and so –

Next Speaker: And maybe we don't necessarily refer to this as project manager, \*\*\*\* project manager.



Next Speaker: So if we jump down to No. 15, \*\*\*\* actually a project manager.

Next Speaker: Yeah.

Next Speaker: \*\*\*\*.

Next Speaker: As, as I understand it, I just want to make \*\*\*\* that part of the clarifications that have been required to this point is that \*\*\*\* this is an important facilitator in the process of \*\*\*\* clinical aspects that someone who's a project manager or \*\*\*\*, that's where \*\*\*\* confusion and clarification required \*\*\*\*. Just clarifying that on the record, uh, \*\*\*\* project manager \*\*\*\*.

Next Speaker: So, uh, you know, it's sometimes easier if we think of \*\*\*\*, um, other than \*\*\*\*. So \*\*\*\* project would be established by – I mean, as we have the two at the moment, but that could be some other project, obviously. It all has to do with training a \*\*\*\* or new \*\*\*\* groups or, or something like that. Um, and the dentists see – I mean, you know, our system is obviously the top of the layer of cake essentially. I mean, because \*\*\*\* some of the ultimate \*\*\*\* dentistry \*\*\*\*. So I can understand that \*\*\*\*. Underneath that, there is in whole bunch of \*\*\*\*. There is a, a supervising \*\*\*\*. There is an external evaluating \*\*\*\*. But to actually ensure that all these, uh, components and elements run \*\*\*\*, uh, clearly, has nothing to do with \*\*\*\*. And, and I just feel that we think, think of it in a very practical sense, and I don't mind having a \*\*\*\* for any pilot project. And a pilot project needs to have a \*\*\*\* or dentist who \*\*\*\*. That's why. Uh, underneath that, we really need to think a little bit of creating \*\*\*\* was creative thinking. So, I mean, to actually trying to get back into \*\*\*\*, you know, where, uh, \*\*\*\*, I mean, that's sort of, it's totally counter to what the thinking was on the \*\*\*\* went into practice. So, so –

Next Speaker: So I think if we clean up the language on No. 17 with \*\*\*\* director, and then look at No. 15 as a project manager \*\*\*\*, creating those role definitions and we can address \*\*\*\*.

Next Speaker: Mm hmm.

Next Speaker: What you said under the \*\*\*\* identical clinical \*\*\*\* so.

Next Speaker: And this is Christina Peters and I, you know, not to belabor the point about hygienists but if a pilot project falls within the scope of practice, that the, completely within the scope of practice of an \*\*\*\* dental hygienists or a dental hygienist I think that we should leave room in the rules for um, extended function of dental hygienists or dental hygienists to also be leading projects and overseeing projects if um, if the scope of this project is within their scope of practice.

Next Speaker: \*\*\*\* should be – it wouldn't be in that pilot project, though, if they're already in the scope of this you wouldn't need to apply it to the \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah. \*\*\*\*.

Next Speaker: But it would be a \*\*\*\* training, say a dental assistant to do something within the scope of practice of a hygienist. Like it, it – I'm not saying a dental hygienists are the, are the subject of the \*\*\*\* project \*\*\*\* but they, they go get high school students and they teach them how to do cleanings, right? That would be something that his dental hygienist could oversee theoretically.

Next Speaker: Okay. We'll \*\*\*\* that \*\*\*\* good.

Next Speaker: All right.

Next Speaker: So next um, in this new – the definitions or, and we look at number 10 and employment/utilization site, means an authority approved by the site \*\*\*\*. The site may be \*\*\*\* a multiple of patients and includes any setting where dental healthcare services are provided by trainees and the facilities are programs described in um, the \*\*\*\* language and to make it clear what that was referencing that, that's from the other rules but just so that you know that that meant you can \*\*\*\* comments here. The reason we were changing this and explaining this was um, each site, like the NARA site the \*\*\*\* had a project to \*\*\*\* or one hundred is uh, it's a NARA site \*\*\*\* of \*\*\*\* different locations where their individual name \*\*\*\* provide services to – for the purposes of their evaluation. \*\*\*\* any sense. Do you have any questions about that?

Next Speaker: Just a clarification.

Next Speaker: And the next new area here is um, \*\*\*\* number 12, no number 13. \*\*\*\* speak to that.

Next Speaker: Uh, so we just want to \*\*\*\* clear definition of what program evaluation \*\*\*\* speak back to \*\*\*\* of \*\*\*\* evaluation \*\*\*\* um, and we just want to have a clear concise definition of \*\*\*\* recommendations?

Next Speaker: \*\*\*\* up recommendations to the next \*\*\*\* –

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: This is \*\*\*\* responsibilities. What does OHA have to do?

Next Speaker: With \*\*\*\* foundation \*\*\*\* –

Next Speaker: Yes \*\*\*\* –

Next Speaker: \*\*\*\* of the program?

Next Speaker: That's \*\*\*\* –

Next Speaker: \*\*\*\* about the program and who the program \*\*\*\* us and/or informed decisions about \*\*\*\* program \*\*\*\*>

Next Speaker: \*\*\*\*.

Next Speaker: Mm hmm

Next Speaker: Yeah.

Next Speaker: That's been this way for the entire \*\*\*\* –

Next Speaker: \*\*\*\* and that's, that \*\*\*\* –

Next Speaker: Okay.

Next Speaker: \*\*\*\*. Um, and then the next time to kind of go on this is number 16 is project evaluation. This is the definition of what the project should be doing. Whether they contract um, external or \*\*\*\* –

Next Speaker: It, it's so much duplicative \*\*\*\* definitions.

Next Speaker: Are they different?

Next Speaker: \*\*\*\* evaluations.

Next Speaker: Yeah, \*\*\*\* –

Next Speaker: \*\*\*\* matter.

Next Speaker: – what is, what is a, what is a program evaluation that is done by you?

Next Speaker: I –

Next Speaker: Uh, is done by somebody about the program of the dental pilot project –

Next Speaker: Okay \*\*\*\* –

Next Speaker: – as a whole program.

Next Speaker: – as a program and \*\*\*\*.

Next Speaker: And the project – is each of the title projects and I would suggest that we use the same definition um, but I also found that additional evaluations should be practical and feasible and conducted –

Next Speaker: Right.

Next Speaker: – within the confines of resources, time and political process. \*\*\*\* and moral issues \*\*\*\* program \*\*\*\* which I think would be great to have \*\*\*\* evaluation \*\*\*\*. What do you think about this?

Next Speaker: That's –

Next Speaker: CDC.

Next Speaker: That CDCs, they \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: I thought you made that up, you \*\*\*\*.

Next Speaker: \*\*\*\* disabled was \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: I would probably have \*\*\*\* I \*\*\*\* –

Next Speaker: Actually \*\*\*\* brilliant so, yeah. \*\*\*\* knows too much \*\*\*\*.

Next Speaker: Um, okay, so moving on. Um, let's go to the next page here. \*\*\*\* you did define trainee as it was not defined \*\*\*\*. Um –

Next Speaker: Quick question for you before you go on, Sarah. So number 17 under sponsor – so currently we have that project in place that's sponsored by Northwest, I think that's –

Next Speaker: Do we need to add that language in there to clarify that something like that can be a sponsor or is it incorporated in the language that's currently written here?

Next Speaker: Uh, it's incorporated \*\*\*\* in a language because they provided health, health services so they technically fell into the uh, \*\*\*\* community \*\*\*\*. Okay so, is – and this actually \*\*\*\* clarify this specific language in here we added I think two years ago the rules were opened up to add in coordinated care, organization or dental care organization because that didn't exist in 2011 \*\*\*\*.

Next Speaker: Okay \*\*\*\*.

Next Speaker: This is Christina. I would just um, I would just add \*\*\*\* to number 17, tribal organization or tribal clinic just so it's clear then the tribes are all provided to participate and that it includes \*\*\*\* tribe.

Next Speaker: \*\*\*\*?

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* tribal organization. That word tribal, it's okay?

Next Speaker: Okay uh, trainee uh, is defined. Does anybody have any questions \*\*\*\* number 20? And the language is pretty much taken from SB738 to define what \*\*\*\*.

Next Speaker: So under usually in employment utilization \*\*\*\* it would be the same thing as we would think of as uh, uh, our uh, \*\*\*\* our uh, when we send students out in the field they're – uh, that's what that would include. I guess my question is so the training program, it has to include um, a \*\*\*\* phase, a clinical phase and then this employment utilization phase or this residency phase that that's optional depending on – 'cause it says and usually an employment phase. So to me usually suggests option. Is that –

Next Speaker: Um, \*\*\*\* okay.

Next Speaker: – I'm just, I'm just curious.

Next Speaker: Yeah.

Next Speaker: I don't really have an opinion, I'm just curious what \*\*\*\*.

Next Speaker: So um –

Next Speaker: \*\*\*\* –

Next Speaker: Sure, sure –

Next Speaker: \*\*\*\*.

Next Speaker: I can tell you that the employment/utilization phase is the part where they're practicing on – working on patients.

Next Speaker: \*\*\*\*.

Next Speaker: They're not entering their \*\*\*\* –

Next Speaker: It's kind of \*\*\*\* –

Next Speaker: So –

Next Speaker: And that's where the pilot project itself –

Next Speaker: Okay.

Next Speaker: – it's like the actual work like – they've gone through the training and now they're off of the site um, and they're doing actual \*\*\*\*.

Next Speaker: But they're still being evaluated um, during that time?

Next Speaker: Yeah.

Next Speaker: And –

Next Speaker: For the purposes of –

Next Speaker: – and that lasts a certain amount of time?

Next Speaker: Nope. The \*\*\*\* pull the project.

Next Speaker: The entire \*\*\*\* projects themselves to – are a demonstration project not a license to operate. These are all \*\*\*\* –

Next Speaker: And so –

Next Speaker: \*\*\*\*.

Next Speaker: – well –

Next Speaker: \*\*\*\*.

Next Speaker: One of these \*\*\*\* are \*\*\*\* you gotta go through this program. Then once they fall into this phase where they're, you know, under employment here, still being evaluated by someone or someone's and that goes on until the state of Oregon decides that they want to officially have the \*\*\*\* of provider and it gets put into statute and whoever is the authority like the EOP or someone were to –

Next Speaker: Sort of.

Next Speaker: – yeah, I'm just, I \*\*\*\* wanna know –

Next Speaker: That is the \*\*\*\* –

Next Speaker: – there has to be an end point –

Next Speaker: There is a –

Next Speaker: – \*\*\*\* program.

Next Speaker: – there is an end point because they –

Next Speaker: \*\*\*\* –

Next Speaker: – all been approved from \*\*\*\* –

Next Speaker: Okay, okay.

Next Speaker: – \*\*\*\* this one um, I can't remember \*\*\*\* –

Next Speaker: 2025.

Next Speaker: Well –

Next Speaker: No.

Next Speaker: 2021.

Next Speaker: Assuming –

Next Speaker: \*\*\*\* the other one.

Next Speaker: – \*\*\*\* have to \*\*\*\* –

Next Speaker: Okay.

Next Speaker: – can't just go on.

Next Speaker: Okay, I just wanna –

Next Speaker: Yeah.

Next Speaker: – put it on record that the word usually for me seems a little nebulous, like there's an option there –

Next Speaker: Yeah.

Next Speaker: – like –

Next Speaker: Oh, I think it's a –

Next Speaker: – usually I don't like that.

Next Speaker: – \*\*\*\* thing. Kinda like the word shall or –

Next Speaker: Yeah – so maybe we can have – do we have an assistant AP that helps us with this like \*\*\*\*.

Next Speaker: Yes.

Next Speaker: Yes.

Next Speaker: Do we \*\*\*\* –

Next Speaker: \*\*\*\* –

Next Speaker: – \*\*\*\* word up to –

Next Speaker: Yeah.

Next Speaker: – him or her?

Next Speaker: Yeah.

Next Speaker: And say hey, is this you know, seems like something could be opted out of that we would not want someone to opt out of.

Next Speaker: Yeah, because there was \*\*\*\* –

Next Speaker: So if we remove the word usually um, I mean then there's an intention that that would be part of the training program. There's not a requirement \*\*\*\*.

Next Speaker: No, exactly. That's where it gets a little bit –

Next Speaker: So not to \*\*\*\* whether or not be \*\*\*\* –

Next Speaker: It includes \*\*\*\* –

Next Speaker: \*\*\*\*?

Next Speaker: So I think –

Next Speaker: Well no, actually there is.

Next Speaker: – \*\*\*\*.

Next Speaker: Includes at least these three phases if we take out the word \*\*\*\*.

Next Speaker: So I think there's a \*\*\*\* here that right we're specifically talking about training program which is only a \*\*\*\* project.

Next Speaker: Okay. Okay.

Next Speaker: And so the utilization phase may be a part of the project but not part of the training program.

Next Speaker: So say they were done with their preceptorship 400, 600, 800 hours –

Next Speaker: Yeah.

Next Speaker: – so this is after the preceptorship?

Next Speaker: Yes.

Next Speaker: \*\*\*\*.

Next Speaker: Well but the, the point of utilization \*\*\*\* still that might be a part of the – might be a part of the training, might be part of the \*\*\*\*.

Next Speaker: It has to be part of something because someone has to be having oversight until –

Next Speaker: It's part of the pilot project? It may not be part of the training program that the trainees go through, you know. It \*\*\*\* –

Next Speaker: So it's not gonna be a loophole for people to fall out of oversight? \*\*\*\* what I was concerned about.

Next Speaker: No.

Next Speaker: \*\*\*\* –

Next Speaker: \*\*\*\* not. There is continuing oversight of the project.

Next Speaker: Okay, got it.

Next Speaker: But \*\*\*\* –

Next Speaker: \*\*\*\* get back to number 9 the previous page employment/utilization phase is the ongoing application of \*\*\*\* clinical knowledge and skills in an employment setting under the supervision of a supervisor.

Next Speaker: Got it. Okay, thank you.

Next Speaker: So it's –

Next Speaker: The first batch.

Next Speaker: The heart of the issue is, um, just to use the \*\*\*\* part of it as an example is they have this defined period of preceptorship time and it's a little bit like, is that part \*\*\*\* still under that training umbrella or are they on that employment – I don't know that that even matters but they're always \*\*\*\* –

Next Speaker: Perfect. That, that was mine too.

Next Speaker: \*\*\*\*.



Next Speaker: Yes, they are.

Next Speaker: Okay. Any other \*\*\*\*?

Next Speaker: \*\*\*\*.

Next Speaker: All right. So um, so let's see. Number 3, the authority will not accept new applications if it a. has determined that there's already a sufficient number of projects to provide a basis for testing the validity, the validity of the model as determined by the authority or, and b. has determined it does not have adequate resources to provide an appropriate level of oversight required by these rules.

Next Speaker: So.

Next Speaker: You \*\*\*\* –

Next Speaker: Well I mean this is funny because it's a \*\*\*\* legislature essentially \*\*\*\* the legislature doesn't uh, uh, fund, fund it \*\*\*\*. I mean that's what –

Next Speaker: Yeah.

Next Speaker: – that's the situation we were in the first two years, right?

Next Speaker: Yeah.

Next Speaker: Bingo.

Next Speaker: \*\*\*\* nothing happened. \*\*\*\* no money. So uh, yeah. Well, I mean that's just the way \*\*\*\*.

Next Speaker: Anybody have any other feedback on that?

Next Speaker: Um, I have a question on \*\*\*\* –

Next Speaker: This is Christina. Oh, go ahead –

Next Speaker: Go ahead, Christina.

Next Speaker: – uh, the only thing I was gonna say um, the, the 3E the adequate \*\*\*\* um, one of the things I was gonna suggest and I, I'm not a big fan of being overly particular in rules but, I do think it would be helpful to provide some sort of, I don't know, baseline of what you're thinking of either staff number, or staff \*\*\*\* something like that, because you know, anybody who's looking at these rules and are applying for grants or other kind of funding you know, what, what's the, \*\*\*\* is it might not be what the project believes is adequate or whoever's writing that grant \*\*\*\*. And so I think it might be helpful to just to put in something to give 'em kind of a hint what you're thinking. That way when they're applying for funding and they're looking for their resources they can be, they can be hitting the mark.

Next Speaker: I think it depends on the project.

Next Speaker: Yeah.

Next Speaker: So \*\*\*\* some, I mean just, \*\*\*\* found that resources to be provide oversight by the authority not, not staffing or whatever \*\*\*\*.

Next Speaker: Okay. Okay.

Next Speaker: Is um, on \*\*\*\* does that mean pretty much of a gray area the way that's worded um, \*\*\*\* other \*\*\*\* projects to provide a basis \*\*\*\* model um, \*\*\*\* the concept \*\*\*\* –

Next Speaker: That is \*\*\*\* –

Next Speaker: Okay.

Next Speaker: What's your \*\*\*\* –

Next Speaker: Well the project applies with a variation of theme and we say no, that's too much like the first one from \*\*\*\* guidelines for determining \*\*\*\*.

Next Speaker: And what – and while I think that, that idea is if you have a project and that's \*\*\*\* and somebody else tries to do the exact same project, right.

Next Speaker: If \*\*\*\* is already –

Next Speaker: Right.

Next Speaker: – it has to be different in that to – I mean, 'cause \*\*\*\* that –

Next Speaker: Yeah, I know \*\*\*\* –

Next Speaker: \*\*\*\* –

Next Speaker: – but I'm just –

Next Speaker: If, if, if there was already enough information to go to the legislature and at that point it's no longer a \*\*\*\* project and \*\*\*\* it's turning into a \*\*\*\* that is not what the spirit is \*\*\*\* –

Next Speaker: \*\*\*\* would be a \*\*\*\* –

Next Speaker: Yeah \*\*\*\*.

Next Speaker: And I think \*\*\*\* that, I do think that \*\*\*\* leave that –

Next Speaker: I wanna leave that open –

Next Speaker: – language \*\*\*\* because like before when we think it's \*\*\*\* really specific then we start setting precedent and you have to go back and you, you \*\*\*\* –

Next Speaker: So I'm gonna keep that –

Next Speaker: – \*\*\*\* something and gives you more authority to say yes or no.

Next Speaker: I like, I like the intent. I just wanna make sure the language is \*\*\*\* –

Next Speaker: I think that this little thing about \*\*\*\* – I mean the whole thing is a little bit muddled by – when \*\*\*\* was in place we did not have to state \*\*\*\*. So now the \*\*\*\* is actually the public \*\*\*\* but it runs on the state \*\*\*\* –

Next Speaker: Mm hmm.

Next Speaker: – that um, and \*\*\*\* not in the public health division or is it –

Next Speaker: Yeah.

Next Speaker: Yes, I am.

Next Speaker: Well, \*\*\*\*, so you \*\*\*\*.

Next Speaker: So hopefully that's good for me \*\*\*\*.

Next Speaker: That, that's, that's kind of what I think it is.

Next Speaker: \*\*\*\* you may wish we were in public health –

Next Speaker: \*\*\*\* this is not my table –

Next Speaker: I officially work in public health and \*\*\*\* and um, \*\*\*\* was \*\*\*\* –

Next Speaker: \*\*\*\* actually just \*\*\*\* authorities \*\*\*\* and that, that's the language that \*\*\*\*. But it seems like nobody's really kind of taking responsibility for this stuff. I mean, I think –

Next Speaker: The authority were first \*\*\*\*.

Next Speaker: Right. And but – and by definition I'm in charge of the pilot project program. \*\*\*\* manages it. Um, I know just by, by um, \*\*\*\* –

Next Speaker: But shouldn't we \*\*\*\* actually not a – but why is it that \*\*\*\*.

Next Speaker: I'm not, I'm not the authority.

Next Speaker: So why don't you take this back.

Next Speaker: Yeah.

Next Speaker: 'Cause we have a lot of pages –

Next Speaker: Yeah.

Next Speaker: – to go.

Next Speaker: Yeah, yeah, yeah.

Next Speaker: And um, –

Next Speaker: Sure. But I'm just \*\*\*\* –

Next Speaker: – and double check back with leadership \*\*\*\* –

Next Speaker: \*\*\*\* –

Next Speaker: Yeah, it goes back to number 8 – the section where it talks about the –

Next Speaker: Where are you at?

Next Speaker: – public health director.

Next Speaker: It, it's \*\*\*\* on it too.

Next Speaker: Yeah.

Next Speaker: But you know when you \*\*\*\* –

Next Speaker: \*\*\*\* yeah.

Next Speaker: \*\*\*\* like a –

Next Speaker: Yeah, so –

Next Speaker: Is, is, is your thinking that on number 3 the authority will not accept the application that it should be something \*\*\*\* like the dental director will not accept? Is that \*\*\*\* –

Next Speaker: Well, I mean the – so – it, it, the responsibilities for this whole thing is pretty fluid actually.

Next Speaker: Right.

Next Speaker: So there was no \*\*\*\* when, when these rules came into play. There was no dental director. And this has all changed.

Next Speaker: Right.

Next Speaker: There's now a dental director office. There is a, there is a staff about uh, one's a pilot project \*\*\*\*. Of course they could go away but I just feel that they actually making new rules. They should, they should kind of be with – they should be reflected on the situation as we have it like it was at that time but \*\*\*\* rules that are put in place last time that was what we had to, had to work with. We had to work with uh, the lack of staff, \*\*\*\* the lack of the dental director. And now it's different \*\*\*\*.

Next Speaker: Right.

Next Speaker: And now by definition –

Next Speaker: Well –

Next Speaker: – I represent the authority \*\*\*\*. If I left and there was a three month period without a dental director then somebody else would be regard the authority.

Next Speaker: I think this is a, a legal issue so –

Next Speaker: Yeah.

Next Speaker: – let's take this back –

Next Speaker: Yeah.

Next Speaker: – to \*\*\*\* because –

Next Speaker: Absolutely, yeah.

Next Speaker: – okay? They may want to keep it with the entity.

Next Speaker: Sure.

Next Speaker: But again with the \*\*\*\*. Okay, so moving on um, \*\*\*\* the \*\*\*\* pages of the \*\*\*\*. Uh, we are –

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* A, a descriptions of improving –

Next Speaker: Yeah. \*\*\*\* um, \*\*\*\* my understanding this is all \*\*\*\* –

Next Speaker: Yeah, I \*\*\*\* –

Next Speaker: So the overall structure of the rules \*\*\*\* we started –

Next Speaker: The application \*\*\*\* processes, \*\*\*\*, standards and \*\*\*\*.

Next Speaker: So it would be helpful to uh, because I was not able to come up with a \*\*\*\* one but I mean if you know it, it's just the section that has moved but –

Next Speaker: Yes.

Next Speaker: – essentially it's the same as it was before, then I don't think we need to \*\*\*\* –

Next Speaker: Yeah.

Next Speaker: \*\*\*\* looks like \*\*\*\* changes um, \*\*\*\*.

Next Speaker: Were there any changes –

Next Speaker: \*\*\*\* no.

Next Speaker: Okay.

Next Speaker: \*\*\*\*.

Next Speaker: It was just moved to the \*\*\*\*?

Next Speaker: Yes.

Next Speaker: This page and the next page \*\*\*\* just moved.

Next Speaker: It was just housekeeping.

Next Speaker: Yeah \*\*\*\*.

Next Speaker: Well I can tell you as, as, as having \*\*\*\* approved the applications that this is immensely important because this is what takes a year to do.

Next Speaker: Right.

Next Speaker: Oh, I didn't mean to imply it wasn't important –

Next Speaker: No, no, no. No, no \*\*\*\*.

Next Speaker: – I mean it's just removing \*\*\*\* –

Next Speaker: – \*\*\*\* you know, you start writing certain new things and you know something \*\*\*\* –

Next Speaker: Sure.

Next Speaker: – it could be pretty consequential –

Next Speaker: \*\*\*\* –

Next Speaker: – for somebody who's actually sitting and writing it up.

Next Speaker: Sure.

Next Speaker: Or, are there things in there that shouldn't be \*\*\*\*?

Next Speaker: Yes.

Next Speaker: \*\*\*\* that \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: The one thing that we did add in here \*\*\*\* E under trainees and was B, the proposed scope of practice for the trainees and that you know, \*\*\*\* career project authority \*\*\*\* like being very specific about actual procedure.

Next Speaker: \*\*\*\*, I did have one question on that one, description \*\*\*\*. And that's a single entity?

Next Speaker: Let me go back here. Are you –

Next Speaker: That's back in definitions.

Next Speaker: You're back \*\*\*\* –

Next Speaker: \*\*\*\* um –

Next Speaker: No, no. Under A \*\*\*\* –

Next Speaker: Oh, okay.

Next Speaker: Yes. And do you know, does that limit it to one sponsor \*\*\*\* sponsors \*\*\*\* –

Next Speaker: \*\*\*\* sponsors. Is that –

Next Speaker: I don't, I mean \*\*\*\* to be –

Next Speaker: Okay. The description of the sponsor or sponsors. We have more than one sponsor.

Next Speaker: \*\*\*\*.

Next Speaker: I would be checking that.

Next Speaker: Let's double check on that.

Next Speaker: Yeah.

Next Speaker: Yeah \*\*\*\* –

Next Speaker: Just for clarity's sake.

Next Speaker: I'm just curious.

Next Speaker: Right, I, I agree. That's what this is about.

Next Speaker: Yeah.

Next Speaker: Right?

Next Speaker: Okay. Um, one question that is confusing \*\*\*\* it says a statement of previous experience in providing \*\*\*\* where it actually should say, where it says related healthcare services. That is if we look at SB738 um, there's one which in SB738 um, \*\*\*\* as a statement of previous experience in providing related healthcare services. And there was –

Next Speaker: Where are you?

Next Speaker: \*\*\*\*

Next Speaker: I'm trying to –

Next Speaker: The same page that starts with \*\*\*\* if you go further down, uh, big F.

Next Speaker: So it says a statement of previous experience of providing \*\*\*\* services. That language is taken directly from SB738. There's confusion about the intent of why that is supposed to be \*\*\*\* is that the sponsor has experience in providing related healthcare services or is it supposed to be \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: It's got to be the sponsor right?

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\* section, the section is about sponsors.

Next Speaker: Right and we put that here 'cause that, that's, that was the interpretation that we had, so there was this back and forth about that and is it appropriate place and I think it was.

Next Speaker: \*\*\*\* question about that \*\*\*\*.

Next Speaker: This is Christina. I have a question on that. So, you know, we're a \*\*\*\* and we work directly with our \*\*\*\* so we don't offer \*\*\*\* so what we \*\*\*\* still qualify under that existing language? I mean obviously we're not providing any services \*\*\*\*. All of the services are happening at clinics that are working with us or \*\*\*\* we are also, uh, \*\*\*\* but all the clinical care is happening \*\*\*\*. So that was my only question on that piece on the sponsor.

Next Speaker: Do you have – it doesn't say you have to have it.

Next Speaker: Right \*\*\*\*.

Next Speaker: It just says you \*\*\*\* statement. You're statement \*\*\*\*.

Next Speaker: And you already have that relationship. That's an existing relationship \*\*\*\*.

Next Speaker: Yes, okay, thank you. I just wanted to clarify that. I wasn't sure.

Next Speaker: Okay, now moving back \*\*\*\*, um, so the topic says \*\*\*\* and this, this is where the new language – it says the proposed scope of practice for the trainees \*\*\*\* making it very clear that it needs to be \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: Yes.

Next Speaker: Anybody have any questions about that?

Next Speaker: \*\*\*\*

Next Speaker: The Xs refer to the numbers that will be developed once \*\*\*\*, uh –

Next Speaker: It's a placeholder.

Next Speaker: – it's a placeholder. Oh, direct policies and \*\*\*\*.

Next Speaker: Well compliance with what? I mean –

Next Speaker: That's a section within this –



Next Speaker: I understand it's a section inside the rules –

Next Speaker: \*\*\*\*

Next Speaker: – but I want to know \*\*\*\*.

Next Speaker: I think that was referring to minimum standards.

Next Speaker: Minimum standards?

Next Speaker: Yeah, I'll find out.

Next Speaker: Which would be later?

Next Speaker: Yeah.

Next Speaker: Yes.

Next Speaker: It would be nice to know.

Next Speaker: I'll find out.

Next Speaker: \*\*\*\*

Next Speaker: Um, then draft policies \*\*\*\*. Draft policies and procedures for conducting background checks on participating trainees. \*\*\*\* there's no language \*\*\*\*. So anybody have any questions about that?

Next Speaker: \*\*\*\* what is \*\*\*\* draft. What, what does that mean draft?

Next Speaker: Draft project would \*\*\*\*.

Next Speaker: \*\*\*\* application process, correct?.

Next Speaker: This is application, yeah.

Next Speaker: \*\*\*\* policies and procedures, you want them to demonstrate policies and procedures by conducting background checks.

Next Speaker: Oh I see what \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: Okay.

Next Speaker: \*\*\*\* done it already.

Next Speaker: That's why they were draft, right?

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\*

Next Speaker: So the reason this is, um, so and one of the projects we have a hygienist who's already licensed with the Board of Dentistry and gone through all background to become licensed and \*\*\*\* in that system \*\*\*\*. The rest of this section here is all the existing rule language. None of this has changed.

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\*

Next Speaker: Did we have costs \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: And here we've actually added in the word estimated cost \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: That's true we did change \*\*\*\*.

Next Speaker: \*\*\*\* into the, the way you deal with \*\*\*\*? What is it \*\*\*\* information?

Next Speaker: \*\*\*\* do you recall \*\*\*\*.

Next Speaker: \*\*\*\* evaluation \*\*\*\*.

Next Speaker: Right, to show the value of the concept, uh, \*\*\*\* care.

Next Speaker: \*\*\*\* decision on \*\*\*\* legislature.

Next Speaker: Right.

Next Speaker: \*\*\*\*

Next Speaker: That's also \*\*\*\* demonstrate the ability \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: But the funny thing is that \*\*\*\* that was never the requirement that funding, that, that, that funding was, um, an assumption to actually get a pilot project approved. If you remember, that was, we didn't have, I mean, we didn't have funding \*\*\*\* it fell away and then we got new funding \*\*\*\*.

Next Speaker: Right.

Next Speaker: But, but there was no actually, there was no actual requirement \*\*\*\* actually be funded.

Next Speaker: Right.

Next Speaker: \*\*\*\* project be funded?

Next Speaker: Yeah, we didn't, we didn't need to prove that we had money to fund it –

Next Speaker: Oh.

Next Speaker: – \*\*\*\* for let's say general funding from the dental school, something \*\*\*\* but I'm just not sure \*\*\*\*. It's kind of interesting because you could have the rule that you would not actually improve \*\*\*\* unless that you could prove that you had funding to do it.

Next Speaker: Well, and that, we might want to consider that because OHA doesn't \*\*\*\*\* -

Next Speaker: Yeah.

Next Speaker: – pilots, right and we also are \*\*\*\* time in monitoring the project. We want to make sure the project has enough support –

Next Speaker: Right.

Next Speaker: – to be able to support \*\*\*\* say they would, right? But, it's something to consider.

Next Speaker: So you would want to see \*\*\*\* funding?

Next Speaker: No, I mean it would be a restriction in a sense, right?

Next Speaker: Yeah \*\*\*\*.

Next Speaker: \*\*\*\* like that if it's not actually written into the legislation.

Next Speaker: I don't know.

Next Speaker: But it's –

Next Speaker: We have to talk \*\*\*\*.

Next Speaker: – \*\*\*\* because I know that even \*\*\*\*, uh, I mean just through the application process \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\*

Next Speaker: Um, so this is, um, we're moving to a small L, says an identified clinical evaluator \*\*\*\*.

Next Speaker: Uh, this is just reiterating and \*\*\*\* but for \*\*\*\* funding application \*\*\*\* the application, yes, clinical evaluation and we, right before that in K we also \*\*\*\* plan, which is \*\*\*\* previously, um, and this is sort of predicated on, on or not – demonstrated on other, uh, \*\*\*\* grants \*\*\*\* put in a preliminary evaluation plan and then if you were funded you made a full-blown app for it afterwards then submit it later, uh, we know – we understand that it's a lot of work to put together an application, um, and if it is approved \*\*\*\* a lot of resources to put \*\*\*\*. So we want a preliminary evaluation plan and then a final evaluation \*\*\*\* submitted for approval after, uh, a certain period of time after the project has been \*\*\*\* approved.

Next Speaker: \*\*\*\*

Next Speaker: Almost like an outline.

Next Speaker: If a project wanted to skip that step and put in a final evaluation grant \*\*\*\* to do so.

Next Speaker: Any comments on that \*\*\*\*?

Next Speaker: I'm not sure where that comes from \*\*\*\*.

Next Speaker: I can tell ya where it came from.

Next Speaker: Yeah?

Next Speaker: So, um, we – Christina \*\*\*\* project you – one of the issues you guys had is it's extremely expensive to get together an evaluation plan, um, and there was concern that what if it didn't get approved and you went out and spend \$100,000.00 to get the evaluation plan designed and concepts and then it didn't get approved. There was a little bit of a \*\*\*\*. That's really kinda where that came from.

Next Speaker: That makes sense?

Next Speaker: It makes sense \*\*\*\*, you know, \*\*\*\*, you know, how we are \*\*\*\* in terms of the \*\*\*\* and then \*\*\*\* concept preliminary evaluation plan which is not \*\*\*\* finalized plan, which I have a bit of a trouble with because \*\*\*\*. I mean you \*\*\*\* and I think \*\*\*\* they don't like, or they will not accept a preliminary evaluation plan, however \*\*\*\*.

Next Speaker: But then I see to that they want outlined \*\*\*\* plan.

Next Speaker: Exactly.

Next Speaker: \*\*\*\* the evaluation plans part of the grant \*\*\*\* you want a much more detailed robust evaluation plan submitted.

Next Speaker: After that you can do that \*\*\*\*.

Next Speaker: Yes.

Next Speaker: Yes.

Next Speaker: Okay.

Next Speaker: So that's the \*\*\*\* that's kind of what we were thinking \*\*\*\* okay can at least provide a minimum –

Next Speaker: Yeah.

Next Speaker: – outline, you know, for the preliminary and the a much more detailed robust evaluation plan would have to be submitted after \*\*\*\* –

Next Speaker: So what does that then refer to \*\*\*\*.

Next Speaker: We'll get to it here in just a second \*\*\*\*.

Next Speaker: Oh. Like it says how long time you have to –

Next Speaker: Yes.

Next Speaker: – to come up with a plan \*\*\*\*?

Next Speaker: Yes, yeah.

Next Speaker: So moving down to application review process, um, the only thing, uh, we changed a few dates in here to give us a little bit more, um, time to review the application. I'd have to go back and look. Um, I think it went to 45 days to 60 days, couple, couple of just date time due. Any questions about that? So moving on to the next page. \*\*\*\* project application and provisional approval \*\*\*\*. So, it's the same, same sequence of steps, um, so small A, a provisional decision to grant application or the denial of application and Number 2 the application is provisionally approved \*\*\*\* requirements and then –

Next Speaker: \*\*\*\* final approval \*\*\*\*.

Next Speaker: If the director denies application, then the denial must be in writing and describe the reasons for denial. An application may be denied for any of these reasons. Small A, application does not demonstrate the project meets the minimum standards or other provisions and rules. Application does not demonstrate \*\*\*\* financially feasible or C the program has previous approved a similar project and then Number 4, um, a sponsor whose project has been denied may not submit an application – this is the same language – within 6 months from the date the \*\*\*\* denied the application, and then \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: Correct.

Next Speaker: \*\*\*\* whatever, such and such.

Next Speaker: \*\*\*\*

Next Speaker: So, just clarify for me, I am, I put in an application on the 1st of January. So by the 1st of March you have to tell me whether it is provisionally approved?

Next Speaker: Sorry.

Next Speaker: Um, no you have \*\*\*\* to tell \*\*\*\* complete.

Next Speaker: I just want, I want to see a timeline.

Next Speaker: Okay.

Next Speaker: \*\*\*\*

Next Speaker: I can do that.

Next Speaker: \*\*\*\* timeline exactly \*\*\*\*.

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\*

Next Speaker: I, I have one, um, upstairs. I will just \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Um, so back to this, um, provisional approval denial. \*\*\*\* move down to final approval, on the project sponsor, Number 1, the project sponsor that has been provisionally approved that's within 3 months of provisional project approval submit the following to the program, with approval; a detailed \*\*\*\*, a detailed evaluation \*\*\*\* that meets the requirements –

Next Speaker: \*\*\*\*

Next Speaker: \*\*\*\*

Next Speaker: Um, evaluation \*\*\*\*.

Next Speaker: Oh, okay.

Next Speaker: It's in the entire section following \*\*\*\*.

Next Speaker: Okay.

Next Speaker: Okay \*\*\*\* read this and answer questions? This is the same but the \*\*\*\* policies and procedures for data collection storage, protection security, patient data, obtain patient informed consent. That's new, that language, um –

Next Speaker: Um, this is the same language as the previous, it's just \*\*\*\* clarification.

Next Speaker: Does anybody change the language on this? Okay.

Next Speaker: What'd you mean?

Next Speaker: Well when you, well okay, when you read this, No. 1, submit the following to the program for approval. First you need to submit a detailed evaluation \*\*\*\*. Then it starts a new sentence. The party must have a \*\*\*\* policy \*\*\*\*. So –

Next Speaker: It's, it should be, uh, and –

Next Speaker: I mean –

Next Speaker: – at the end of a, little a, and they must submit those and submit.

Next Speaker: But what I'm, what I'm thinking –

Next Speaker: \*\*\*\*.

Next Speaker: – what I'm, I'm –

Next Speaker: \*\*\*\*.

Next Speaker: – pointing out is that the, the sentence starts with submit the following –

Next Speaker: Yeah, they're correct.

Next Speaker: – to the program for approval, and then there needs to be some level of parallel sentence start –

Next Speaker: Yeah.

Next Speaker: – I mean you can't suddenly have something \*\*\*\* maybe, and maybe this one is then \*\*\*\* obtain and patient \*\*\*\*.

Next Speaker: Right. Okay.

Next Speaker: Because –

Next Speaker: Yeah.

Next Speaker: We'll clean that up.

Next Speaker: Yeah.

Next Speaker: Yeah, I think we'll –

Next Speaker: I think what we're, the intent is that, uh, detailed evaluation plans and, and policies and procedures –

Next Speaker: Yeah, exactly.

Next Speaker: – that are submitted have been through these –

Next Speaker: Mostly, yeah.

Next Speaker: Yeah. So we'll clean up that.

Next Speaker: Our requirements, I'm sure they're questioned maybe for those type of events the policy listed \*\*\*\* project \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Does that need to be further clarified \*\*\*\*?

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: If, if it cannot, if it cannot stop, then it would make sense, then it, then it does make sense right, \*\*\*\* preliminary onset because then you have to wait 5 months, 3 months after you're completely approved –

Next Speaker: So what –

Next Speaker: – to be able to start your project and so you have your final evaluation plan approved.

Next Speaker: So the, in the past \*\*\*\* for example, the \*\*\* project, uh, received preliminary appro, uh, approval and then that started, submitted evaluation plan for approval, and during that time period they were starting to send students to be trained at the training base but no, no utilization phase, no treatment was provided before that final approval.

Next Speaker: \*\*\*\* in Alaska?

Next Speaker: Yeah.

Next Speaker: But we didn't have it in Oregon without anybody in the sense that people involved a lot. Do you know what I mean?

Next Speaker: Yes.

Next Speaker: Had it been in Oregon, that would a been the \*\*\*\*.

Next Speaker: But that's \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah, yeah. \*\*\*\*, but, but this goes back to this whole thing about, you know, \*\*\*\*, but anyway, you'll figure that out. Because there, I mean, you know, just think of terms like they having actually – like say we go through a funding phase where we actually get funding from an external funder and then we get money from them and then we go through the approval and then we, we come after the states after funding I mean even though the rules state for the fund or we probably won't start the project until 6 months later, I don't think, but, you know, it's not \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: So at, at this –

Next Speaker: The two –

Next Speaker: – \*\*\*\*.

Next Speaker: Okay. \*\*\*\*, um, uh, so we're on the next page where \*\*\*\* have been followed written standard operating policies and procedures for specific use by the improved pilot project. Standard operating policies and procedures \*\*\*\* define what those will be so there's something that the clients have \*\*\*\* sites, um, that they can reference \*\*\*\*. So we don't have –

Next Speaker: Is this the –

Next Speaker: – to do the next day but that's something –

Next Speaker: So that's really broad \*\*\*\* –



Next Speaker: That's why we –

Next Speaker: – more specific as to –

Next Speaker: – need to spell –

Next Speaker: – what \*\*\*\*.

Next Speaker: Is this where we have \*\*\*\* trouble with certain things? This is, so this is the key issue right there? Where there hasn't been direction, it say, you know, you can't do this or you have to do this.

Next Speaker: Yeah. Needs to be a gap –

Next Speaker: So and –

Next Speaker: – maybe that ho, whole side \*\*\*\* and –

Next Speaker: Procedures for example of how you \*\*\*\*, um, \*\*\*\* percent of your customers \*\*\*\*, um –

Next Speaker: \*\*\*\*.

Next Speaker: – section is whole procedures.

Next Speaker: That's only one in that \*\*\*\*. Why did you use –

Next Speaker: Yeah, but the draft version's intact.

Next Speaker: Why is that, why is that even \*\*\*\* approval section? Why, why –

Next Speaker: I see what you're –

Next Speaker: – why is that –

Next Speaker: Oh, yeah.

Next Speaker: – \*\*\*\* about that –

Next Speaker: – found, why do we not ask for that in the, as a basic –

Next Speaker: Right.

Next Speaker: – basic part of the \*\*\*\* approval?

Next Speaker: Okay. So let's move this to the application.

Next Speaker: \*\*\*\* yeah.

Next Speaker: Right.

Next Speaker: That should be part of your review and not actually ask members of procedures in place. O, o, in other words after you approve it, after you approve something and then state well finally we don't need some \*\*\*\*.

Next Speaker: Great. Perfect.

Next Speaker: So is that what happened here or was there, what are the standards in place that weren't followed?

Next Speaker: I, I don't know. I mean –

Next Speaker: And, and –

Next Speaker: – you know, uh, but because we're setting up a new seven rules –

Next Speaker: Yep. Right.

Next Speaker: – and the only thing I'm saying is when we actually work on the application process, we obviously go through all the details of what will this project, uh, comprise and part of it is it will be just the layout. What are the standard and procedures?

Next Speaker: I completely agree. I'm, I'm in 100 percent \*\*\*\* with you on that. My question is more general I think. In reference to Project 100 where we're having these issues, was this because we weren't clear on what the standards were in the application and after what we were evaluating, or was it because they were clear, they just weren't followed? That's what I'm trying to understand.

Next Speaker: I think it's a lack of clarity.

Next Speaker: The lack of clarity, okay.

Next Speaker: And, and the, I think a lot of the confusion, uh, wasn't between the authority and the project, but it was between the project and the management \*\*\*\* application of the project \*\*\*\* rules \*\*\*\*.

Next Speaker: And so that's what we're trying to define here. That's, that's this second –

Next Speaker: Yeah.

Next Speaker: – line here \*\*\*\* –

Next Speaker: \*\*\*\*.

Next Speaker: – \*\*\*\* down to the clinic level.

Next Speaker: \*\*\*\* applicant, um, you know, are forced to think about those. Why did we approve the application? I would think that –

Next Speaker: Sure.

Next Speaker: – that actually would sort of highlight \*\*\*\*.

Next Speaker: So are these defined or will they be defined?

Next Speaker: We're looking for input on –

Next Speaker: Into, on what those –

Next Speaker: – \*\*\*\* –

Next Speaker: – those should \*\*\*\*.

Next Speaker: Yeah, I always looked at the conscience for that. That is \*\*\*\*. So we don't necessarily have to be that strict but, um, that will part of this process –

Next Speaker: I think it will be –

Next Speaker: – and \*\*\*\* –

Next Speaker: – helpful too for us, and I know we have documents \*\*\*\* this in the last meeting and I was having, \*\*\*\* what's about, where the shortfalls were, where the concerns were. I –

Next Speaker: Mm hmm.

Next Speaker: – think if we start it there that's gonna help us come up with, 'cause I mean this is a really broad thing –

Next Speaker: Uh, yeah.

Next Speaker: \*\*\*\* –

Next Speaker: – this is \*\*\*\* –

Next Speaker: – it could be huge.

Next Speaker: – this is the DPA.

Next Speaker: I know, yeah –

Next Speaker: Yeah, yeah.

Next Speaker: Right there.

Next Speaker: But we can't just be \*\*\*\*.

Next Speaker: Yeah. Yeah. I understand that, but there's a whole bunch of the DK that speaks to the –

Next Speaker: Yes.

Next Speaker: – assignment. What is the scope of practice? What can you do, can't you do?

Next Speaker: Yeah.

Next Speaker: Um, and –

Next Speaker: And there are –

Next Speaker: \*\*\*\*, um, for later on in the minimum standards there are certain references to \*\*\*\* when asked what are the most important parts in terms of minimum care provided and \*\*\*\* minimum standards \*\*\*\* you would like to see \*\*\*\*.

Next Speaker: I think it's more, I think it's –

Next Speaker: \*\*\*\*.

Next Speaker: – longer than – well –

Next Speaker: \*\*\*\*.

Next Speaker: Yeah. I'm just gonna submit the whole damn thing.

Next Speaker: Yeah. That's okay.

Next Speaker: The whole thing's important. Every word.

Next Speaker: Well the problem with, the problem \*\*\*\* mentioned here, and I \*\*\*\* document, the Dental Practice Act, is that \*\*\*\* licensees. Licensees placed –

Next Speaker: \*\*\*\*

Next Speaker: – \*\*\*\* –

Next Speaker: So then it's gonna be affordable?

Next Speaker: – \*\*\*\* licensed.

Next Speaker: Right.

Next Speaker: So we need to go back and really look okay \*\*\*\*. Pull out that word, that sentence, and change it to trainee or you know what I mean.

Next Speaker: Yeah.

Next Speaker: That's part of the problem is that –

Next Speaker: Sure.

Next Speaker: – you have to say \*\*\*\* surprise –

Next Speaker: Yeah, you can't \*\*\*\*. You –

Next Speaker: – you never see –

Next Speaker: – \*\*\*\* gonna approve your document. Look this is a hell of a template right here –

Next Speaker: Yeah, so –

Next Speaker: – \*\*\*\* so, you know.

Next Speaker: – which parts are important \*\*\*\* though \*\*\*\* –

Next Speaker: Yeah, well –

Next Speaker: – it's not to say the whole thing isn't important \*\*\*\*.

Next Speaker: Yeah, but which are, which are relevant, right –

Next Speaker: Which is relevant.

Next Speaker: – which, which are relevant to what we're –

Next Speaker: Yes.

Next Speaker: – doing and, and –

Next Speaker: No, no.

Next Speaker: – something that possibly need to look at.

Next Speaker: Yeah.

Next Speaker: And I think that's why you and I \*\*\* not here to \*\*\*\* because of some fact that any suggestion \*\*\*\* maybe from starting I think first, you know, this, this is a document obviously that, that ev, everyone's kind of, requires as much clarity as possible, um, \*\*\*\* linked, uh, for \*\*\*\* practice to the dental practice site for clarity plus \*\*\*\* most \*\*\*\* practice that they, um, \*\*\*\* everything in the project, but –

Next Speaker: Yeah.

Next Speaker: – put the onus on them to identify and say here's, here's where –

Next Speaker: \*\*\*\*.

Next Speaker: Without us having to rewrite the whole thing.

Next Speaker: Right.

Next Speaker: Well that and then there are gonna be areas of malpractice that are gonna be updated.

Next Speaker: Yeah.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah –

Next Speaker: Yeah –

Next Speaker: – which will make it –

Next Speaker: – and then that –

Next Speaker: – \*\*\*\*.

Next Speaker: – will make it live with –

Next Speaker: \*\*\*\* you have to be a little bit careful because if you'll remember back to when 738 was approved, the dental board was very carefully kept out of it.

Next Speaker: Well we were kept out of it as far as having any kind of authority over the project –

Next Speaker: Right.

Next Speaker: – which makes sense.

Next Speaker: \*\*\*\*.

Next Speaker: Right, that makes sense, but as far as the standard of care, the practice of dentistry in our state, this document should be very much part of, and so I think if there was, to, to \*\*\*\* idea of, of referencing this, um, and then saying in that language to reference the DPA that, you know, where, where the word licensee shows up, substitute that with trainee or program attendant or whatever, however we're gonna identify these individuals that are being trained. Um, I don't think we have to rewrite everything.

Next Speaker: The, the standard of care, um, is that, is that defined in the, uh –

Next Speaker: Well it's not acceptable –

Next Speaker: – in the practice act?

Next Speaker: – \*\*\*\* care –

Next Speaker: No. Standard of care –

Next Speaker: – \*\*\*\*.

Next Speaker: – standard of care is what any reasonable dentist in that community would provide, and that's very subjective and that's one of the reasons we have these long meetings.

Next Speaker: Yeah.

Next Speaker: The dental board is determine whether or not someone did something is that, does that meet the standard of care. So it's, it's, it's subjective.

Next Speaker: So, so, so –

Next Speaker: Yeah \*\*\*\* –

Next Speaker: – so, but that, that's what I mean by, by, by, I mean, so we have to be very careful because it is not necessarily dentists who are in these pilot projects.

Next Speaker: Right.

Next Speaker: The dentists \*\*\*\* but we are actually maybe trying to, as \*\*\*\* says, we are trying to develop a new provider for \*\*\*\* so it's not a dentist. So it's that, it's actually the dentist's source and/or care we are referring to.

Next Speaker: I –

Next Speaker: \*\*\*\* especially with –

Next Speaker: – agree with that –

Next Speaker: – something that –

Next Speaker: – yeah.

Next Speaker: – \*\*\*\* patient safety and so on. I'm talking about sort of a, a, a, a, sort of attacking them or something like that because that would be part of the application that, that would ensure that, that of course the \*\*\*\*, that's why we have \*\*\*\* evaluators and supervisors and what, what have you. I mean to ensure that, that, uh, that patients are, are kept safe during that process.

Next Speaker: Would a different state of affair apply to that procedure? Understood, just making, just, just the idea. Would there be a different standard of care for a hygienist to do that procedure than a dentist?

Next Speaker: \*\*\*\*.

Next Speaker: I was thinking like just from like a –

Next Speaker: Uh, this is Christina –

Next Speaker: – broad –

Next Speaker: – and I just, I'm, I just wanna make sure I'm understanding you 'cause I don't know, I don't wanna \*\*\*\*. I, I feel like that all of the providers should be held to the same standard of care that a dentist is provided, no more and no less, but, um, is what you're, what, I don't think I understand what you're saying 'cause I don't think what you're saying is that the standard care should be different. I think you're saying something else but I don't understand.

Next Speaker: Okay. I'm just asking if there is a definition of standard of care and I know that there isn't, but I was just asking to have it noted, um, because clearly, you know, standard of care is moving. I mean the standard of care is not today what it was in 1950s. I mean and so on and so forth, but, uh, so I would get, I mean, you know, we can refer to the Dental Practice Act but I'm not sure it will help us.

Next Speaker: Yeah.

Next Speaker: Okay.

Next Speaker: Also, um –

Next Speaker: Un, unless there is something –

Next Speaker: \*\*\*\*.

Next Speaker: – I mean I would like to see the language \*\*\*\* what it refers to.

Next Speaker: So I guess I'm, I'm confused. So, let's, let's talk about one issue that we have with 100. Let, let's pick one issue and talk about how it would apply to standard of care, just so I can understand \*\*\*\* –

Next Speaker: Okay. This –

Next Speaker: – \*\*\*\*.

Next Speaker: – \*\*\*\* I'm, I'm not in 100 so I'm not sure –

Next Speaker: Oh. Somebody –

Next Speaker: – but –

Next Speaker: – well, okay. So what was one of the issues that we had? Just because this is why we're here –

Next Speaker: Yeah.

Next Speaker: – right, and let's just call it what it is. This is why we're here. So what, what are the issues, somebody help me 'cause I can't remember all of them, um, I've got a lot on my plate.

Next Speaker: The documentation.

Next Speaker: Okay. No –

Next Speaker: \*\*\*\*.

Next Speaker: – documentations. Okay. So the standard of care or the rules that we have is that you have to document all treatment, all park, all informed consent etc. in the chart notes. So that is a standard. If that is not met, then someone is practicing or providing a level below what we as the community, the dental community expect, at what the Oregon or \*\*\*\* suspect as a standard of care for treatment. So I pick up one, it is hard to define a standard of care, and it is a livable, breathing document that changes. You're right. It's, it's different \*\*\*\*. \*\*\*\* 5 years it's change. The standard of care has changed, uh, um, a little bit since then.

Next Speaker: Okay. So –

Next Speaker: But we have to reference something –

Next Speaker: – okay –

Next Speaker: – \*\*\*\*.



Next Speaker: – then I understand what you're saying. So my suggestion would be of course when you write an application, you want to be as specific as possible. You also want to know what the framework is that you're working within. That's why, you know, when you write an application you always want to be sure that you know the language of whoever is actually putting out the \*\*\*\*. Right?

Next Speaker: Okay.

Next Speaker: So my suggestion would then be to define what, what it is that we want people to say in the application. What is it that we want? We want documentation. We want \*\*\*\*. We want this. We want that, and that should all be listed so that that it is possible to put it in so that we know what it is that we actually trying to do.

Next Speaker: What if she referenced the patient chart record section \*\*\*\* on the side?

Next Speaker: That's fine. I mean, you know if –

Next Speaker: Without rewriting the whole sentence thing.

Next Speaker: – does, does that – no for sure.

Next Speaker: \*\*\*\*.

Next Speaker: It's like, you know, sometimes in the rules you want to be sure that, that you actually have the text that you want because \*\*\*\* could be changed and then, you know, it's \*\*\*\*.

Next Speaker: Mm hmm.

Next Speaker: \*\*\*\* suggestion \*\*\*\*.

Next Speaker: Okay \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: So –

Next Speaker: Well, we're very, we're very careful in the DK not to give a specific definition of standard \*\*\*\* changes.

Next Speaker: It's standards of practice is one of the areas \*\*\*\* practice \*\*\*\* patient care.

Next Speaker: Sure.

Next Speaker: And professional conduct, \*\*\*\* there \*\*\*\* in these rules have already \*\*\*\* old rules, so I think about \*\*\*\* reference some of these very-specific things in here, um, under \*\*\*\* standards of practice \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* and, and \*\*\*\* application \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: But also, some of, some of the content for the standard operating procedures \*\*\*\* requiring all outside medical –

Next Speaker: Right.

Next Speaker: – \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Yes, \*\*\*\* as well. Now, they're gonna comply with her project \*\*\*\*.

Next Speaker: Well, and \*\*\*\* Heather \*\*\*\* finding from our \*\*\*\* of that it doesn't have to do \*\*\*\* what are we doing \*\*\*\* after we're \*\*\*\* between \*\*\*\* you know, and I think that what's \*\*\*\* is that there are a lot of practices around \*\*\*\* support the project that don't really have anything to do with what's happening \*\*\*\* set it up for these procedures \*\*\*\* this is how you do that. I mean, it really is, like, this is how I think it should be \*\*\*\* approved application and your approved evaluation plan and then someone's \*\*\*\* so like \*\*\*\* we are meeting all of the things \*\*\*\* your evaluation plan, um, and, and then anything that's gonna make it more clear \*\*\*\* simple and easy for the clinics to use.

Next Speaker: Okay. Okay, and so, let's see. We're back to this, so No. 2, the program will review the documentation requirements \*\*\*\* approval \*\*\*\* private sponsor \*\*\*\* policies and procedures are acceptable, the program may request additional confirmation, um, so, it, No. 3 says the final approval, or this is what \*\*\*\* to the project and telling them what they determined \*\*\*\* public project \*\*\*\* any conditions of the, to the state the authority –

Next Speaker: \*\*\*\*.

Next Speaker: Okay. When the time the project operates from between 3 to 5 years \*\*\*\* 'cause that was the intent \*\*\*\*. Um, and then, um, program \*\*\*\*. Anyone have any questions about \*\*\*\*?

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* one thing that I thought might be helpful in \*\*\*\* is \*\*\*\* communications plan between Oregon Health Authority and \*\*\*\* I mean, I think that, you know, I, I think \*\*\*\* say that, you know, some of the challenges were really between the project and \*\*\*\* in our project, but I would also say that some of the problems also really stem from OHA and the clinics and the project not really having a mutual understanding of our, for example, our valuing to monitoring plan and other things like that, but I think that it would be valuable to either in this section of one of the things along with your \*\*\*\* procedures and other

things like that it's really a negotiated communications plan for how the, like the Health Authority and the private sector are gonna interact, uh, either in this section or a separate section that talks about, you know, the, the rights of \*\*\*\* and then how they're gonna interact with the Oregon Health Authority.

Next Speaker: \*\*\*\*.

Next Speaker: Okay, thank you. Okay, so we're moving back to \*\*\*\* Sanders. Okay, um, \*\*\*\* things added in here and \*\*\*\* provide for patients' safety as follows. Um, we'll leave the previous \*\*\*\* really defined that \*\*\*\*. Um, so A, make sure that every patient is presented information and gives informed consent prior to treatment in accordance with –

Next Speaker: \*\*\*\*.

Next Speaker: – the section \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: And they are given \*\*\*\*.

Next Speaker: Should \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: It should \*\*\*\* is provided information and given informed consent.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: The patient is given \*\*\*\* I mean, \*\*\*\* this person \*\*\*\*.

Next Speaker: The patient is giving \*\*\*\*.

Next Speaker: The patient's providing \*\*\*\* so this is different \*\*\*\* the treatment plan.

Next Speaker: This is –

Next Speaker: \*\*\*\*.

Next Speaker: – a totally separate thing.

Next Speaker: So we're giving informed consent every single time they come in for a procedure?

Next Speaker: \*\*\*\* informed consent every time, and that \*\*\*\* right?

Next Speaker: And then my next question is, is that for \*\*\*\* as well, just \*\*\*\*?

Next Speaker: Every procedure that \*\*\*\*.

Next Speaker: So, I can, I, I \*\*\*\* work perspective I can see that how we look at that, so, there should be, we call those PRQ conferences, P-R-Q.

Next Speaker: Yep.

Next Speaker: And so, \*\*\*\* out of an overabundance of caution for myself in my practice, I PRQ every single procedure I do, but the minimum standards \*\*\*\* when you're reviewing cases if there is a treatment plan that has X-number of things on it, and the patient is informed consent to that treatment plan, then every time the patient comes in to do whatever's in that treatment plan, you don't need to inform consent unless it changes, and that includes something as small as No. 3 \*\*\*\*.

Next Speaker: All right.

Next Speaker: Then you have to get a new PRQ.

Next Speaker: Okay.

Next Speaker: Anything that comes up like an, uh, an extraction, a surgical procedure, endo procedure, implant that's, that needs to have a very-specific informed consent that lists all of the risks, complications, etc.

Next Speaker: Okay. Thank you.

Next Speaker: Yeah, and you do have your informed consent, we're skipping ahead, actually, to the informed consent \*\*\*\* we're having this conversation now, but do you do all of your informed consent in writing or are, or are there some procedures for which you receive verbal informed consent?

Next Speaker: \*\*\*\*, would that be \*\*\*\*?

Next Speaker: Yeah.

Next Speaker: Uh, you mean my private practice? I don't know what \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah \*\*\*\*.

Next Speaker: \*\*\*\* informed consents could be \*\*\*\*.

Next Speaker: \*\*\*\* the standard of care for \*\*\*\* get written informed consent for every procedure every time it's done or are there procedures where, like you said you have the, the treatment plan and you talked to them about all the things on the treatment plan and the informed consent is done \*\*\*\* to understand what, um, like, logistically what you're saying.

Next Speaker: So, for minor changes on something, it would be a verbal informed consent which we would document in the chart in the form of a PRQ conference, P-R-Q, for specific procedures that are surgical that come up, you would need a written informed consent where the patient signs and the provider signs and then usually witnesses.

Next Speaker: Okay, I'm just asking because it says in the language about informed consent \*\*\*\* could be here, and, I mean, it could \*\*\*\* to be, uh, \*\*\*\* for \*\*\*\* so I'm just trying to understand better what informed, written informed consent \*\*\*\* could \*\*\*\*.

Next Speaker: No, I was speaking more along the lines of what is the minimum standard of care that the Board perceives, not necessarily what this committee wants to recommend, um, and what, you know, I, I think an overabundance of caution is fine. You can, you can PRQ every single procedure like I do in my office every single time. It doesn't \*\*\*\* to that.

Next Speaker: Okay, so we're gonna keep in order there, and then we'll get there when we get there, 'cause there's a whole section of that \*\*\*\*.

Next Speaker: All right, sorry.

Next Speaker: That's okay, so the –

Next Speaker: \*\*\*\* I still, I still have an objection to this \*\*\*\*.

Next Speaker: Where are you objecting?

Next Speaker: It's the language. I mean –

Next Speaker: Well, we'll take, I'll take a look at that. \*\*\*\*.

Next Speaker: An approved \*\*\*\* provided, unsure, provided, complied \*\*\*\* complies then suddenly, and this is the packet, and then suddenly in between there's an unrelated thing \*\*\*\* gives consent. This is not about the patient, this is about the project.

Next Speaker: No, I'm sure \*\*\*\* make sure, make sure the patient gives informed consent.

Next Speaker: That's another thing, it needs to be parallel to the other one.

Next Speaker: But it is written that way.

Next Speaker: No, it's not –

Next Speaker: Well, wouldn't, wouldn't the received informed consent from the patient \*\*\*\* more \*\*\*\* what you're saying, ensure that every patient is provided information and \*\*\*\* received informed consent prior \*\*\*\* blah, blah, blah, isn't that \*\*\*\* concern and need to \*\*\*\*?

Next Speaker: \*\*\*\*.

Next Speaker: Okay, well, we'll look at it.

Next Speaker: \*\*\*\* I mean, it's like this \*\*\*\*.

Next Speaker: And it may be, it may be how \*\*\*\*, but we'll look at that. Okay \*\*\*\* this is the same language in the other \*\*\*\* provide \*\*\*\* does not expose a patient to risk of harm when the \*\*\*\* or provided treatment \*\*\*\* to a patient is available. \*\*\*\* RS, um, this is relating to, um, radiation. Uh, and \*\*\*\* and it's also there's a whole separate \*\*\*\* legislation \*\*\*\*. Um, and prohibit, prohibit a trainee from performing procedures the trainee is not capable of performing based on the trainee's level of education, trainee

experience, or which are outside of a trainee's approved scope of practice as is set out in the \*\*\*\* and approved by the authority. Any questions?

Next Speaker: \*\*\*\* still allow for somebody to be trained outside of the \*\*\*\*?

Next Speaker: Yes, we just –

Next Speaker: Yes.

Next Speaker: – can't \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: It has to be within that approved project.

Next Speaker: \*\*\*\*.

Next Speaker: Yeah, and it provides \*\*\*\* provide an infection control procedures and \*\*\*\* and this is where \*\*\*\* H \*\*\*\* missed it \*\*\*\* section of the Oregon \*\*\*\* Act, and this is where, um, what we've \*\*\*\* records \*\*\*\* after that, and maybe it's homework. \*\*\*\* that, okay? There's a lot \*\*\*\*. Does anybody have any questions about that?

Next Speaker: So, \*\*\*\* another way \*\*\*\* procedures \*\*\*\* or what?

Next Speaker: Well, and this, this \*\*\*\* but patient records.

Next Speaker: Yes.

Next Speaker: There's nothing with that for rules that say, um, \*\*\*\* a certain \*\*\*\*.

Next Speaker: Right \*\*\*\* –

Next Speaker: \*\*\*\*.

Next Speaker: – need to be there. We should be doing that, and, and to make sure that that does happen it will \*\*\*\*.

Next Speaker: Is that duplicating \*\*\*\* other \*\*\*\*?

Next Speaker: No, \*\*\*\* referencing \*\*\*\* if what's in the \*\*\*\*.

Next Speaker: \*\*\*\* Act.

Next Speaker: \*\*\*\* standards of the project are standards \*\*\*\* to on their project successfully. \*\*\*\* plan, their data, how, how they're accounting \*\*\*\*.

Next Speaker: So that's not, I thought before that they gave before informed consent \*\*\*\* so \*\*\*\* practice \*\*\*\* more \*\*\*\*.

Next Speaker: Um, \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: So that, this –

Next Speaker: Well –

Next Speaker: – I think that they, 'cause that seemed nebulous, and that was kinda, and we talked about things that are really \*\*\*\* minimum standards than –

Next Speaker: Yeah, we did.

Next Speaker: Yeah, that's right, so now, that helps define standard operating procedures \*\*\*\* standard \*\*\*\* conversation \*\*\*\*.

Next Speaker: Some are \*\*\*\* and some \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* are not gonna be in the \*\*\*\*.

Next Speaker: Right \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Right.

Next Speaker: Yeah, exactly.

Next Speaker: \*\*\*\*, I think that in \*\*\*\* that you make clear was that \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: Because I, like, in general I don't \*\*\*\* I want to see what \*\*\*\* and I want to see it in the right place, and \*\*\*\*. I don't think you can ask people for second \*\*\*\* actually \*\*\*\* about, I mean, like \*\*\*\* do \*\*\*\* 'cause \*\*\*\* know what that is. We know what X-ray machines \*\*\*\* and so on.

Next Speaker: Exactly.

Next Speaker: But we don't know \*\*\*\*.

Next Speaker: Well, that's why it's \*\*\*\*.

Next Speaker: Yeah, I understand, but I would like to see what, I mean, you must have been thinking about something \*\*\*\*.

Next Speaker: Well \*\*\*\* records that \*\*\*\* –

Next Speaker: So \*\*\*\*.

Next Speaker: – unacceptable. Well, yeah, I mean, this is \*\*\*\*, this is can, can we do that and this comes back to \*\*\*\* licensees \*\*\*\* if it's in \*\*\*\* that's that whole legal part of this that I'm not \*\*\*\*.

Next Speaker: Well, and –

Next Speaker: \*\*\*\*.

Next Speaker: – I think part of the process too, is like, like Eli said, we get everything put in. We don't worry so much about the specific legal \*\*\*\* an AG that's going to look this over –

Next Speaker: Yes.

Next Speaker: – and make sure that we're legally compliant and –

Next Speaker: Exactly.

Next Speaker: – \*\*\*\* legally, so, I, I agree with –

Next Speaker: Mm hmm.

Next Speaker: – what you're saying as far as stuff listed specifically. He wants to know specifics and \*\*\*\* we can \*\*\*\* –

Next Speaker: \*\*\*\*.

Next Speaker: – for this, and then if the, if the attorney decides that we can't use the re-licensee then we \*\*\*\*.

Next Speaker: We've got to change it.

Next Speaker: We have no problem with you plagiarizing any part of this document that you want.

Next Speaker: Okay.

Next Speaker: Okay \*\*\*\* come back with some –

Next Speaker: \*\*\*\* there.

Next Speaker: – \*\*\*\* and then \*\*\*\*.

Next Speaker: Yeah.

Next Speaker: \*\*\*\* so, \*\*\*\* first round \*\*\*\* go to \*\*\*\*. The intent of it was to have \*\*\*\* involvement \*\*\*\* test it is to have one of the best \*\*\*\* consultation \*\*\*\* the structure is in place \*\*\*\* uh, the process. Would it make more sense that \*\*\*\* consultation \*\*\*\* had an opportunity to wait \*\*\*\* something that –

Next Speaker: \*\*\*\* try to overly define.



Next Speaker: – \*\*\*\* all intents \*\*\*\* as possible, uh, as much a part \*\*\*\* be doing \*\*\*\* assets. They've \*\*\*\* coming into the \*\*\*\*. Is there a downside to \*\*\*\* that you \*\*\*\*.

Next Speaker: So, I approved the project's \*\*\*\* but I'm just –

Next Speaker: \*\*\*\*.

Next Speaker: So, doing a formal, like, take this to the Board –

Next Speaker: \*\*\*\*.

Next Speaker: – um, for approval or just, uh –

Next Speaker: \*\*\*\*.

Next Speaker: – having a couple members sit down and be yeah, it looks okay, 'cause if we're having like a formal thing I will tell that your, your timeline is going to extend –

Next Speaker: \*\*\*\*.

Next Speaker: – by 6 months to a year because it has to go through this whole process. You know, we have certain rules \*\*\*\*.

Next Speaker: \*\*\*\* know about the legislative in 10.5. I do remember certain things from \*\*\*\* and \*\*\*\* was an idea in terms of not asking \*\*\*\* because there was this whole thing about \*\*\*\* Board essentially sitting on the, the practice of dentistry \*\*\*\* and you want to go outside of the regular sort of borderline \*\*\*\* that was the whole idea of coming up with this idea of trying to create some new \*\*\*\* that \*\*\*\* and, and, um, I just, I just think that \*\*\*\* here \*\*\*\* for the last few years and this is, \*\*\*\* more restricted, kind of, um, kind of \*\*\*\* restricting a lot of things that were not there originally, and it may still be okay. I mean, as long as it's, uh, in the spirit of the, but I mean, if the, if you make it so restrictive that nobody really follows through \*\*\*\* because you know that this is not going the way \*\*\*\* then of course we will \*\*\*\* exactly the opposite of \*\*\*\* was \*\*\*\* -

Next Speaker: Yeah.

Next Speaker: – and we really feel that that's not the way \*\*\*\*.

Next Speaker: Well, that's something \*\*\*\* person that will still allow \*\*\*\*. It's still something to \*\*\*\* person \*\*\*\* license, so that covers our standard of care conversation. I don't really \*\*\*\* the details of the project. I mean, if this is about \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: Even though \*\*\*\* practice outside \*\*\*\*.

Next Speaker: Well, I will tell you \*\*\*\* the application that's \*\*\*\* recall \*\*\*\* part of the \*\*\*\* step for \*\*\*\* on that, and so \*\*\*\* legit involved \*\*\*\*.

Next Speaker: Well, I think \*\*\*\* was fantastic, we're very happy to be here, but I don't want, we don't want, and I think you'll agree, you know, we don't want it to have our, put our stamp on anything as a collective \*\*\*\* that's –

Next Speaker: Right.

Next Speaker: – gonna drag you guys down and we, we've got enough on our plate \*\*\*\* –

Next Speaker: \*\*\*\*.

Next Speaker: – involvement.

Next Speaker: Right.

Next Speaker: Absolutely.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* involved \*\*\*\*.

### **Agenda Topic: Public Comment**

Next Speaker: Okay, so we need to move, um, so we're gonna stop here with this. Um, we'll do it next week, and then we haven' um, if we don't have any requests in the room or public comments from anybody on the phone who would like to make a public comment?

Next Speaker: \*\*\*\* I'm just \*\*\*\*.

Next Speaker: Go ahead.

Next Speaker: \*\*\*\* findings of \*\*\*\* by \*\*\*\* come back \*\*\*\* and then \*\*\*\* if we have to \*\*\*\*.

Next Speaker: Yes, and I have a \*\*\*\* attitude \*\*\*\* locked up there \*\*\*\*. Uh \*\*\*\* organized.

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: And \*\*\*\* to that and then you –

Next Speaker: Yeah.

Next Speaker: – \*\*\*\* be great.

Next Speaker: \*\*\*\* okay, so our next meeting is \*\*\*\* just given the \*\*\*\*.

Next Speaker: Again, is anybody on the phone?

Next Speaker: \*\*\*\*.

Next Speaker: Nope? All right.

Next Speaker: No, I, this is Heather Simmons, I'm on the phone, but I don't have any further comments.

Next Speaker: Okay, thanks, Heather.

Next Speaker: I'm on the phone, you've heard all my comments.

Next Speaker: \*\*\*\*. Okay, so –

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\* is, um, I was gonna \*\*\*\* earlier about the \*\*\*\*, uh, to oversee \*\*\*\* that is the \*\*\*\* within the \*\*\*\*.

Next Speaker: Thank you, Quanita.

### **Agenda Topic: Next Steps**

Next Speaker: Okay, so our next meeting is, um, June 25th between 9:00 a.m. and 11:00, and \*\*\*\* and that \*\*\*\* to follow up documents.

Next Speaker: And apparently \*\*\*\* purpose \*\*\*\*.

Next Speaker: \*\*\*\* people \*\*\*\*.

Next Speaker: Thank you for bringing these –

Next Speaker: And if you could keep your packets we'll keep adding to them.

Next Speaker: \*\*\*\*.

Next Speaker: \*\*\*\*.

Next Speaker: We're conserving. Thanks, you guys.

Next Speaker: Yeah, thank you guys \*\*\*\* –

### **Meeting adjourned 10:56am.**

Next RAC meeting:

June 25, 2018

9:00 AM - 11:00 AM

OHA Public Health Division 800 NE Oregon Street Portland, OR 97232

Conference Room 1E – First Floor

**333-010-XXXX**

**Dental Pilot Projects: Purpose**

(1) The Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy by 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. ~~The oral health status of Oregonians is poor and the most vulnerable are those with the least access to services.~~ The purpose of the Dental Pilot Projects are to improve access to oral health care, reduce oral health disparities, and improve the oral health of Oregon’s vulnerable and underserved populations.

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(2) These rules establish the requirements of Dental Pilot Project applications, the process for reviewing application, approval or denial of applications, minimum standards for approved projects, evaluation and monitoring of Dental Pilot Projects, suspension or termination of an approved Dental Pilot Project, and discontinuation or closure of a project.

(3) These rules apply to:

- (a) Applications for dental pilot projects received on or after November 1, 2018; and
- (b) Dental pilot projects approved before or after the effective date of these rules.

**Commented [KSE1]:** Time for existing projects to come into compliance.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

**333-010-XXXX**

**Dental Pilot Projects: Definitions**

For purposes of OAR 333-010-XXXX through 333-010-XXXX, the following definitions apply:

**Commented [KSE2]:** Definitions are in Alphabetical order A...Z

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

(2) "Authority" means the Oregon Health Authority.

(3) "Clinical evaluator" means a dentist, licensed in Oregon or another state who is responsible for conducting a clinical evaluation of an approved dental pilot project who is unaffiliated with the project and who has no financial or commercial interest in the project's outcome.

**RED=Tracked Changes**

**BLUE=New language**

**BLACK=Existing language**

Dental Pilot Project Program  
Amended Oregon Administrative Rules  
RAC Meeting #2

(4) "Clinical phase" means instructor supervised experience with a patient during which a 9/trainee applies knowledge presented by an instructor.

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

(6) "Didactic phase" means an organized body of knowledge presented by an instructor.

(7) "~~Project Dental Director Project Manager~~" – means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist licensed in the State of Oregon or an individual approved by the Authority.

~~(8) "Director" means the Public Health Director within the Oregon Health Authority, or his or her designee.~~

**Commented [KSE3]:** no longer referenced in other portions of the OARs.

(8) "Employment/Utilization Phase" means ongoing application of didactic and clinical knowledge and skills in an employment setting under the supervision of a supervisor.

(9) "Employment/Utilization Site" means an Authority approved project site. Each site may be comprised of multiple locations and includes any setting where dental health care services are provided by the trainees, and the facilities or programs described in ORS 680.205(1).

(10) "Instructor" means a person qualified to practice or teach the knowledge or skills a trainee is to learn.

(a) "Clinical instructor" is a person who is certified or licensed in the field for which clinical instruction is occurring.

(b) "Non-clinical instructor" is a person with specific training or expertise as demonstrated through a degree or years of experience relevant to the content of instruction.

(11) "Program" means the Dental Pilot Projects program administered by the Authority.

(12) "Program evaluation" means the systematic method for collecting, analyzing and using data to examine the effectiveness and efficiency of pilot programs by program staff.

(13) "Program staff" means the staff of the Authority with responsibility for the program.

(14) "Project" means a Dental Pilot Project approved by the ~~director-Authority or delegate.~~

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(15) "Project director" means the individual designated by the sponsor of a dental pilot project who is responsible for the conduct of the dental pilot project staff, instructors, supervisors, and trainees.

(16) "Project evaluation" means [a systematic method for collecting, analyzing and using data to examine the effectiveness and efficiency of pilot programs by project sponsor.](#)

(17) "Reviewer" means an individual designated by program staff to review and comment on all or portions of a project application.

(18) "Sponsor" means an entity that is a non-profit educational institution, professional dental organization, community hospital or clinic, coordinated care organization or dental care organization, [tribal organization or clinic](#) that:

(a) Submits a dental pilot project application; and

(b) If a dental pilot project is approved, has overall responsibility for ensuring the project complies with these rules.

(19) "Supervisor" means a person designated by the project sponsor who already possesses the skills to be taught the trainees and is certified or licensed in Oregon to practice dentistry.

(20) "These rules" means OAR 333-010-XXXX through 333-010-XXXX.

(21) "Trainee" means an individual who is part of an existing category of dental personnel; a new category of dental personnel or a previously untrained dental personnel who has agreed to participate in an approved dental pilot project and will be taught the scope of practice as part of an approved dental pilot project.

(22) "Training ~~Phase program~~" means an organized educational program within a dental pilot project that includes at least a didactic phase ~~and~~; a clinical phase ~~, and usually an employment/utilization phase.~~

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### 333-010-XXXX

#### Dental Pilot Projects: Application Procedure

(1) A sponsor [who wishes to operate a pilot project must](#) submit an application [in a form and manner](#) prescribed by the Authority.

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Commented [KSE4]: DOJ Question: Can a project have more than one sponsor? A co-sponsor? Several sponsors?

(2) The application must demonstrate how the pilot project will comply with the requirements of these rules.

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

(a) Has determined that there is already a sufficient number of projects to provide a basis for testing the validity of the model as determined by the Authority.

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

(5) An application must include, at a minimum, the following information and documentation:

(a) The goals of the project, including whether the project can achieve at least one of the following:

- (A) Teach new skills to existing categories of dental personnel;
- (B) Accelerate the training of existing categories of dental personnel;
- (C) Teach new oral health care roles to previously untrained personnel; or
- (D) Develop new categories of dental personnel.

(b) **Sponsors.**

(A) A description of the sponsor, including a copy of an organizational chart that identifies how the project relates organizationally to the sponsor;

(B) A copy of a document verifying the sponsor's status as a non-profit educational institution, professional dental organization, community hospital or clinic, coordinated care organization or dental care organization;

(C) A description of the functions of the project director, ~~dental-project dental director manager~~, instructors, and other project staff;

(D) **Documentation of** the funding sources for the project;

(E) Documentation of liability insurance relevant to services provided by trainees; and

(F) **A statement of previous experience in providing related health care services.**

**Commented [KSE5]:** DOJ question: Number of sponsors?  
Can there be more than one?

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(G) Have and follow written standard operating policies and procedures for specific use by the approved pilot project. Standard operating policies and procedures shall consist of the following

**Commented [s6]:** Needs to be defined  
Clinic Protocols  
Project Protocols

(c) Instructor and Supervisor information:

- (A) The criteria used to select instructors and supervisors;
- (B) Instructor-to-trainee ratio;
- (C) The background of instructors in training techniques and methodology;
- (D) The number of proposed supervisors and **qualification of supervisors; and**
- (E) An explanation of how instructors and supervisors will be oriented to their roles and responsibilities and these rules.**

(d) A **training program** that includes but is not limited to a description of:

**Commented [s7]:** This was previously its own section titled Curriculum. There is no new language here. Does not say Curriculum Plan see language page 10.

- (A) The instructional content required to meet the level of competence;
- (B) The skills trainees are to learn;
- (C) The methodology utilized in the didactic and clinical phases;
- (D) The evaluation process used to determine when trainees have achieved the level of competence;
- (E) The hours and months of the time required to complete the didactic and clinical phases; and
- (F) The level of competence the trainee shall have before entering the employment/utilization phase of the project.

(e) Trainees.

- (A) The criteria that will be used to select trainees;
- (B) The number of proposed trainees;
- (C) A copy of the contract that trainees will be required to enter into with the sponsor should the project be approved;**

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(D) The proposed scope of practice for trainees;

(E) Draft policies and procedures for ensuring compliance with OAR 333-010-XXXX [Minimum Standards] and

(F) Draft polices and procedures for conducting background checks on participating trainees.

(f) Documentation that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase.

(g) The location or locations where patient care will be provided and the criteria used to select these locations.

**Commented [s8]:** The criteria used to select an employment/utilization site.

(h) A description of how the project will provide care to populations that evidence-based studies show have the highest disease rates and the least access to dental care.

**Commented [s9]:** Language from SB738

(i) Costs:

**Commented [s10]:** Request that projects must demonstrate financial resources prior to final approval?

(A) The average cost of preparing a trainee, including but not limited to the cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs;

(B) The estimated cost of care provided in the project, the likely cost of this care if performed by the trainees subsequent to the project, and the cost for provision of this care by current providers thereof.

(C) A budget narrative that lists costs associated with key project areas, including but not limited to:

(i) Personnel and fringe benefits for project director, project dental director, instructors, and staff associated with the project;

(ii) Contractors and consultants to the project;

(iii) Materials and supplies used in the clinical, didactic, and employment/utilization phases of the project;

(iv) Equipment and other capital costs associated with the project; and

(v) Travel required for implementing and monitoring the project.

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(j) An explanation of the feasibility of achieving the project objectives.

(k) A preliminary evaluation plan that includes but is not limited to:

(i) how the project sponsor will monitor and evaluate the project.

(ii) a description of the key activities and their intended effects.

(ii) how the project sponsor intends to use evaluation results for program improvement and decision making.

(l) An identified clinical evaluator, unaffiliated with the project and with no financial or commercial interest in the outcome of the project who will conduct the clinical evaluation of the project in accordance with the evaluation plan.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-XXXX**

#### **Dental Pilot Projects: Application Review Process**

(1) The program staff shall review an application to determine if it is complete within **60 business** days from the date the application was received.

(a) If an applicant does not provide all the information required and the application is considered incomplete, the program shall notify the applicant of the information that is missing, and shall allow the applicant **30 business** days to submit the missing information.

(b) If an applicant does not submit the missing information within the timeframe specified in the notice the application shall be rejected as incomplete. An applicant whose application is rejected as incomplete may reapply at any time.

(2) An application deemed complete will continue through a review process.

(3) The program may have individuals outside the program review applications but no individual who has contributed to or helped prepare an application will be permitted to do a review.

(4) Program staff may request additional information from an applicant during the review process.

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(5) Once project staff complete an application review a Notice of Intent to **provisionally** approve or deny an application will be provided to the applicant and the Notice and application will be posted for public comment for a period of 10 business days. The Notice will be sent to interested parties.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### 333-010-XXXX

#### Dental Pilot Projects: Project **Application Provisional Approval or Denial**

(1) Following the close of the public comment period described in OAR 333-010-XXXX [Application Review Process] the ~~director~~ **Authority or his or her designee** shall review the public comments that were received and issue, within 30 **business** days of the close of the public comment period:

(a) A **provisional decision to grant an application; or**

(b) A **denial of the application.**

(2) If the application is **provisionally approved, the project sponsor must comply with the requirements in OAR 333-010-XXXX [ Provisional Approval; Final Approval] before it can receive final approval.**

(a) Projects that receive provisional approval may not operate until final approval is received from the Authority.

(3) If the ~~Authority director~~ **denies the application the denial must be in writing and must describe the reasons for the denial. An application may be denied for any of these reasons:**

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

(b) The application does not demonstrate that the project is financially feasible; **or**

(c) The program has previously approved a similar project.

(4) A sponsor whose project has been denied may not submit a new application within six months from the date the ~~Authority director~~ denied the application.

**Commented [s11]:** There was a request that the project must demonstrate that the project is financially feasible; a project will not be approved if it does not demonstrate this component.

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Statutory/Other Authority: 2011 OL Ch. 716  
 Statutes/Other Implemented: 2011 OL Ch. 716

**333-010-XXXX**

**Dental Pilot Projects: Provisional Approval; Final Approval**

(1) A project sponsor that has been provisionally approved, must, within 3 months of provisional project approval, submit the following to the Program for approval:

(a) A detailed evaluation and monitoring plan that meets the requirements in OAR 333-010-XXXX. [Pilot Project Evaluation and Monitoring by Sponsor]

(b) The project must have and follow policies and procedures for:

(i) Data collection and storage;

(ii) Protection and security of patient data;

(iii) Obtaining patient informed consent.

(iv) The provision of emergency treatment for patients and provide or arrange for emergency treatment for a patient currently receiving treatment as necessary;

~~(d) Have and follow written standard operating policies and procedures for specific use by the approved pilot project. Standard operating policies and procedures shall consist of the following~~

(2) The Program will review the documentation required in section 1 of this rule and notify the project sponsor if the plan and policies and procedures are acceptable. The program may request additional information and may request that the project sponsor revise the plan or policies and procedures to meet the requirements in these rules.

(3) Once the program has received an acceptable plan and policies and procedures it will notify the project sponsor that the project has been approved, along with the plan and policies and procedures. The final approval letter must include:

(a) The permitted scope of the project;

(b) Any conditions the Authority ~~director~~ deems are necessary; and

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- (c) The length of time the project can operate, **from between three to five years.**
- (6) The **p**Program staff shall notify the Oregon Board of Dentistry when a project is approved.

### **333-010-XXXX**

#### **Dental Pilot Projects: Minimum Standards**

An approved dental pilot project shall:

- (1) Provide for patient safety as follows:

(a) **Ensure that every patient is provided information and gives written informed consent prior to treatment in accordance with OAR 333-010-XXXX.** [Informed Consent]

(b) Provide treatment that does not expose a patient to risk of harm when equivalent or better treatment with less risk to the patient is available;

(e) Comply with ORS 453.605 to 453.755 and OAR 333, Divisions XX to XX relating to the use of x-ray machines;

**(f) Prohibit a trainee from performing procedures the trainee is not capable of performing based on the trainee's level of education, training and experience, or which are outside of the trainee's approved scope of practice as is set out in the application and approved by the Authority;**

(g) Comply with the infection control procedures in OAR 818-012-0040; and

(h) Comply with [listed applicable sections of the Oregon Dental Practice **Act**].

(2) **Have** appropriately qualified instructors to prepare trainees.

(a) A project must have a number and distribution of qualified instructors sufficient to meet project objectives, **who have been approved by the Authority; and**

**(b) Instructors must be currently licensed in dentistry, dental hygiene or another appropriate health discipline** and have current knowledge and skill in topics they will teach.

**(3) Provide instruction to trainees following the curriculum plan approved by the Authority.**

(4) Assure that trainees achieve a minimal level of competence before they are permitted to enter the employment/utilization phase. The sponsor must provide notice to program staff within 14 calendar days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to the following:

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**Commented [s12]:** Oregon Dental Practice Act. DOJ question – DPA terms “licensee”

**Commented [s13]:** See Page 4. Curriculum Plan language changed to training program.

- (a) Name, work address, [email](#) and telephone number of the trainee; and
- (b) Name, work address, [email](#), telephone number and license number of the supervisor.
- (a) Information regarding the trainee's responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules.
- (b) [A disclaimer that there is no assurance of a future change in law or regulations that will allow them to practice without a license outside an approved dental pilot project.](#)
- (6). A description of the process used to orientate supervisors to their roles and responsibilities.
- (a) [Training materials must be provided to the Authority upon request.](#)
- (7) Comply with the requirements of the Dental Pilot Projects statute, Oregon Laws 2011, chapter 716, these rules, and the approved application, including but not limited to the evaluation and monitoring plan
- (8) Evaluate quality of care, access, cost, workforce, and efficacy [in accordance with the evaluation and monitoring plan approved by the Authority and as described in OAR 333-010-XXXX.](#) [Pilot Project Evaluation and Monitoring by Sponsor]
- (9) Report [serious](#) adverse events to the Authority the day they occur.
- (10) [Submit detailed quarterly monitoring data in a format requested by Program staff.](#)

Statutory/Other Authority: 2011 OL Ch. 716  
 Statutes/Other Implemented: 2011 OL Ch. 716

**333-010-XXXX**  
**Dental Pilot Projects: Informed Consent**

- (1) A sponsor must ensure that [each patient or person legally authorized to provide consent on behalf of the patient, is provided written information about the dental pilot project and who will be providing treatment, gives written consent to be treated by the dental pilot project, and gives informed consent for treatment.](#)
- (2) [Written information about the project and who will be providing treatment must include but is not limited to:](#)

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(a) An explanation of the role and status of the trainee, including the availability of the trainee’s supervisor for consultation;

(b) An explanation that the patient can refuse care from a trainee without penalty for such a request;

(c) Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient.

(d) A description of the trainee’s level of training and experience, whether the trainee is licensed or unlicensed, who is supervising the trainee, and the trainee’s approved scope of practice.

(3) 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 the treatment I can receive from this dental pilot project and I agree to the trainee of this project providing me treatment.”

\_\_\_\_\_  
Signature of patient or person acting on patient’s behalf

\_\_\_\_\_  
Date

(4) Informed consent for treatment.

(a) Each patient must give informed consent to each procedure or treatment. Informed consent means:

(A) Explaining, in a language the patient understands, in general terms the procedure or treatment to be undertaken; that there may be alternative procedures or methods of treatment, if applicable; and the risks to the procedure or treatment, if applicable.

(B) After the explanation in subsection (A) of this section, asking the patient if the patient wants a more detailed explanation. If the patient requests further explanation, such an explanation must be provided, including in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. In determining that further explanation would be materially detrimental the dental project manager shall give due consideration to the standards of practice of reasonable dental practitioners in the same or a similar community under the same or similar circumstances.

(b) Informed consent for treatment must be obtained in writing and such consent must be included and documented in the patient’s record.

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Statutory/Other Authority: 2011 OL Ch. 716  
 Statutes/Other Implemented: 2011 OL Ch. 716

### 333-010-XXXX

#### Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Sponsor

(1) Pilot project sponsors must submit a detailed Evaluation and Monitoring Plan to the Authority in accordance with OAR 333-010-XXXX. [Provisional Approval; Final Approval]

(2) A Project Evaluation and Monitoring Plan must include but is not limited to:

(A) A logic model to depict the project activities and intended effects;

(B) A description of key evaluation questions to be addressed by the pilot project, including relevant process and outcome measures;

(C) A detailed description of the baseline data and information to be collected about the availability or provision of oral health care delivery, or both, prior to utilization phase;

(D) A detailed description of baseline data and information to be collected about trainee performance, patient and community satisfaction, and cost effectiveness;

(E) A detailed description of the methodology and data sources to be used in collecting and analyzing the data about trainee performance, acceptance, **quality of care** and cost effectiveness;

(F) Defined measures to evaluate safety and quality of care provided; and

(G) A process for review of the evaluation plan for continuous quality improvement purposes.

(H) The evaluation plan must include an ongoing quarterly monitoring component that ensures at a minimum:

(i) Patient safety; **The provisions for protecting the safety of patients seen or treated in the project;**

(ii) Trainee competency;

(iii) Supervisor fulfillment of role and responsibilities;

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(iv) Employment/utilization site compliance; and

**333-010-XXXX**

**Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Program**

(1) Program staff shall monitor and evaluate approved pilot projects to determine the project's compliance with these rules and to check on the progress of the project. Monitoring and evaluation may include but is not limited to:

- (a) Requesting written information or documents from the project;
- (b) Interviews with the project sponsor, instructors, supervisors, other staff or trainees; and
- (d) Quarterly submitted data as described in 333-010-XXXX [Minimum Standards].

(2) Program staff shall conduct site visits, at least once a year, to project offices, locations, or both, where trainees are being prepared or utilized.

(a) An interdisciplinary team composed of representatives of the dental boards, professional organizations, and other state regulatory bodies may be invited to participate in site visits.

(b) 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; and

(C) Reviews of patient records to evaluate patient safety and trainee competency and quality of care.

(b) The program will, unless there are concerns about patient or trainee safety, provide at least 14 business days notice to the sponsor prior to the date of a site visit.

(c) Following a site visit the program will:

(a) Within 60 business 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.

(b) Within 180 business days of receipt of a plan of correction, issue a final report to the sponsor.

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(c) If there are no corrections needed, the program will issue a final report within 180 business days.

(4) Failure of a sponsor or anyone involved with an approved pilot project to cooperate with a request for records, interviews or a site visit is grounds for the program to suspend or terminate a project. Failure to cooperate includes but is not limited to failure to provide information or documents in a manner requested by the program or within the timeframe requested by the program.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### 333-010-XXXX

#### Dental Pilot Projects: **Project Modifications**

(1) An approved dental pilot project may make minor modifications to the project with written approval of the program. Proposed minor modifications must be submitted to the program in writing for approval or disapproval, except as described in section (3) of this rule.

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

(a) Changes in selection criteria for trainees or supervisors

(b) Changes in employment/utilization sites; removing sites or adding sites within the approved scope or nature of the project.

(c) Changes in project staff or instructors.

(3) Changes in project staff or instructors 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.

**Commented [s14]:** In the section, the Authority is not required to approve project staff or instructors – contradicts requirements under Minimum Standards, 2 a

(4) Any modification to an approved pilot project that is not a minor modification is not permitted though the project sponsor could submit a new application.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### 333-010-XXXX

#### Dental Pilot Projects: **Discontinuation or Completion of Project**

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(1) An approved project must notify the Authority in writing if it intends to discontinue its status as a Dental Pilot Project, at least 60 business days prior to discontinuation. Notification must include a closing report that includes but is not limited to:

- (a) The reasons for discontinuation as a pilot project;
  - (b) A summary of pilot project activities including the number of persons who entered the employment/utilization phase; and
  - (c) A description of the plan to inform trainees of the project's discontinuation, and that they are precluded from performing the skills authorized under the pilot project after discontinuation unless the role has been legalized.
- (2) The project must obtain written acknowledgement from trainees regarding notification of the project's discontinuation and preclusion from performing skills authorized under the pilot project after discontinuation unless the role has been legalized and the trainee has met necessary licensure requirements.

(3) Project completion.

(a) A project sponsor must:

(A) Provide a full report of findings to the Authority within 180 business days of the completion of the project.

(B) Inform the Oregon Board of Dentistry that the project is completed and provide a list of trainee names associated with the project at least 14 business days prior to discontinuation.

(4) Program staff shall conduct an independent evaluation of the project upon its completion and prepare a final report that may include but is not limited to;

- (a) The new dental skills taught or extent that existing skills have been reallocated.
- (b) Implication of the project for existing licensure laws with suggestions for changes in the law where appropriate.
- (c) Implications of the project for dental services curricula and for the health care delivery systems.
- (d) Teaching methods used in the project.
- (e) The quality of care and patient acceptance in the project.

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(f) The extent that persons with the new skills could find employment in the dental health care system, assuming laws were changed to incorporate their skill.

(g) The cost of care provided in the project, the likely cost of this care if performed by the trainees subsequent to the project, and the cost for provision of this care by current dental providers thereof.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-XXXX**

#### **Dental Pilot Projects: Suspension or Termination of Project**

(1) A pilot project may be suspended or terminated for violation of 2011 Oregon Laws, chapter 716 or any of these rules.

(2) If the Authority determines that a dental pilot project is in violation of 2011 Oregon Laws, chapter 716 or these rules, the Authority may:

(a) Work with the project to bring the project into compliance; or

(b) Issue a Notice of Proposed Suspension or Notice of Proposed Termination in accordance with ORS 183.411 through 183.470.

(3) A sponsor who receives a Notice may request an informal meeting with the ~~Authority director~~ and program staff. A request for an informal meeting does not toll the time period for requesting a hearing as described in section (4) of this rule.

(4) If the Authority issues a Notice of Proposed Suspension or Notice of Proposed Termination the sponsor is entitled to a contested case hearing as provided under ORS Chapter 183. The sponsor has 30 calendar days to request a hearing.

(5) If the Authority terminates a dental pilot project the order shall specify when, if ever, the sponsor may reapply for approval of a dental pilot project.

Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

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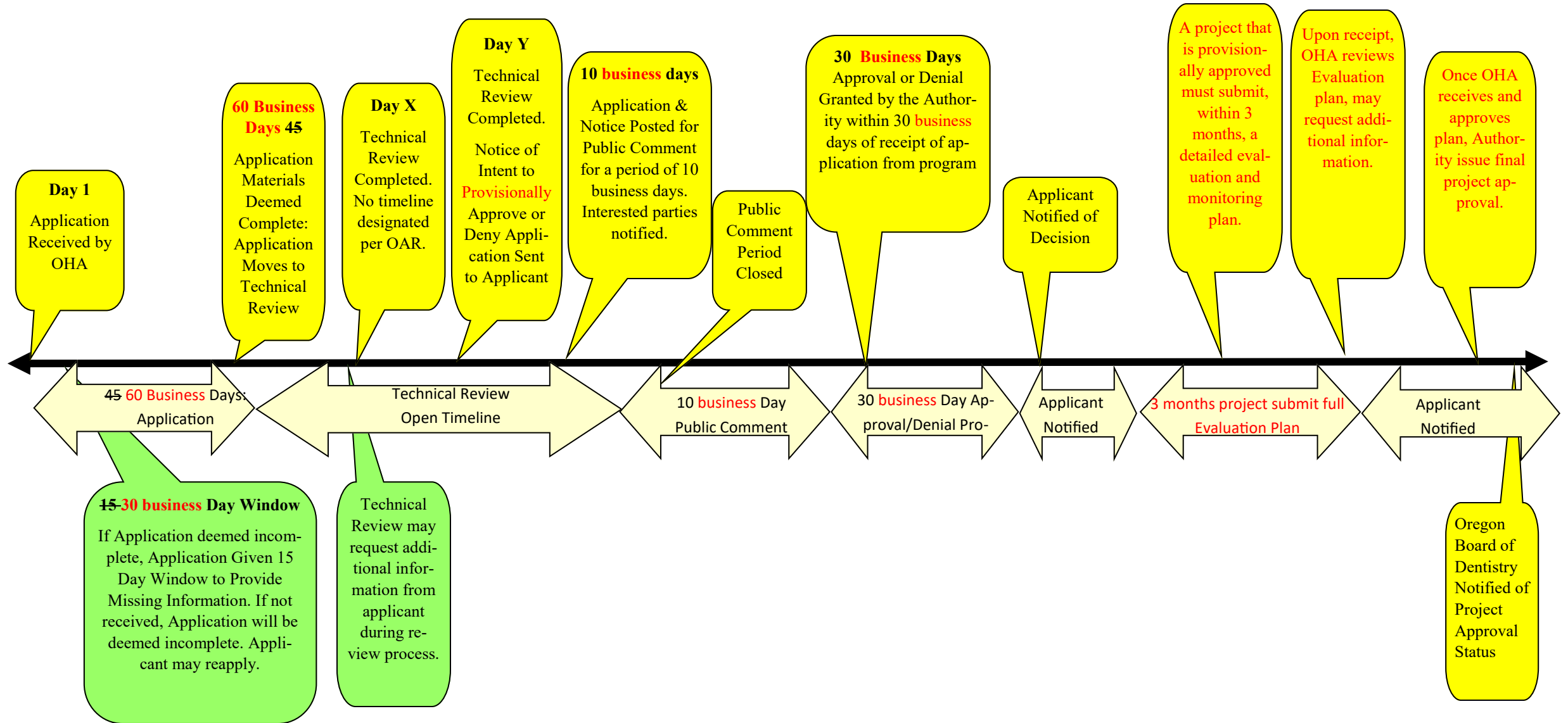
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# Dental Pilot Project Application Phase Timeline **DRAFT**



Adverse Event and Patient Safety Reporting Annotated Bibliography

Title	Lead Author	Journal	Year	AMA/APA Citation	Notes
An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office	Kalenderian	Journal of the American Dental Association	2013	Kalenderian E, Walji M, Tavares A, Ramoni R. An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. <i>Journal Of The American Dental Association (1939)</i> [serial online]. July 2013;144(7):808-814. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	<p><b>AE definition:</b> “Harm caused by medical treatment, regardless [of] whether it is associated with error or considered preventable. ...It is from the point of view of a patient that harm can sometimes be easily ascertained: ‘If I were the patient, would I be happy if this happened to me?’” – a very broad umbrella definition.</p> <p>Describes a “trigger” or, search tool with trigger words, for inclusion of a chart for review for Adverse Events. Three triggers framed to gain insight into AEs – Incision and Drainage Trigger (CDT C7510 and D7520), Implant Failure Trigger (CDT D6100 EZCode 563101), Multiple-Visits Trigger (&gt;6 visits)</p> <p>Calculated positive predictive values for each trigger, showing the likelihood of a trigger presenting a record with a true AE.</p> <p>“In [the] study population, more than one-third of the randomly selected patients had experienced and AE.” – This is of a random selection, i.e. not those “triggered” records.</p> <p>“Our study results show that the trigger tool approach is capable of identifying AEs more efficiently: 50 percent of records that were positive for any of the three dental triggers contained an AE, whereas 34 percent of randomly selected patient records indicated an AE.”</p> <p>It is their recommendation that “all dental care teams should initiate regular assessments of AEs that occur within their practices, including conducting records reviews.”</p> <p>“In the context of the trigger tool, an AE involves harm to the patient, regardless of whether the AE is associated with error... Focusing on errors shifts the discussion toward individual blame, whereas concentrating on events experienced by patients helps to keep the focus on systemic improvement to reduce patients’ suffering.”</p>
				Kalenderian, E., Walji, M. F., Tavares, A., & Ramoni, R. B. (2013). An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. <i>Journal Of The American Dental Association (1939)</i> , 144(7), 808-814.	
An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland	Hiivala	Acta Odontologica Scandinavica	2016	Hiivala N, Mussalo-Rauhamaa H, Tefke H, Murtomaa H. An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland. <i>Acta Odontologica Scandinavica</i> [serial online]. 2016;74(2):81-89. Available from: MEDLINE, Ipswich, MA. Accessed July 26, 2017.	<p>Each incident was assigned to one of eight types of PSI (Patient Safety Incident) – diagnostics, dental treatment, equipment and supplies, medications or prescription drugs, hygiene or infection control, communication, physical environment related and other.</p> <p>Patient safety: The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.</p> <p>Patient safety incident: An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. An incident can be reportable circumstance, a near miss, a no harm incident or a harmful incident (adverse event)</p> <p>Harmful incident (adverse event): An incident which resulted in harm to the patient</p> <p>“In primary care other than dentistry, diagnostic errors account for the majority of malpractice claims followed by medication errors... Most dental patient allegations concern treatment and diagnostics, while PSIs are most often related to treatment, diagnostics, communication, dental equipment and medications.”</p>
				Hiivala, N., Mussalo-Rauhamaa, H., Tefke, H., & Murtomaa, H. (2016). An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland. <i>Acta Odontologica Scandinavica</i> , 74(2), 81-89. doi:10.3109/00016357.2015.1042040	

Attitudes toward patient safety standards in U.S. dental schools: a pilot study	Leong	Journal of Dental Education	2008	<p>Leong P, Afrow J, Weber H, Howell H. Attitudes toward patient safety standards in U.S. dental schools: a pilot study. <i>Journal Of Dental Education</i> [serial online]. April 2008;72(4):431-437. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Leong, P., Afrow, J., Weber, H. P., &amp; Howell, H. (2008). Attitudes toward patient safety standards in U.S. dental schools: a pilot study. <i>Journal Of Dental Education</i>, 72(4), 431-437.</p>	<p>“The purpose of this study was to test the hypothesis that the patient safety culture in US dental school clinics is less developed than in hospitals by utilizing a survey instrument developed to measure patient safety culture in US hospitals.” – They found that “there are areas of perceived weakness in the patient safety culture of the dental schools visited.”</p> <p>AHRQ Hospital Survey on Patient Safety Culture.</p> <p>“All three dental groups (faculty, staff, and students) surveyed gave less positive responses to the three questions on the reporting of problems than the medical benchmark. There could be several reasons for the less positive responses including the lack of a user-friendly reporting system in dental school clinics and the lack of feedback to all three dental groups about the usefulness of incident reports and changes made to reduce errors as a result of timely reporting.”</p> <p>“The dental school survey respondents rated dental schools lower than the medical benchmark in the area of proactive activities toward patient safety. Few of the sites visited had a process in place to summarize and trend patient safety incident data that would allow them to focus on preventive rather than reactive activities.”</p>
BigMouth: A multi-institutional dental data repository	Walji	Journal of the American Dental Association	2014	<p>Walji M, Kalenderian E, Ramoni R, et al. BigMouth: a multi-institutional dental data repository. <i>Journal Of The American Medical Informatics Association: JAMIA</i> [serial online]. November 2014;21(6):1136-1140. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Walji, M. F., Kalenderian, E., Stark, P. C., White, J. M., Kookal, K. K., Phan, D., &amp; ... Ramoni, R. (2014). BigMouth: a multi-institutional dental data repository. <i>Journal Of The American Medical Informatics Association: JAMIA</i>, 21(6), 1136-1140. doi:10.1136/amiajnl-2013-002230</p>	<p>Work to develop a data repository of EHRs.</p> <p>“Secondary uses of data already stored in dental EHRs have great potential to improve the data-driven knowledge base in dentistry and answer basic questions such as ‘how long do tooth-colored fillings last?’ and ‘how often do patients with diabetes receive the recommended periodontal screenings?’ Linking data from dental EHRs with medical EHRs may also clarify the relationship between oral and general health.”</p> <p>BigMouth is a limited dataset – patients are de-identified with the exception of dates and zip codes.</p>
Classifying Adverse Events in the Dental Office	Kalenderian	Journal of Patient Safety	2017	<p>Kalenderian E, Obadan-Udoh E, Walji M, et al. Classifying Adverse Events in the Dental Office. <i>Journal Of Patient Safety</i> [serial online]. June 30, 2017; Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p>	

**Table 2** Demographic characteristics, oral health status, and selected procedures of patients in the clinics of four dental schools in the BigMouth Dental Data Repository database between January 1, 2010 and December 31, 2011

	School of dentistry			
	School 1	School 2	School 3	School 4
<b>Demographics</b>	N=15 219	N=34 126	N=34 318	N=13 927
Mean age (SD)	48 (17.0)	47 (17.8)	50 (23.2)	45 (17.5)
<b>Sex (%)</b>				
Male	42.4	46.1	45.3	39.2
Female	55.7	53.9	53.3	55.9
Others/don't know	1.9	0.0	1.4	4.9
<b>Diagnosis</b>	N=6227	N/A	N=10 451	N=3775
Defective restoration (%)				
Open margin	4.6		5.6	1.7
Removable prosthodontics (%)				
Partially edentulous maxilla	2.2		1.7	4.0
<b>Forms</b>	N=11 171	N=24 715	N=20 942	N=3588
Dental history (%)				
Sensitive to cold, hot, sweet, or pressure	19.0	16.1	37.7	12.9
Medical history (%)				
Hypertension	9.8	13.4	14.4	21.5
<b>Oral health status</b>	N=15 219	N=34 126	N=34 318	N=13 927
Missing teeth				
Mean number of missing teeth (SD)	4.1 (5.7)	5.8 (7.5)	5.2 (6.6)	4.1 (6.7)
Dental caries (%)	N=5698	N=8641	N=8128	N=2434
Dental caries	75.5	72.2	71.1	84.0
	N=913	N=2671	N=4918	N=5913
Periodontitis (%)				
Periodontitis	54.9	78.5	87.8	71.3
<b>Procedures</b>	N=14 526	N=30 732	N=32 163	N=13 594
Diagnostic X-ray (%)				
Intraoral X-ray-complete series	20.7	21.0	20.6	19.0
Preventive procedure (%)				
Prophylaxis	42.5	39.8	34.5	17.5
Therapeutic procedure (%)				
Extraction, erupted tooth, or exposed root	7.8	23.3	3.1	21.8

				<p>Kalenderian, E., Obadan-Udoh, E., Maramaldi, P., Etolue, J., Yansane, A., Stewart, D., &amp; ... Walji, M. F. (2017). Classifying Adverse Events in the Dental Office. <i>Journal Of Patient Safety</i>, doi:10.1097/PTS.0000000000000407</p>	<p><b>TABLE 1. Dental AE Type Classification</b></p> <table border="1"> <thead> <tr> <th>AE Category</th> <th>AE Count</th> </tr> </thead> <tbody> <tr><td>Pain</td><td>56</td></tr> <tr><td>Infection</td><td>17</td></tr> <tr><td>Hard tissue damage</td><td>12</td></tr> <tr><td>Nerve injury</td><td>6</td></tr> <tr><td>Soft tissue damage/inflammation</td><td>5</td></tr> <tr><td>Other orofacial harm</td><td>2</td></tr> <tr><td>Allergy, toxicity, or foreign body response</td><td>1</td></tr> <tr><td>Aspiration or ingestion of foreign body</td><td>1</td></tr> <tr><td>Wrong site, wrong patient, or wrong procedure</td><td>0</td></tr> <tr><td>Bleeding</td><td>0</td></tr> <tr><td>Other systemic harm</td><td>1</td></tr> <tr><td>Other harm</td><td>0</td></tr> <tr><td>Total</td><td>101</td></tr> </tbody> </table> <p>Medicine seminal report, 'To Err is Human.' It states that quality consist[s] of the following three domains: (1) safety, defined as "freedom from accidental injury"; (2) practice consistent with current medical knowledge and best practice; and (3) responsiveness to customer-specific values, expectations and preferences."</p> <ul style="list-style-type: none"> <li>- This could be expanded for the use in pilot projects: monitoring for patient safety and quality includes the imperative to make sure the patients are (1) free from accidental injury, (2) receive care equivalent to the quality found in existent dental best practice and (3) receiving care according to their expectations and needs.</li> </ul> <p>The authors also posit a Dental AE Severity Tree in Figure 1 for classifying AEs into several categories. These categories can help delineate reporting requirements and timelines for AEs as well as help guide root cause analysis in chart reviews.</p>	AE Category	AE Count	Pain	56	Infection	17	Hard tissue damage	12	Nerve injury	6	Soft tissue damage/inflammation	5	Other orofacial harm	2	Allergy, toxicity, or foreign body response	1	Aspiration or ingestion of foreign body	1	Wrong site, wrong patient, or wrong procedure	0	Bleeding	0	Other systemic harm	1	Other harm	0	Total	101	<p>"Harm refers to any 'impairment of structure or function of the body and/or any deleterious effect arising there from.'" However, "dental AEs do not neatly fit into the categories developed in the medical realm." Developed a Dental AE Type Classification – handpicked by consensus with input from an advisory committee, which was then pilot tested via a chart review process.</p> <p>They used the same dental triggers as described previously, with the caveat that "a 'trigger' is an opportunity or clue used to identify AEs in a patient's dental record but do not represent AEs themselves." When reviewing these records, "it is important to realize the difference between harm and contributing factors that may lead to harm"</p> <p>"The patient safety revolution can be traced to the seminal Institute of</p>
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Clinical documentation of dental care in an era of electronic health record use	Tokede	The Journal of Evidence-Based Dental Practice	2016	<p>Tokede O, Ramoni R, Patton M, Da Silva J, Kalenderian E. Clinical documentation of dental care in an era of electronic health record use. <i>The Journal Of Evidence-Based Dental Practice</i> [serial online]. September 2016;16(3):154-160. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p>	<p>"Regardless of any true consensus on the ideal content of a 'good' dental record, patient care is clearly not served if practitioners and allied health professionals do a suboptimal job of documenting and maintaining records." Provider feedback sought through a Delphi process on "what a typical dental clinical record should contain and the frequency of update of each entry."</p> <p>"Although the ADA and the AAPD provide a list of what should be included in a dental record, they do not at this time provide guidance as to how often those should be updated."</p> <p>"health care providers resent forces that decrease the amount of time available for patient care or for other needs."</p>																													



				<p>Tokede, O., Ramoni, R. B., Patton, M., Da Silva, J. D., &amp; Kalenderian, E. (2016). Clinical documentation of dental care in an era of electronic health record use. <i>The Journal Of Evidence-Based Dental Practice</i>, 16(3), 154-160. doi:10.1016/j.jebdp.2016.07.001</p>	<p>"Dental providers agree that complete and accurate record keeping is essential to patient care and those items such as histories, examination findings, diagnosis, radiographs, treatment plans, consents, and clinic notes should be recorded. There, however, does not seem to be universal agreement on how frequently such items should be recorded in the dental record."</p>
The Evaluation of Patient Safety in Oral and Dental Health Centers	Yanik	American Journal of Public Health Research	2014	<p>doi: 10.12691/ajphr-2-5-3</p>	<p>"One of the most important indicators of quality in health services is the provision of patient safety."  "Patient safety is the absence of erroneous treatments and avoiding and preventing injuries and adverse outcomes which derive from the presentation of health services"  "Harm involves all types of threats and unsafe conditions against safety. Event corresponds to all deviations from generally accepted medical services. These deviations carry the risk of harming patients."</p>
From good to better: toward a patient safety initiative in dentistry	Ramoni	Journal of the American Dental Association	2012	<p>Ramoni R, Walji M, Kalenderian E, et al. From good to better: toward a patient safety initiative in dentistry. <i>Journal Of The American Dental Association (1939)</i> [serial online]. September 2012;143(9):956-960. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Ramoni, R. B., Walji, M. F., White, J., Stewart, D., Vaderhobli, R., Simmons, D., &amp; Kalenderian, E. (2012). From good to better: toward a patient safety initiative in dentistry. <i>Journal Of The American Dental Association (1939)</i>, 143(9), 956-960.</p>	<p>Four element patient safety initiative from AHRQ to minimize patient safety hazards:  Element 1: Identifying threats to patient safety. "Two approaches that have proven successful in medicine are adverse event reporting systems (AERSs) and focused chart reviews." Another important part would be a list of "never-events" such as wrong site surgery that should never happen.  Element 2: Identifying and evaluating effective patient safety practices. Root cause analyses and health care failure mode and effect analyses (HFMEA) are two approaches that have been refined in the medical field. Root cause analysis is retrospective; the objective is to find the root, or underlying, cause of the event or near miss. HFMEA is prospective; the intention is to evaluate a health care process to identify potential vulnerabilities. "The focus of the HFMEA is defined on the basis of information regarding the prevalence and severity of adverse events or patient risk factors."  Element 3: Educate, disseminate, implement and raise awareness. Within dentistry, the Organization for Safety, Asepsis and Prevention distributes best-practice information in the area of infection control, including a checklist for dental offices.  Element 4: Continually monitor and evaluate threats to patient safety to ensure that a positive safety culture is maintained and a safe environment continues.</p>
How dental team members describe adverse events	Maramaldi	Journal of the American Dental Association	2016	<p>Maramaldi P, Walji M, Kalenderian E, et al. How dental team members describe adverse events. <i>Journal Of The American Dental Association (JADA)</i> [serial online]. October 2016;147(10):803. Available from: MasterFILE Premier, Ipswich, MA. Accessed July 26, 2017.</p>	

Maramaldi P, Walji M, Kalenderian E, et al. How dental team members describe adverse events. *Journal Of The American Dental Association (JADA)* [serial online]. October 2016;147(10):803. Available from: MasterFILE Premier, Ipswich, MA. Accessed July 26, 2017.

Defined AEs as “harm caused to the patient by dental care, regardless of whether it is associated with an error or is considered preventable.”  
 “Our work includes proposing the adoption of the Agency for Healthcare Research and Quality’s patient safety initiative which incorporates 4 major elements to address patient safety: identifying threats to patient safety; identifying and evaluating effective patient safety practices; educating, disseminating, implementing, and raising awareness; and monitoring threats to patient safety to ensure that a positive safety culture is maintained and a safe environment continues.”  
 Goal of this study was to develop an inventory of AEs generated by interviewing dental team members.  
 “Examples of reported dental AEs include aspirated crowns and lacerations due to the use of high-speed handpieces.” Analyses indicated that respondents confused causes with AEs. “Aspiration or ingestion was cited the most, whereas pain was cited the least.”  
 “An unanticipated finding was the number of identified AEs that we classified as quality-of-care issues.”... “an incident would have to ‘stand the test of our peers,’ meaning that our colleagues would most likely agree that the event could indeed be considered an AE. Examples included most often were those for which the actual harm was not easily identifiable or ‘defensible to our peers,’ such as esthetic issues after treatment, a failed provisional crown, or an underfill of an endodontically treated canal.”  
 – Think more about this.

TABLE 2

Dental adverse event classifications based on Agency for Healthcare Research and Quality classifications for medical errors with examples.*	
ADVERSE EVENT CLASSIFICATION	RESPONSES FROM RESPONDENTS (UNWEIGHTED)
Allergy, Toxicity, or Foreign Body Response	<ul style="list-style-type: none"> <li>■ Nitrous oxide toxicity</li> <li>■ Allergic reaction to dental materials</li> <li>■ Drug-drug interactions</li> <li>■ Upper vascular epinephrine injections resulting in rare allergic reactions</li> </ul>
Aspiration or Ingestion of Foreign Body	<ul style="list-style-type: none"> <li>■ Tracheostomy resulting from aspiration of foreign body</li> <li>■ Swallowed components</li> <li>■ Aspiration of teeth</li> <li>■ Swallowing of orthodontic brackets</li> </ul>
Infection	<ul style="list-style-type: none"> <li>■ Sinusitis due to unintended sinus lift</li> <li>■ Infection postsurgery</li> <li>■ Medication-induced candidiasis</li> <li>■ Development of a deep space infection warranting additional treatment</li> </ul>
Procedure on Wrong Site or Wrong Side, Procedure on Wrong Patient, Wrong Treatment Due to Misdiagnosis, or Other Wrong Treatment Errors	<ul style="list-style-type: none"> <li>■ Failed crowns due to wrong material selection</li> <li>■ Treating the wrong tooth</li> <li>■ Endodontic treatment of nonrestorable teeth</li> <li>■ Performing surgical procedure in the wrong area</li> </ul>
Bleeding	<ul style="list-style-type: none"> <li>■ Perforation of arteries during surgical procedure</li> <li>■ Postsurgical complications: hematoma</li> <li>■ Anesthetic complication resulting in bleeding</li> <li>■ Excessive bleeding of the donor site after soft-tissue grafting</li> </ul>
Pain	<ul style="list-style-type: none"> <li>■ Root sensitivity after dental surgery</li> <li>■ Inadequate anesthesia resulting in pain</li> <li>■ Excessive pain after oral surgery</li> <li>■ Inaccurate crown adjustment leading to tooth pain, discomfort, and temporomandibular disorder</li> </ul>
Hard-Tissue Damage	<ul style="list-style-type: none"> <li>■ Bone fracture during extraction</li> <li>■ Bur injury to adjacent tooth</li> <li>■ Root fractures in the process of placing posts</li> <li>■ Mandible fracture during third-molar extraction</li> </ul>
Soft-Tissue Injury or Inflammation	<ul style="list-style-type: none"> <li>■ Lip laceration</li> <li>■ Improper elevator use resulting in damage to floor of the mouth</li> <li>■ Injuries to soft tissue during debonding in orthodontics</li> <li>■ Swelling after osseous surgery</li> </ul>
Nerve Injury	<ul style="list-style-type: none"> <li>■ Mandibular nerve injury</li> <li>■ Improper location of injection to parotid gland causing temporary paralysis of facial nerve</li> <li>■ Surgical damage to the posterior, superior alveolar nerve</li> <li>■ Nerve damage during placement of the implant</li> </ul>
Other Systemic Complications	<ul style="list-style-type: none"> <li>■ Seizure induced by dental treatment</li> <li>■ Cardiac depression due to anesthesia overdose</li> <li>■ Ingestion of fluoride resulting in irritation to gastrointestinal lining</li> <li>■ Development of degenerative joint disease after orthognathic surgery</li> </ul>
Other Harm	<ul style="list-style-type: none"> <li>■ Damage to the patient’s dental appliances</li> <li>■ Unintentional laser burns causing vision damage</li> <li>■ Provider communication resulting in patient anxiety</li> <li>■ Unintended harm to adjacent anatomic structures when using any instrumentation</li> </ul>
Quality-of-Care Issue	<ul style="list-style-type: none"> <li>■ Delivering poor-fitting dentures</li> <li>■ Impression material lodged in mouth</li> <li>■ Poor-fitting crowns</li> <li>■ Esthetic failure, crowns are completely different color than patient’s teeth</li> </ul>

\* Source: Agency for Healthcare Research and Quality.<sup>27</sup>

Lessons learned from dental patient safety case reports

Obadan

Journal of the American Dental Association

2015

Obadan E, Ramoni R, Kalenderian E. Lessons learned from dental patient safety case reports. *Journal Of The American Dental Association (JADA)* [serial online]. May 2015;146(5):318. Available from: MasterFILE Premier, Ipswich, MA. Accessed July 26, 2017.

Obadan, E. M., Ramoni, R. B., & Kalenderian, E. (2015). Lessons learned from dental patient safety case reports. *Journal Of The American Dental Association (JADA)*, 146(5), 318. doi:10.1016/j.adaj.2015.01.003

Overview of Dental Adverse Events by Type of Harm.

Type of Harm <sup>¶</sup>	Example of Patient Harm	Frequency (n)	Percent (%) <sup>*</sup>
		<i>n</i> =270	100
Delayed appropriate treatment/ disease progression and/ or unnecessary treatment associated with misdiagnosis	Melkersson-Rosenthal syndrome misdiagnosed as angioedema and dental abscess resulting in multiple tooth extractions	62	23.0
Other systemic complications including adverse reactions to dental device/material/procedure	Intracerebral hematoma after tooth extraction	57	21.1
Allergy/ Hypersensitivity reactions	Latex allergy (bitewing radiograph pack, rubber dam, prophylaxis cup)	29	10.7
Systemic infection	Cerebral abscess after dental procedure	28	10.4
Soft tissue injury/ inflammation	Accidental injection of formalin into soft tissues instead of local anesthetic	23	8.5
Aspiration of foreign body	Aspiration of rubber mouth prop	11	4.1
Nerve damage or injury	Paresthesia of infraorbital region	11	4.1
Hard-tissue damage	Root perforation during endodontic treatment	8	3.0
Psychological distress/ disorder	Anorexia nervosa induced by painful orthodontic treatment	7	2.6
Toxicity/ drug overdose	Injection of 1:1000 adrenaline versus 1:100,000	7	2.6
Orofacial infection	Necrotizing fasciitis of infraorbital region	6	2.2
Poor hemostasis/ prolonged bleeding	After traumatic tooth extraction in hemophilic patient	6	2.2
Ingestion of foreign body	Ingestion of endodontic file	5	1.9
Other orofacial complications	Tear of suspensory ligaments in temporomandibular after excessive digital manipulation of chin by dentist	5	1.9
Retention of foreign object(s) with sequela(e)	Breakage of surgical bur and retention within bone	3	1.1
Poor aesthetic results postdental treatment	Malpositioned implants	2	0.7

\* p-value: <0.001

¶ Arranged in descending order of frequency.

adverse events occur to foster better understanding of contributors to dental adverse events; developing checklists, protocols and computerized decision aids to reduce reliance on memory;...standardizing operating procedures to minimize variability based on dentists' training or practice styles..."

Used a Dental Adverse Event Severity Scale to group cases according to the degree of harm that the patient experienced. The largest category was "delayed appropriate treatment/disease progression and/or unnecessary treatment associated with misdiagnosis." \*\*\*\*\*

"Categorizing the adverse events we identified in the case reports proved very challenging due to the absence of an established dental patient safety taxonomy as well as the tremendous variability in scope and content of the published case reports."

\*\* "The path has been illuminated by safety science in other domains... e.g., establishing nonpunitive incident reporting systems and conducting thorough root cause analyses when

Degree of Harm<sup>\*</sup>

Degree of Harm	Frequency (n)	Percent (%)
	<i>n</i> =270	100
E1 (Temporary minimal harm w/ minimal intervention)	18	6.7
E2 (Temporary minimal harm w/ significant intervention)	12	4.4
E3 (Temporary significant harm w/ minimal intervention)	23	8.5
E4 (Temporary significant harm w/ significant intervention)	38	14.1
F (Temporary harm w/ emergency room transfer/hospitalization)	65	24.1
G1 (Permanent minimal harm w/ minimal intervention)	3	1.1
G2 (Permanent minimal harm w/ significant intervention)	6	2.2
G3 (Permanent significant harm w/ minimal intervention)	16	5.9
G4 (Permanent significant harm w/ significant intervention)	41	15.2
H (Intervention required to sustain life)	18	6.7
I (Patient death)	30	11.1

\* See appendix 2 for details of the Dental Adverse Event Severity Scale

Open wide: looking into the safety culture of dental school clinics

Ramoni

Journal of the American Dental Association

2014

Ramoni R, Walji M, Kalenderian E, et al. Open wide: looking into the safety culture of dental school clinics. *Journal Of Dental Education* [serial online]. May 2014;78(5):745-756. Available from:

"...dentists had nearly the same rate of reports (1.66 per practitioner) to the National Practitioner Data Bank as did physicians (1.87 per practitioner). The National Practitioner Data Bank is 'an information clearinghouse to collect and release all licensure actions taken against all health care practitioners and health care entities, as well as any negative actions or findings taken against health care practitioners or organizations by Peer Review Organizations and Private Accreditation Organizations.'"

				MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	Goal of the study was to “benchmark the patient safety culture within three dental schools, identifying areas for improvement... the first ever use of the MOSOPS [Medical Office Survey on Patient Safety Culture] in the dental outpatient setting.” “Like medical procedures, dental procedures are inherently risky.”
				Ramoni, R., Walji, M. F., Tavares, A., White, J., Tokede, O., Vaderhobli, R., & Kalenderian, E. (2014). Open wide: looking into the safety culture of dental school clinics. <i>Journal Of Dental Education</i> , 78(5), 745-756.	
Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice	Yamalik	International Dental Journal	2012	Yamalik N, Perea Pérez B. Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice. <i>International Dental Journal</i> [serial online]. August 2012;62(4):189-196. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	<p><b>Definition of patient safety:</b> “The reduction (or elimination as far as possible) of damage to patients resulting from health care processes or accidents associated with them.”</p> <p><b>Adverse event:</b> “Unexpected result of medical treatment that causes the prolongation of treatment, any type of morbidity, mortality or any other damage to which the patient should not have been exposed. This is a broad concept that includes errors, accidents, delays in care, negligence, complications associated with treatment, etc. It does not include the symptoms of the patient’s presenting illness. The definition of ‘adverse event’ as it is commonly used across the health care sector is difficult to apply to dental care. Adverse events may be avoidable or unavoidable. An example of a preventable adverse event is the prescription of a drug to which a patient is allergic as a result of failing to consult clinical records. An example of a non-preventable adverse event is and adverse reaction to the administration of a local anesthetic in a patient without clinical pathology or allergic history. However the fact that an adverse event is not preventable does not mean that we should be unprepared to act quickly and appropriately if it occurs.”</p> <p>An “important feature of patient safety is its ‘non-punitive’ character.”</p> <p>“Firstly, and as the primary consideration, the promotion of patient safety is an ethical obligation in any health care profession.” <b>“Patient safety is closely linked to the concept of quality care.</b> Any dental care in which all possible risk factors can be controlled represents the highest-quality dental care, and there is a clear relationship between the quality of treatment and the success of outcomes.”</p>
				Yamalik, N., & Perea Pérez, B. (2012). Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice. <i>International Dental Journal</i> , 62(4), 189-196. doi:10.1111/j.1875-595X.2012.00119.x	
Patient safety in dental care: A challenging quality issue? An exploratory cohort study	Mettes	Acta Odontologica Scandinavica	2013	Mettes T, Bruers J, van der Sanden W, Wensing M. Patient safety in dental care: A challenging quality issue? An exploratory cohort study. <i>Acta Odontologica Scandinavica</i> [serial online]. November 2013;71(6):1588-1593. Available from: MEDLINE Complete, Ipswich, MA. Accessed September 26, 2017.	

Mettes, T., Bruers, J., van der Sanden, W., & Wensing, M. (2013). Patient safety in dental care: A challenging quality issue? An exploratory cohort study. *Acta Odontologica Scandinavica*, 71(6), 1588-1593. doi:10.3109/00016357.2013.777471

“Using patient records as a method to identify AEs has the advantage of a clear sampling frame, but its validity highly depends on the quality of record keeping.”  
 “We used a broad definition of an adverse event which was defined as an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient. We considered patient safety at stake if the adverse event was preventable.”  
 In 1000 records over a 5 year period, 46 AEs were identified (4.6%) – 18 were assessed as “preventable.”  
 “The agreement values regarding the identification of AEs between the four dental expert reviewers was 92%.”

Table III. Preventable adverse events and potential adverse events, categorized by domain, cause, actual damage and final harm.

	Adverse events	Domain <sup>a</sup>	Cause (ECM code) <sup>b</sup>	Actual damage <sup>c</sup>	Seriousness final harm <sup>d</sup>
1	Removal of permanent tooth by accident	Diagnoses treatment	HRI/ HRV	2,3	-
2	First molar removal (46) root fragment left <i>in situ</i> , no further testing, diagnoses and therapy	Diagnoses treatment	OC/ HRM	5	-
3	First molar removal (26) root fragment left <i>in situ</i> , no further testing, diagnoses and therapy	Diagnoses treatment	OC/ HRM	5	-
4	First premolar removal (45) root fragment left <i>in situ</i> , no further testing, diagnoses and therapy	Diagnoses treatment	HRI/ HRM	5	-
5	Root canal treatment: excessive filling, material in periapical alveolar bone, no further treatment	Treatment	HRV	5	-
6	Root canal treatment: fractured instrument <i>in situ</i> after root canal treatment, no further treatment	Treatment	OM/ HRI	5	-
7	Root canal treatment: file failure, during irrigation <i>in situ</i> , no further treatment	Treatment	OM/ HRI	5	-
8	Removal (13), broken root fragment left <i>in situ</i> , no further testing, diagnoses and therapy	Diagnoses treatment	PRF/ HRM	5	-
9	Root canal treatment: file fractured in 16 MB-canal, no further treatment	Treatment	OM/ HRV/ HRI	5	-
10	Root canal treatment: instrument broken during root canal treatment, perforation in other root canal	Diagnoses treatment	PRF/ HKK/ HRM	3,2	-
11	Root canal treatment 16: leakage in periodontal apical region NaOCl	Treatment	HRI/ HKK	3,2	-
12	Root canal treatment: perforation by opening, prognosis unfavorable	Treatment	HRI	3,2	-
13	Complicated removal first molar 46, fixed partial prosthesis lost and swallowed by patient	Diagnoses treatment communication	OC/ HKK	3,2	-
14	Root canal treatment: failure file broken, no further treatment	Treatment	OM/ HRI	5	-
15	Swallowing fixed full crown, no reported further treatment	Treatment	OC/ HRM/ HRI	5	-
<i>Potential adverse events:</i>					
16	Removal third molar (38) without prior X-ray	Diagnoses	OC/ HRV	2,2	-
17	Removal third molars (28 & 18) without prior X-ray	Diagnoses	OC/ HRV	2,2	-
18	Removal third molar 38 without prior X-ray	Diagnoses	OC/ HRV	2,2	-

<sup>a</sup> Domains: organization/communication/prevention/diagnoses/treatment.  
<sup>b</sup> Codes from Eindhoven Classification Model (ECM): TD, technical-design; TC, technical-construction; TM, technical-materials; O-EX, organization-external; OK, organizational-knowledge transfer; OP, organizational-protocols; OM, organizational-management priorities; OC, organizational-culture; H-EX, human-external; HKK, human-clinical reasoning; HRQ, human-qualifications; HRC, human-co-ordination; HRV, human-verification; HRI, human-intervention; HRM, human-guarding the process; HSS, human-tactile intervention; PRF, patient-related factors.  
<sup>c</sup> In 'Severity of outcome' according to the International Taxonomy of Medical Errors in Primary Care: Score 1-5 (1 = no adverse event, 4 = death of patient, 5 = harm was not possible to determine).  
<sup>d</sup> ++ most likely; + likely; - unlikely.

Patient safety in dentistry - state of play as revealed by a national database of errors

Thusu  
 British Dental Journal

2012  
 Thusu S, Panesar S, Bedi R. Patient safety in dentistry - state of play as revealed by a national database of errors. *British Dental Journal* [serial online]. August 2012;213(3):E3. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.  
 Thusu, S., Panesar, S., & Bedi, R. (2012). Patient safety in dentistry - state of play as revealed by a national database of errors. *British Dental Journal*, 213(3), E3. doi:10.1038/sj.bdj.2012.669

Table 2 Classifications of patient safety incidents

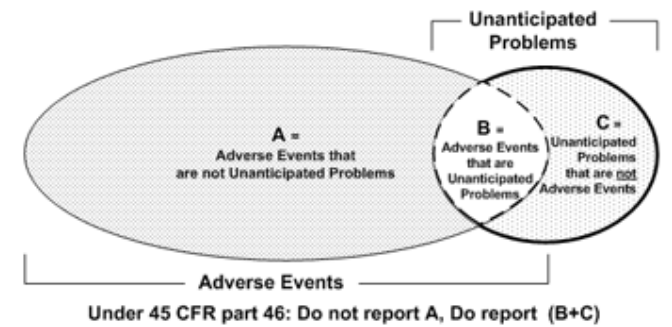
Adverse reaction	Patient experienced an adverse reaction due to procedure
Clerical	PSI due to wrong notes/cancellations/delayed procedures/wrong name tags but no harm
Communication	PSI due to poor/lack of communication between healthcare professionals + poor/lack of communication with patient
Equipment failure	Use of medical/dental equipment that failed to work leading to potential of patient harm but not resulting in actual harm
Fall	Injury due to patient's fault or external environment not related to treatment or clinical environment
Infection control	Harm or potential of harm due to poor infection control
Inhalation	Procedure or treatment leading to patient inhaling foreign objects
Injury	Treatment/procedure leading to direct injury to patient
Management	PSI due to poor clinical management
Medical	Incident due to underlying medical condition not exacerbated by procedure or treatment
Operator injury	Accidental injury to the dentist or member of the dental team eg needles/tick injury to dentist
Radiographs	Avoidable repeated exposure to radiation due (very relevant to dentists as they take their own radiographs and report on them, similar to radiologists and radiographers)
Wrong site extraction	Wrong site extraction (NB not extractions resulting in new injury)

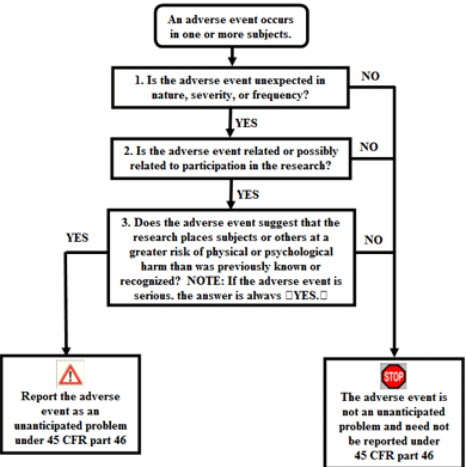
Study to investigate the types of patient safety incidents that occur in dentistry and the accuracy of the National Patient Safety Agency database in for the NHS in England.

Patient safety in primary care dentistry: where are we now?	Bailey	British Dental Journal	2014	<p>Bailey E, Tickle M, Campbell S. Patient safety in primary care dentistry: where are we now?. <i>British Dental Journal</i> [serial online]. October 2014;217(7):339-344. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Bailey, E., Tickle, M., &amp; Campbell, S. (2014). Patient safety in primary care dentistry: where are we now?. <i>British Dental Journal</i>, 217(7), 339-344. doi:10.1038/sj.bdj.2014.857</p>	<table border="1"> <thead> <tr> <th colspan="2">Table 1 Definitions of patient safety</th> </tr> </thead> <tbody> <tr> <td>The Institute of Medicine, 2000</td> <td>The prevention of harm to patients</td> </tr> <tr> <td>Vincent, 2006</td> <td>The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare</td> </tr> <tr> <td>The World Health Organisation, 2011</td> <td>The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum</td> </tr> <tr> <td>The National Advisory Group on the Safety of Patients in England, 2013</td> <td>Avoiding harm from the care that is intended to help</td> </tr> </tbody> </table>	Table 1 Definitions of patient safety		The Institute of Medicine, 2000	The prevention of harm to patients	Vincent, 2006	The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare	The World Health Organisation, 2011	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum	The National Advisory Group on the Safety of Patients in England, 2013	Avoiding harm from the care that is intended to help	<p>“...a peculiarity to dentistry is that the manifestation of a complication caused by dental treatment is frequently treated by other healthcare providers such as paramedics and hospital emergency departments. Due to this, the dental practitioner may not be aware that an adverse event has occurred.”</p>
Table 1 Definitions of patient safety																
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The National Advisory Group on the Safety of Patients in England, 2013	Avoiding harm from the care that is intended to help															
Systematic review of patient safety interventions in dentistry	Bailey	BMC Oral Health	2015	<p>Bailey E, Tickle M, Campbell S, O'Malley L. Systematic review of patient safety interventions in dentistry. <i>BMC Oral Health</i> [serial online]. November 28, 2015;15:152. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Bailey, E., Tickle, M., Campbell, S., &amp; O'Malley, L. (2015). Systematic review of patient safety interventions in dentistry. <i>BMC Oral Health</i>, 15152. doi:10.1186/s12903-015-0136-1</p>	<p>“It is estimated that between 5 and 80 patient safety incidents occur per 100,000 consultations in primary medical care settings, with approximately 11% of prescriptions containing errors.”</p> <p>“Epidemiological data from studies relating to dentistry are uncommon. One recent review from the Netherlands used systematic retrospective analysis to review the electronic records for any patients where a potential adverse event was identified. The researchers analyzed 1000 records that were made up of 50 patients from the 20 practices that participated in the study; this amounted to 13,615 patient contacts over the 5-year period of analysis. The authors found that 18 adverse events had occurred...”</p> <p>In discussing the 2013 Kalenderian paper on and adverse event trigger tool, they note that <b>“the study concluded that the dental clinic trigger tool was more effective in identifying adverse events than was a review of randomly selected records.”</b> They did also note, however, that there was no inter-rater reliability assessment between the assessing dentists.</p> <p>“Significant event reviews are an important tool for learning from incidents when they do occur.”</p> <p>Conclusions: “There is little understanding of basic epidemiology of patient safety in dentistry: we do not know if patient safety is a problem in dentistry, and if it is, the nature and size of the problem.”</p>											
What Exactly is Patient Safety	Emanuel		2008	<p>Emanuel L, Berwick D, Walton M, et al. What Exactly Is Patient Safety?. [serial online]. August 2008; Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Emanuel, L., Berwick, D., Conway, J., Combes, J., Hatlie, M., Leape, L., &amp; ... Walton, M. (2008). What Exactly Is Patient Safety?.</p>	<p>“In 1998, the IOM convened the National Roundtable on Health Care Quality, which adopted the following definition of quality that was widely accepted: ‘Quality of care is the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.’”</p> <p>Definition of patient safety:</p> <p>“Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.”</p> <p>“...in open, interacting systems, unpredictable events will happen...Berwick and others have collaborated with Amalberti to apply Shewhart’s notion of statistical quality or error levels to health care. Systems are categorized by their level of adverse events.”</p> <p>“The patient safety discipline acknowledges the need to include harm due to omission of action, as well as the obvious harm due to actions taken.”</p>											



				<p>“...patient safety designs can be thought of as falling into two types: those that are for types of routine care that vary little and can best be managed with protocols allowing for little deviation, and those that are for unique situations where on-the-spot innovation and significant deviation from protocol are required.”</p> <p>2 analytic methods: “root cause analysis” (RCA) is retrospective. A prospective method is “failure modes and effects analysis” (FMEA)...”usually taken early in the development of a product, [it] seeks to imaginatively identify potential failures and their effects. Knowledge from past failures might contribute to a designer’s ability to foresee potential failures in their design.” <i>FMEA could be seen as identifying potential complications and adverse events that could arise from the implementation of the new product (workforce model), based upon knowledge of complications and adverse events from previous models.</i></p>
Unanticipated Problems Involving Risks & Adverse Events Guidance		HHS Office of Human Research Protections	2007 <a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html</a>	<p>Definitions: Unanticipated problems involving risks to subjects or others include any incident, experience, or outcome that meets all of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described and (b) the characteristics of the subject population being studied.</li> <li>2. Related or possibly related to participation in the research, and;</li> <li>3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.</li> </ol> <p>Adverse Event : Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.</p> <p>Serious Adverse Event: Any adverse event temporally associated with the subject’s participation in research that meets any of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Results in death;</li> <li>2. Is life-threatening;</li> <li>3. Requires inpatient hospitalization or prolongation of existing hospitalization;</li> <li>4. Results in a persistent or significant disability/incapacity;</li> <li>5. Results in a congenital anomaly/birth defect; or</li> <li>6. Based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition</li> </ol> <p>Unexpected adverse event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:</p> <ol style="list-style-type: none"> <li>1. The known or foreseeable risk of adverse events associated with the procedures involved in the research; or</li> </ol>



				<p>2. The expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.</p> <p>“...an incident, experience, or outcome that meets the three criteria above [for unanticipated problems] generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.”</p> <p>The diagram illustrates three key points:  The vast majority of adverse events occurring in human subjects are not unanticipated problems (area A).  A small proportion of adverse events are unanticipated problems (area B).  Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events (area C).</p>  <pre> graph TD     Start([An adverse event occurs in one or more subjects.]) --&gt; Q1{1. Is the adverse event unexpected in nature, severity, or frequency?}     Q1 -- NO --&gt; EndNot([The adverse event is not an unanticipated problem and need not be reported under 45 CFR part 46.])     Q1 -- YES --&gt; Q2{2. Is the adverse event related or possibly related to participation in the research?}     Q2 -- NO --&gt; EndNot     Q2 -- YES --&gt; Q3{3. Does the adverse event suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized? NOTE: If the adverse event is serious, the answer is always YES.}     Q3 -- YES --&gt; EndYes([Report the adverse event as an unanticipated problem under 45 CFR part 46.])     Q3 -- NO --&gt; EndNot </pre>
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