Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Frenotomy with breastfeeding support

June 13, 2025

DISCLAIMER

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Janna Friedly

Are we almost, almost at quorum?

Val Hamann

Yes. I think the only. We have two others that should be joining us. So, we should be at 7 right now.

Janna Friedly

Why don't we give it another minute or two, then? Since we're expecting them, before we get started. How many do we need for, for quorum?

Val Hamann

There's Dr. Sham. So the only other person I was expecting today is Dr. Bramhall so we're at 8 now.

Janna Friedly

Okay. Um. Well, we can probably go ahead and get started, then.

Val Hamann

Oh, and there's Dr. Bramhall.

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Janna Friedly

Perfect. There we go. Then we can definitely get, get started. Um. Before we get started, um, uh, Josh, did you want to, should we go, um, and do a formal role call?

Josh Morse

Yes, uh, let's do a can we do a roll call and, um, we have our clinical expert here, Dr. Lewis.

Janna Friedly

Great. Welcome, Dr. Lewis.

Josh Morse

So we can maybe we can do a round robin, do quick introductions of the committee?

Janna Friedly

Sure, um, why don't we, we can do introductions, and that'll serve as, as our role call.

Josh Morse

Yeah. And then I'll do the brief presentation, then we'll get into previous meeting business.

Janna Friedly

Sounds great. Okay, sounds great.

Josh Morse

Thank you.

Janna Friedly

Um, so I'll, I'll start, uh, so I'm Dr. Janna Friedly, I'm a physiatrist and professor and chair of the Department of Rehabilitation Medicine at the University of Washington. I am the chair of this committee. Um, and, uh, I, uh, would like to pass it off, uh, to, uh, Laurie.

Laurie Mischley

Yeah, my name is Laurie Mischley, I'm a naturopathic doctor specializing in Parkinson's disease, and I do epidemiology research at Bastyr and nutritional deficiency research in the radiology department at University of Washington.

Janna Friedly

Great, and then, uh, Tony? I'm just going to, um, uh, call on people as they appear in my on my screen.

Tony Yen

Hi, I'm Tony Yen. I am a hospitalist at Evergreen.

Janna Friedly

Great, thank you. And, uh, Clint?

Clint Daniels

Hi, I'm Clint Daniels and I'm the chiropractic supervisor for VA Puget Sound, and affiliated with Rehab Medicine at University of Washington as well.

Janna Friedly

Great, thank you. And Jonathan?

Jonathan Sham

Good morning, Jonathan Sham. I'm Chief of the hepatobiliary surgery at the University of Washington Fred Hutch Cancer Center, and do clinical trials through SWOG and the NCTN.

Janna Friedly

And John Bramhall?

John Bramhall

Hey, good morning. Uh, I'm, uh professor at the university, anesthesiology, uh, and uh worked at Harborview clinically for 30 years. I've stopped doing that now. I'm still active teaching, uh, and delighted to be here. Welcome.

Janna Friedly

Thank you. And Evan?

Evan Oakes

Hi everybody, I'm Evan Oakes, I'm a family medicine by training, I'm the Chief Health Officer at the HealthPoint Federally Qualified Health Center organization.

Janna Friedly

Thank you. Okay, and Amy?

Amy Occhino

Good morning, my name is Amy Occhino. I am an OB hospitalist at Sacred Heart Medical Center in Spokane, and I am also clinical faculty for both UW and WSU Med School Spokane campus.

Janna Friedly

Okay, thank you. And Chris?

Chris Hearne

My name is Chris Hearne, I'm a nurse practitioner. I work with the hospital medicine team at Swedish. Happy to be here.

Janna Friedly

Great. And so I think that's, that's all of our, um, committee members. Um, Dr. Lewis, um, we would love to, um, have you introduce yourself.

Charlotte Lewis

Sure, uh, my name's Charlotte Lewis. I've been at the University of Washington for 27 years, um, I'm a professor of pediatrics there. I've done a wide variety of things. Um, for the first 15 years, uh, I worked in craniofacial clinic at, um, Children's, which is a multidisciplinary clinic taking care of kids with craniofacial anomalies. And, um, since then, for the last 10 or so years, I've been running an infant feeding team at Seattle Children's. I also attend on the newborn nursery the University of Washington and have ankyloglossia tongue tie clinic there, uh, at UW, as well.

Janna Friedly

Great, thank you so much for joining us today. We really appreciate it.

Charlotte Lewis

Sure.

Janna Friedly

And I'll turn it back to Josh. Um, Josh, did you want to do introductions for the staff as well?

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Josh Morse

Yeah, sure, we can do that. That's a good idea. My name is Josh Morris, I'm the program director for the Washington State Health Technology Assessment Program, and I will turn it to Melanie.

Melanie Golob

Okay, good morning, uh, I'm Melanie Golob, I'm the, uh, HTA program manager at Health Care Authority.

Val Hamann

Hi and I am Val Hamann. I am the program specialist for the HTA program here at HCA.

Josh Morse

Great. Uh, so that's the program staff. I think we'll meet some of the medical directors, um. later in the… as we move ahead with the new topics, new topic. So, I gotta clear my screen here. Do you our brief presentation. Yes, it is showing correctly. Okay, so, uh, welcome. This is our HTCC meeting for June 13th, 2025, um, as I said, I am the program director for the Washington State Health Technology Assessment Program. We are recording this meeting, uh, transcripts of the meeting, meetings are available after, um, after the meeting, we post that information. We, um, we don't use chat during this meeting, it's problematic, so we ask that you please do not use the chat function during the meeting if, um, we also will only ask you to use the raise hand function during the public comment period, so please also do not use the raise hand function unless requested to do so. Thank you.

So a little background on this program. The HTA program is administered by the Washington State Health Care Authority. This program brings evidence reports to the Health Technology Clinical Committee to make coverage decisions for selected medical procedures and tests based on review of evidence for the safety, efficacy, and cost effectiveness of those technologies. Multiple state agencies are participating in this process to identify topics, and ultimately to implement the policy decisions, and they include the programs here at the Health Care Authority, which are uniform Medical Plan, and the Apple Health Medicaid Program, the Department of Labor and Industries is participating as is the Department of Corrections is using the outcomes from this process. The state agencies implement these determinations from this process within their existing statutory frameworks. The purpose of this process is to ensure that medical treatments, devices, and services that are paid for with state health care dollars are safe and proven to work. This program provides resources for the state agencies that are purchasing health care. Through this process, we developed scientific, evidence-based reports

on the selected medical devices, procedures, and tests that are reviewed by the HTCC. And we support the HTCC to make these determinations for the selected technologies based on the available evidence.

There are multiple ways to participate. Anyone may sign up to receive notifications from our program via email. Anyone is welcome to provide comments at multiple stages through the course of a review, including on the proposed topics, on key questions, on draft and final reports, and on draft decisions, anyone may attend these public meetings and present comments directly to the committee, and anyone is welcome to nominate technologies for review or for rereview and we have the link here, you can find this information on the Health Care Authority's webpages.

So our agenda, uh, oh, this slide, apologies, was not updated, but this is a pretty standard agenda. We've done introductions, um, we may want to mention disclosures. Our previous meeting business will be the first, um the next item after we conclude this with the minutes from March and, um, we will go over the draft decisions from hyperbaric oxygen and continuous glucose monitoring. And then we will address the new topic today, which is frenotomy and frenectomy with breastfeeding support. And actually, this slide was updated, I was incorrect about that, this is accurate information.

So, public comment, if people, we do not have anybody signed up prior to the meeting for public comment, but we may have people who wish to comment and raise their hand when we get to that portion today. Public comment will be limited. We will ask for people to raise their hands, um, when we get to that period there, attendees, we don't have scheduled public comments, so I'll skip that bullet. We ask that, uh, comments are limited to the time allotted, and we will time that, and then ask people to, um, to limit their comments at the end of that time. And then people who are providing comment will be elevated to the panelist level so that they can, um, come on camera and provide the comment, and then they will be reassigned as an attendee after that. These are the instructions for those providing public comment. We ask people to state their name, declare any conflicts, um, during this time of the meeting.

So, following our meetings, the program publishes the approved minutes and transcripts from the committee and draft determinations. Draft determinations are then open for a public comment period for 2 weeks. Those comments are then brought back to the committee at the, uh, next public meeting. Our next meetings. So, July 18th, we have a, um, short meeting scheduled in the morning of the 8 for the morning of the 18th, uh, to go over the min, meeting outcomes from today, so that will just be the previous meeting business on July 18th. We then have scheduled in September a new topic review, which is balloon angioplasty and stenting for

lower extremity peripheral artery disease and that topic is in process right now. So that concludes this presentation. If there are any questions, please let me know. Thank you.

Jonathan Sham

Josh, can I just ask, do we know the exact time of that July 18th meeting? It'll be 8 a.m. as well, or are we still figuring that out?

Josh Morse

I'll ask Val that question. Val, can you answer that?

Val Hamann

Yeah, we're, we're planning for an 8 a.m. start time.

Jonathan Sham

Thanks so much.

Josh Morse

Good question, thank you.

Janna Friedly

Great. Thanks, Josh. So I think next, next on the agenda is to, um, uh, address, uh, previous meeting business, um, and um, so the first, um, item on the agenda is, uh, to approve the previous meeting minutes. Um, so, um, Uh, for your reference, these are um, were, um, available, um, in the, um, materials for today's, um, uh, meeting, um, in the agenda. Um, so we will need a motion to approve the minutes.

Tony Yen

I move to approve.

John Bramhall

And I'll second.

Janna Friedly

Great. Any, um, any discussion, or anyone opposed? Okay, all those in favor of approving?

Laurie Mischley

I.

Tony Yen

I.

Janna Friedly

Great. Okay, we can call those approved.

Melanie Golob

Okay.

Janna Friedly

Okay. Thank you. Um, so next, uh, on our agenda are, um, addressing, uh, two previous, um, comments for two previous, uh, decisions. Um, the first is the hyperbaric oxygen therapy for sudden sensor, sensorineural hearing loss. Um, draft findings and decision. Um, and uh, there was, um one, uh, comment, um, that we need to, uh, address here, um, and this was, uh, really a technical question or concern, uh, that was raised by Ty Jones. Um, who, uh, is the Senior Medical Director for Regents, um, Blue Shield, uh, regarding, um, the concern, uh, about having two, um active policies that, uh, that conflict, um, uh, with the new with the new policy as written. Um, so Josh, it might be helpful for you to help us, um to address this, uh, particular concern. Um, are you able to provide us a little bit of context about how to address this particular concern?

Josh Morse

Um, yes, and I think, uh, our team, um, we have addressed these issues in the past on multiple decisions that have been updated. Um, Melanie, do we have a plan for consolidating these two, which is or are we?

Melanie Golob

Yeah, we'll, we'll usually mark on it if one supersedes another, and we'll archive a previous decision if we have one that, um, takes the place of another. So, um, and Val, correct me if I'm wrong, but I don't see an issue with doing that with this as well, if it does get approved.

Val Hamann

Correct.

Melanie Golob

Okay.

Josh Morse

Yeah, in the interest of simplicity, or uh, administrative burden, I think we would combine the new and the old into one.

Melanie Golob

Yeah. Mm-hmm.

Josh Morse

And archive the old. So, that's how the program will address this issue.

Janna Friedly

Okay, okay, so this, so this, for all intents and purposes, this is not something that we as a committee need to be concerned with.

Josh Morse

No.

Janna Friedly

Or is there anything that we need to do in terms of a vote here, or, um, or.

Josh Morse

You need to vote to approve the final decision. This is, yeah, this is not one that presents new evidence, or that questions the language intent. Uh, in my opinion, this is one that's more administrative.

Janna Friedly

Okay, okay, so then we, we just need a motion to approve the hyperbaric oxygen therapy decision.

John Bramhall

Yeah, I move approval.

Josh Morse

Val, are, are we doing a formal vote, Val?

Val Hamann

Uh, I can go down the list and of everybody's name, and we can go from there.

Josh Morse

Yeah, after the, if there's a motion and a second. I, sorry to interrupt you, Janna.

John Bramhall

And so, just to be clear, we're gonna consolidate those two elements and respond to the request for updated language, uh, from the 2013.

Josh Morse

Correct.

John Bramhall

Efficient, right, as requested. It just makes total sense, yeah. Okay.

Janna Friedly

Okay, so we need we do need a motion to approve?

John Bramhall

I'll move approval.

Laurie Mischley

I second.

Val Hamann

Great. So, um, I'll go down the list, so John Bramhall.

John Bramhall

Yes, approve.

Val Hamann

Clint Daniels?

Clint Daniels

I'm gonna need to abstain.

Val Hamann

Okay. Uh, Janna Friedly?

Janna Friedly

Approve.

Val Hamann

Chris Hearn?

Chris Hearne

Approve.

Val Hamann

Laurie Mischley?

Laurie Mischley

Approve.

Val Hamann

Evan Oakes?

Evan Oakes

Approve.

Val Hamann

Amy Occhino?

Amy Occhino

Approve.

Val Hamann

Jonathan Sham.

Jonathan Sham

Abstain due to absence.

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Val Hamann

Okay. And Tony Yen.

Tony Yen

Approve

Val Hamann

So we have.

Josh Morse

That that is approved?

Val Hamann

Yes

Josh Morse

We have a quorum. Thank you.

Janna Friedly

Okay, great. Um, so moving on to the next um, item, and that is, uh, the, uh, continuous, uh, glucose, uh, monitoring decision. Um, and again, um, we have a draft, um decision. Um, and, um, and there were for this one, as you can see, um. There were a number of, of comments, um and those are listed here, so, so, um it looks like 40, um, uh, comments uh, regarding this, um, and thank you to the staff for um, summarizing these, that's really helpful, um, to have this, since there are so many um, uh comments, um, and so, just to remind people that the task for us here is to assess whether or not there, these in these comments um, whether there is, um, have any evidence that we did not consider, um, with our decision maker, or any, any if there was, um any of the comments presented evidence that we, um, that we may have missed, uh, or did not consider that would change, uh, the, um, the outcomes or the, uh, the findings, um, uh, or, um, that sway that the decisions. Um, so I have reviewed, uh, these, and it does appear that, you know, sort of the big category of, um, concerns or, um, suggestions, uh, are that, uh, we loosen the restrictions of the continuous glucose monitoring to uh, to patients, uh, that are not on insulin, um, uh, therapy um, is, uh, sort of the big, uh, category of, uh, of requests. Um, uh, and some that may be on, uh, insulin, but, uh, with, um with fewer restrictions. I'm curious to hear from the group, um, as you look through this, um, if Um, if you have any thoughts about, um, whether or not Um, there was any information in here that, um, that provided new

information that we did not consider. I did not see any new evidence, or evidence that we did not that we failed to take into consideration in the in the report, uh, or our decision-making, but I would love to hear from the rest of the committee.

John Bramhall

Well, I'll start. I mean, we went, um, we went through the evidence, um. We made our decision. I think the comments, and again, yes, thank you to the staff for combining all these, because there's a lot of comments uh, because it's a big issue. Um, to be honest, I hadn't thought of, at the time we reviewed everything, that just hypoglycemia on its own as a standalone entity, uh, would be something that we would consider. I don't think it's unreasonable. But I don't think it falls into the scope of what we discussed, and it should be approached at some other time, the whole idea of somebody who's not is unaware of the hypoglycemia, I mean, it just opens up a very large population of patients, presumably, who would be very difficult to categorize, and so I think I would, I would suggest we leave that alone, but I'm not saying that it's an unreasonable request by, what, 7 people made that comment. And not really well enough informed to know about the addition to the preferred drug list for CGMs, I think that's a little bit bureaucratic. Um, anything that increases the ease with which patients can get hold of these pieces of equipment is, is, uh, if they're in our category, is to be supported. They're not expensive, I was surprised when we reviewed it how cheap the actual monitors are or can be. I mean, almost a trivial amount of money for most people, not every, I guess the supply is at a component to it. But that's a technical issue that I would take guidance from the from the staff on, on, uh preferred drug list, uh, for, like, effectively DME. Um, and then, um, the comment about, um, uh, unable to achieve a target, uh, hemoglobin A1C, So 32 people wrote saying that that was too exclusionary and I'd be very interested to know what we as a group decide about the language on that. I mean, we, we we're trying to be objective, we were objective, and we tried to delineate the conditions under which someone ought to have access to this equipment, and in part of that, what we said was, well. The data coming from A1C measurements is useful in determining the pool of patients that would benefit from this device, so I think that's a fairly important component to be honest, in what decision-making process included. And I'm not sure that I agree with the 32 people that say it's too exclusionary, but be very interested to hear if there's any conversation about that.

Tony Yen

Hey Janna. So, I think that I would agree with perhaps the first comment about updating the criteria to say to individuals with diabetes who are on insulin therapy, uh, really, this is really, that is standard of care these days. Um the second bullet point over there, I would actually tend

to agree with that, that it's so long as, but it's kind of falls underneath the category, you know, you're on insulin therapy and that's a qualifier for requiring the use of CGM, so I think, uh, if we actually included the first bullet point, it would actually take care of the second bullet point. That's really from my perspective.

Janna Friedly

Josh, could we, could we project the, um, the draft language?

Josh Morse

Yes. Uh, Melanie, I will, um share from a Word version, if that's okay?

Melanie Golob

Yeah, yeah, and I would say I could just scroll up if that's easier.

Josh Morse

Oh, yeah, why don't we do that? If there's edits, I can… I do have a Word version up.

Melanie Golob

Um, yeah, and if it's helpful, I also did a breakdown of, um the comments that were received and those that cited evidence and whether or not that evidence was already included in the report or if it was included in scope of this, uh, of this topic. So, if that's helpful at any point, happy to share that. Sorry, too many things.

Josh Morse

I think the draft is at the very bottom. Yeah.

Melanie Golob

Oh, is it? Okay. Thank you.

Josh Morse

You're welcome.

Melanie Golob

Okay. There it is.

Janna Friedly

Yeah, so I'll just, um Tony, um in thinking about the insulin therapy, if I recall correctly from our discussion, um, we had, you know, included type 1 diabetes, um, presumably all, you know, on insulin. Um, and then with type 2 diabetes, on insulin, um, there we had quite a bit of discussion um, and with our, our expert about these criteria, um, to have some, some criteria, um, that it wasn't all, all, all patients, necessarily, but that there was some there was some evidence that there was a need for the continuous monitoring, and so I think the there was the target, um, hemoglobin A1C, um, uh, being difficult to achieve, or hypoglycemia, uh, or hypoglycemia unawareness, um, which I think was intended to address Um, the conditions under which they were they were talking.

Um, you could remove all of those restrictions and just have individuals with type 2 diabetes who are on insulin therapy um, but, um, I would need to go back to our the transcript for our discussion to, um to look at the details of why we came up with those specifically, but it was in, um in, uh, consultation with our clinical expert.

Josh Morse

Can I also add, um the language in this decision aligns with the inclusion criteria for this, and there may be some risk if you alter that of including conditions that were not within the scope.

Janna Friedly

What do you mean, Josh?

Josh Morse

Well, if I'm understanding the conversation, if you're talking about the language suggestion to change, um people with type 2 on insulin to people using insulin. Is that the conversation?

Janna Friedly

Well, I think the suggestion from the comments is either to just say individuals on insulin. Um, or individuals with type 2 diabetes who are on insulin and remove all of the criteria below that, that all of the and, or's below that.

Josh Morse

Oh, I see. Okay.

Janna Friedly

That's my understanding of what the suggested edits are, um, from the commenters.

Josh Morse

Yeah, the way the key, the inclusion criteria read is, uh, it's type 2 who are using insulin.

Laurie Mischley

I would be in favor of removing the bullets only for the purposes of the logical loop we find ourselves in, because you're using the continuous glucose monitor to fix those three things, right? So, if you now can achieve a normal hemoglobin A1C now that you're wearing the monitor, do you no longer qualify? I mean, we're just in this situation where it's part of healthcare, it's how they take care of their condition. So the fact that they're on insulin means they probably have a need for it. I don't like the idea that the solution we're suggesting. Anyway, the logic loop. Do you need to continue to qualify is a silly concept. Like, I don't want to create that situation where they're now that they're wearing it, their hemoglobin A1C is under control, then they don’t qualify

Janna Friedly

And then they can't qualify for it anymore. Yeah, that's a that's a good point, Laurie, I do feel like we had, uh talked about that, uh Dr. Chen, you have your hand up.

Christopher Chen

Thanks. I think, um, that is something that, um we would, um, be able to address, um, I mean, historically, this has been a criteria, and so this is not a new criteria, the unable to achieve target A1C, we have had a CGM policy in place and the way that that is implemented, um, is that with the initial request

um, that, um, that criteria is taken into consideration, but renewals or continuations of the CGM device, um, as, uh, um, a slightly different. So, you can decide to either kind of affirm that in the policy, or, um, and in implementation, we don't say that someone has to continually have uncontrolled A1C to reapprove.

Janna Friedly

Yeah, I would definitely feel much better if that was explicitly stated, if we keep these criteria that that's for initial approval. Because I agree that that loop doesn't make sense to me, either. What do others, uh, feel? And I'm, I'm still trying to pull up, um, the transcript from, um, our, uh, previous, um, go through that to look at the, um the comments so that I can make sure. I'm not missing.

Chris Hearne

I'll just give my thought. I'm just trying to think up a hypothetical patient. who would be on insulin, but has a controlled A1C and is not having hypoglycemia and nonetheless want to, want to have a CGM or start having a CGM. Um, I'm not sure what the evidence said about patients like that, and I'm not sure we heard anything about patients like that, and my suspicion is that It's probably a relatively small number of patients who their diabetes is totally well controlled, and they're not having problems, and they still want to get a CGM, maybe that's a small group of people. And I guess the question is should we restrict? That probably relatively small patient population from, from obtaining a CGM. I'm not sure what the evidence said, and I can't recall. My, my recollection is that we didn't, like I said, hear anything about that. My bias is that common sense probably says it doesn't really make sense to restrict from that group if they're If they're interested in optimizing, further optimizing their diabetes control with the CGM. That's my initial bias.

Evan Oakes

I'll share. Um, I'm all for simplifying. I'm uncomfortable, I'm glad you're looking up the transcript, because I'm uncomfortable with the fact that we you know, went through a lot of discussion on this when our last meeting, so it's a little bit hard to, um, imagine revisiting that, and then what are, you know, what is the discussion required to make the changes? So I'm, I have a bit, that's my take at the moment. I'm not… I would love to simplify, that would be ideal. Um, Christopher mentioned that we've had these restrictions in the past. There was a comment about how complicated this might be for people, that concerns me, usually, um, I don't know how that is for the HTCC or Medicaid in terms of these, um, more, um, qualifications to, um, getting the CGMs, but, um, I'm of the mindset to not go back and change things too much, knowing that we had a pretty detailed discussion at the time about it. And that's kind of where I'm at, at the moment. Thank you.

Janna Friedly

Yeah, and that's, um… sorry, I'm… I am, uh, trying to scour the transcript, which is a little more, um, difficult than I, uh, than I thought it was going to be. Um, it's a lengthy discussion that we had. Um, uh, but I agree, and I do recall we had a very lengthy discussion about these, um, these, uh, specific, uh, criteria, so it does make me a little bit uncomfortable to, um, to remove them without careful consideration, uh, reconsideration of the reasons that we Um, that we had, um, that we had those in there.

Evan Oakes

As we all know, these have never been easy conversations. They're always very complex, and so we've had this detailed conversation, and I sort of, of the mindset that, um, as much as I appreciate the comments from people, it's hard to justify changing unless there's really new information that comes up in them and that's kind of what I'm, where I'm landing at the moment.

Laurie Mischley

I certainly don't think any new information is being presented here.

Janna Friedly

Mm-hmm.

Laurie Mischley

But wait, Val, did you say, Melanie, you had a spreadsheet of what was new.

Melanie Golob

Yeah, and that's, that's essentially the takeaway of the spreadsheet, is that there is no new evidence, um, that was cited in any of the comments, um, that could potentially or based on the scope, uh, there's no new evidence presented. I'm happy to share that if that's.

Janna Friedly

Um. So I think, um, we have two it seems like we have two options here. We, we could, um We could take a vote, um, on, uh, the coverage decision, um, now, um, or, uh, Josh, is there an option to table this until the next, um, meeting, the next meeting in July, uh. So that we can go back to the transcript in a little more detail if people are not comfortable that we have enough, um

Josh Morse

Well, I think that there's, there's risk in re-litigating, right, and going back and looking, and the question before the committee For these purposes, is there new evidence that was essentially, is there evidence that was missed, information that was missed. Um, and Melanie's showing you the assessment of the evidence that was provided, and you I believe, based on what on Melanie's careful analysis, that there was not new information that was not included in the report that you didn't consider at the last meeting.

Melanie Golob

That's correct.

Josh Morse

Um, the next question before the committee is, is the intention, is your language clear about what was your intent? Um, in the, um, in the decision you made it the last time. And the reason that the committee process is outlined that way is because we are this is not a time for a second evidence review, right? This is a time for considering the comments, and if something was missed In your last evidence review, when you had your clinical expert here, and you had um, your epidemiologist who analyzed the information, so my suggestion would be unless you have, like, a very outlying question that's not clear, uh, try to wrap that up today.

Tony Yen

So, Josh, I like the way that you framed it, and also how Melanie has framed it as that there is no new evidence that's being presented. Um, the decisions that we made previously, that was displayed was actually based on evidence. I guess what I, what I want my comments earlier were really that what the standard of care has really evolved into, um, that anybody who is using insulin. I mean, Type 1 or type 2 diabetes, um, these people are being qualified for CGMs. Typically by third-party payers, that's kind of, like, what's out there. Now, that standard of care practice is not necessarily always evidence-based and I think that's, that's the disparity. I'm just trying to, like bring up, uh, declare relief. That out in our community, uh, so long as you're on insulin, you qualify for a CGM if you would like to use it. And so the CGMs are actually, I think, quite a bit more useful as a tool for optimizing care, even if you do not meet any of the criteria that are bulleted out. Um. That's, that's kind of the bottom line, and so I just want to bring that type of awareness. I think that decisions that we made are definitely evidence-based. And so that's, that's where we, we stand at this, this kind of, like, intersection of We are using evidence to make our decisions for this committee I really appreciate that, and I still feel strongly that's the way that we need to go, but I just wanted to spring awareness. Standard for Care has and oftentimes is may move beyond the scope of the evidence that we have.

Janna Friedly

Yeah, and that’s true Tony, for many, many procedures and treatments that we evaluate. The things that we do become incorporated into clinical care regardless of the evidence of whether or not they change outcomes. Um, so I think, I think at this point, we should, um, uh, we should go ahead and take a vote, um, and see where we see where we land, uh, on, on this, um, and if we need to, we can you know, depending on the outcome of the vote, we can, you know, revisit

next, uh, uh, next, uh, meeting, but let's, let's take a, let's take a vote on um, on the decision as it's as it's written, uh, here from the last meeting.

Val Hamann

Sounds good. Uh, Tony Yen?

Tony Yen

Um, I'd like to change the language according to what I've said before about taking away those limitations of those three bullet points underneath the type 2 diabetes.

Val Hamann

Amy Occhino?

Amy Occhino

Um, I'd like to leave the language, because I, uh, was at the last meeting, and I feel that we reviewed the data. Uh, and came up with a decision as stated.

Val Hamann

Evan Oakes?

Evan Oakes

Uh, like, same, stay the same.

Val Hamann

Laurie Mischley?

Laurie Mischley

Well, I wanted, they should stay the same. I want them to go away, but based on the conversation we had, and the rules that we are abiding by, they should prob, I vote to keep them.

Val Hamann

Chris Hearne?

Chris Hearne

I would vote to alter the language, um, to get rid of those bullet points, those disqualifications.

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Val Hamann

Janna Friedly?

Janna Friedly

Uh, I vote to keep the language as it is.

Val Hamann

John Bramhall.

John Bramhall

Yeah, I vote the same, to keep the language, and it's on that narrow, but rather important element that Josh described, which is, look, is there new evidence? And there's no new evidence. And so, on that narrow sort of basis, I would support keeping the language, but I'm emotionally quite, um, swayed by Tony's comment that, uh, you know, come on down. If it's gonna help improve the population health, let's do it. And Laurie, you made the same kind of point, that some of these things are a bit subjective, and they get put into practice, and they're very effective, but that's not what our committee is designed to adjudicate, right? It's adjudicating on the basis of evidence, so sorry, to be long-winded, um, a proof-keeping language.

Val Hamann

Okay, so we have 5 to approve the current language, and then two who are requesting to change the language.

Josh Morse

Did Dr. Sham vote?

Jonathan Sham

I'm abstaining, I wasn't part of the last meeting.

Val Hamann

Yeah. Yeah, Sham and, uh, Dr. Daniels abstained.

Josh Morse

Okay, thank you. Yeah, I, so, as Val stated, there's 5 to approve, and I think there were 2 recommending a change.

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Janna Friedly

Okay, thank you, that was a really helpful discussion.

Josh Morse

So, Janna, is that your final formal vote? That part was a little unclear if you were taking the temperature, or if we were doing a final vote.

Janna Friedly

Oh, I, I assumed that was a final vote, but um, do we need to take, do we need another final vote? That, I was taking that as a final vote, but.

Josh Morse

Okay, any committee members concerned that that was not a final vote? Okay, thank you. It was just me that was confused. Thanks.

Janna Friedly

Sorry, it's just that we were, uh, when we were saying our final votes, we were talking as well, giving an explanation with our final votes.

Josh Morse

Gotcha. Right. So, for the record, there were 5 approves, uh, two that did not approve, and two that abstained. Thank you.

Val Hamann

Correct.

John Bramhall

Josh, do we, um is there a feedback we're not going to feedback individually to all 40 people, but is there a mechanism for, uh, including some type of feedback language to assuage the people's concerns, uh or do we I mean, I don't recall that we've ever done that, but is there a mechanism?

Josh Morse

We have, um yeah. I'm sorry, Dr. Bramhall.

John Bramhall

No, that's, it seems, so, I don't want to be so seem too abrupt in just dismissing these concerns. I don't think that they're unreasonable comments at all. I think the useful comments, and my guess is that they get incorporated into a rereview at some point in the future, right? I mean, that's, that's what is likely to happen, um, but do we have a mechanism within the committee structure to provide a comment that answers, or politely responds to these comments?

Josh Morse

Uh, technically, no. Um the committee has discussed this in the past, and if and you can draft a note that we can include with this decision, that the committee considered the comments, um, on the final decision, and I'm, you know, we can draft that right now. I would not want to craft that myself, um, or the program, but if the committee wants to include a statement about consideration of the comments for this decision, there is room in a notes section on this document where that could be contained.

Laurie Mischley

Or at least referring them back to this conversation that will be recorded, and let.

John Bramhall

Oh, right, right. Oh, okay.

Josh Morse

That's a great idea.

John Bramhall

Yeah, that's, uh, yeah.

Janna Friedly

And Josh, uh, this does remind me that we did have a discussion about the issue of, um of this applying to the initial prescription for the continuous glucose monitor, and not for the renewal, um, or continuance of the monitor, um, and making sure that that somehow incorporated into the administration, as Dr. Chen pointed out. Um, so I just want to make sure that that's somehow reflected. If not in the we didn't include that into the language here, but if that can be included into the administrative Um, language, or process. That would assuage the issue that Laurie brought up.

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Josh Morse

Do these notes? Are you hopefully you're seeing my screen.

John Bramhall

Yeah. Yeah, that's very helpful. Thank you, Josh.

Josh Morse

Janna, does this meet, okay.

Janna Friedly

Yes. Yes, that's helpful. Thank you.

Josh Morse

Any other questions or concerns? Any concerns from the medical directors about these notes? Or the note, specifically with initial approval?

Christopher Chen

No concerns from me, Josh. This is Chris.

Josh Morse

Thanks, Chris. Okay, uh, we will incorporate these notes, this is the draft that you were considering just in a Word document. And we can take this as the final. And I'm gonna hit save, since I've had save issues in the past. Anything else, Dr. Friedly?

Janna Friedly

Nope, I think we can move on to new business.

Josh Morse

Thank you. So we are at a little before 9, and um I think we're a few minutes behind schedule. So next step is the, uh, agency medical director's presentation.

Heather Schultz

Josh, I believe Val was gonna share the slides for me.

Josh Morse

Okay.

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Heather Schultz

Great. Um, good morning, everyone. I'm Heather Schultz. I'm an Associate Medical Director at the Health Care Authority and I will be presenting for the agency medical director group this morning on the topic of frenotomy. Next slide. So before we get into current state agency policies, and looking at the utilization, I wanted to provide a brief bit of background and context for the topic this morning. So, starting with what is ankyloglossia, this is an image of a newborn who has uh, ankyloglossia. Which, as this picture shows, is a shortened lingual frenulum. And the lingual frenulum is a fold of tissue that is arising from the floor of the mouth and is attaching to the tongue. The, uh, when it's a shortened frenulum, that's a normal anatomic variant that we describe as ankyloglossia. And for the majority of babies who have this anatomic variant, it does not cause any sort of pathology, they're able to breastfeed normally. But there is a subset of newborn infants who do have this shortened frenulum that's attaching closer to that tip of the tongue, like in this image, where they're not able to extend fully and elevate the tongue and that can interfere with getting a proper latch and lead to breastfeeding difficulties. What's important to note is that there's no standardized definition for what a symptomatic ankyloglossia is, so, ankyloglossia that's interfering with breastfeeding. There are some tools that grade the degree of ankyloglossia, but across the different medical specialties whether that's ENT or pediatric dentistry, or pediatrics, there's no agreed-upon standard definition for how to define when ankyloglossia is the source of breastfeeding difficulties, and there is wide variety of opinion on when intervention is needed. Next slide. The intervention that is used for some infants with ankyloglossia is frenotomy, and this image is showing a newborn who is post frenotomy. So, this is a pretty straightforward surgical procedure, does not involve general anesthesia, typically topical anesthesia is not involved either um, and usually just surgical scissors are used to make a small incision. Some providers use lasers to do ablation of the tissue instead. Um, and infants are able to breastfeed immediately, um, after the procedure. Next slide.

So, why the focus and interest on frenotomy? This slide here shows, uh, two graphs that were pulled from the American Academy of Pediatrics recent publication on ankyloglossia and breastfeeding difficulties. And the data for these graphs was pulled, actually, from a earlier publication in the Journal of Otolaryngology that looked at National claims data, um, from an inpatient database, so this is looking at that initial newborn hospitalization after birth. And you can see that for, um, the initial period from the mid-90s to around 2005, the diagnosis of ankyloglossia and the utilization of lingual frenotomy were pretty stable and then we started seeing this uptick um, as the graphs show, um, that got quite dramatic, um, with this exponential growth in both the diagnosis and the utilization of the procedure. And while there

are some reasons that we would expect there to be a small uptick um, during this time period, like increased breastfeeding rates and increased provider awareness about the diagnosis and the ability to use the procedure, um, that exponential growth in what is an anatomic variant that exists in somewhere between 1% to 10% of newborn infants is concerning for the possibility of over-diagnosis and overutilization of the procedure itself. Next slide. So, our agency medical director group rated concern for efficacy high and that is largely in part due to the quality of the evidence base and the lack of standardization of a definition of when ankyloglossia is symptomatic and requires intervention. For safety, our concerns were medium. The safety concerns for this procedure are primarily related to complications from the procedure itself, um, so things like bleeding, or unintentional damage to other oral structures and this, uh, reported in the literature is pretty rare, um, but our concern remained medium because of the concern for overutilization of this procedure, and the possibility that this is being used in otherwise healthy newborn infants. So we feel like there should be, um, really low level of tolerance of any risk exposing otherwise healthy newborn infants. And then for cost, we had a similar, uh, rationale for our medium concern. So, as you'll see on our utilization and cost slides, the individual procedure itself is not terribly expensive in the grand scheme of the American healthcare system. So, depending on the setting, the price ranges from typically, or at least what the state is paying, between $100 to $500. But when you look at, in aggregate, the large number of infants that this is being done on, um, across the state, um, it really gets close to around a million dollars a year, um, is being spent. And again, um, when used in the appropriate situation, that could be a reasonable use of state dollars, but we do have concern that there's over-diagnosis and overutilization. Next slide.

So, here's our current state agency policies. So, starting with the Uniformed Medical Plan and the Uniform Dental Plan, because the frenotomy procedure is covered under both the medical and the dental benefit. Um, as a reminder, the Uniform Medical plan and dental plan is the plan for PEBB and SEBB members, so, PEBB are our state employees, and SEBB are our K-12 school employees. The medical benefit is currently covering it with criteria, so the diagnosis of ankyloglossia needs to be made by a qualified healthcare professional, and there does have to be some evidence that it's interfering with breastfeeding. Currently, the dental benefit is covering without any criteria. For our Apple Health clients, Apple Health is the health plan for Washington State's Medicaid clients and that is also the frenotomy procedure is currently covered under both the dental and medical benefit, uh, without criteria. And then for L&I, since this is a diagnosis and a procedure that is utilized for newborn infants, it's not relevant to job-related illness or injury, and is not um, currently a policy.

Next slide. So, when we thought about how to look at utilization and cost, we ended up landing on breaking it down into 3 different categories. So the first category is looking at lingual frenotomies that are done in a medical setting. And we wanted to take a look at that separate from other, other sites of use and other indications, because despite the evidence base, there is a consensus among, again otolaryngology, pediatrics, and pediatric dentistry, when you look at their policy statements or their guidelines, that, despite all of those groups also believing that there's overdiagnosis and overutilization, they do call out that there are a subset of newborn infants where this would likely be of benefit. So we wanted to get a sense, how often is it being used in that setting? The second category that we wanted to look at is, um one that we, I haven't really discussed yet, so there are additional frenula in the mouth, other than the lingual frenulum um, including to labial frenula, so there is a piece of connective tissue that goes from the lip to the gum, um, upper and lower. And there is, as you saw in the evidence report no existing evidence that supports the use of labial frenotomy to improve breastfeeding difficulties. And there is, again, a consensus among the different medical specialties that there's no mechanical reason that we would expect a tight labial frenulum release to, um, assist with a better latch. So we wanted to get a sense of how often is a procedure that we believe to be medically unnecessary being done in this newborn population. And then the third category that we wanted to look at was how often is this being done in the dental, in a dental site of care. So, doing a frenotomy is well within the scope of practice of a dentist um, and that's appropriate, what is outside the scope of a dentist is the diagnosis of breastfeeding difficulties, or managing the overall healthcare of a newborn infant. So, we wanted to get a, a sense of how often is this being done in a dental setting, um, knowing that we can't tease apart whether it's being done in coordination with a primary care provider or not, um, but we still wanted to get a sense. And then, just as with looking at labial frenotomy being done in a medical setting, we wanted to get an idea of how many labial frenotomies are being done um, in dental offices, because we do believe that that is a medically unnecessary use for breastfeeding difficulties, specifically. Next slide.

So this first slide is looking at that first bucket for the Apple Health clients. And you can see, looking at the utilization graph over the last couple of years, when you look, it's probably, I would call this, like, a stable utilization. 2024 did show a drop-off. It's unclear whether that will continue that trend. Um, but it's been pretty stable use, and you can see the cost on the other side of the slide um, and the bulk of the cost is coming from this procedure. Next slide. On the Uniform Medical Plan, you see a similar stable, if not maybe a little bit of decrease over the last couple years. The volume is smaller on the Uniform Medical Plan side, which we would expect uh, just because differences of the population size, so there are approximately 2 million Apple Health clients not newborns, but the entire population of Apple Health clients and then on the

UMP side, it's closer to a little over 400,000 members, so it looks like probably a proportionally similar, uh, volume of newborns are having this procedure done, um, on the UMP side as well. Cost for the lingual frenotomy in the medical setting looks pretty similar between Apple Health and UMP. Next slide. When we look at the Apple Health clients who are getting labial frenotomy, it's a smaller number than we're seeing for lingual frenotomy, but you do see a trend over the last several years um, of upticking a bit, which is concerning for the reasons I had described earlier. Next slide. And then we see a stable trend, and again, smaller numbers for the Uniform Medical Plan, which is a smaller population uh, but still concerning that we are seeing consistent use of labial frenotomy in this age group um, without a medical indication. Next slide. For the dental frenotomy information uh, we pulled both the lingual and the labial information on the same slide. So, you can see the lingual frenotomy, which is the procedure that we believe there's a subset of newborns where this would be appropriate, is in the darker color. Um, on both the utilization and the cost side, and then label frenotomy is, is lighter um, and we can see that lingual frenotomies are being done in smaller numbers than in a medical setting for the Apple Health clients. Um, you do see a general uptick over the last couple years. Um, what is more concerning for me as I review these slides is seeing the volume of labial frenotomies that are being done in a dental setting. Uh, it's much larger than what we were seeing in the medical setting for Apple Health. Um, and you also see this slow uptick over the last several years of utilization of labial frenotomy in the dental setting. Next slide. And we see similar patterns in the Uniform dental plan as well. So, um, again, smaller numbers of lingual frenotomy compared to being used in the medical setting, but a rise in that dental setting, and then again, this concerning, consistent use of labial frenotomy in the dental setting that has been increasing over time. Next slide. So, our takeaways in looking at this utilization data are that medical lingual frenotomy use is pretty stable in Apple Health, and probably declining potentially, um, and a little bit decreasing in UMP. Labial frenotomy use is occurring, which is concerning to us, despite the lack of evidence in both Apple Health and UMP members. And then, when we look at our dental data, um, we do see that lingual frenotomy is being done, and some of that is likely appropriate and being done in consultation with medical providers, but there is a concerning increased use um, of both labial frenotomy and lingual frenotomy um, and again, it's not entirely clear whether that is in coordination with the medical providers that are providing the overall care for these newborn infants. Next slide.

So, we took a number of things into consideration when we put together our, uh, director group recommendation. Starting with, uh, the significant limitations to the evidence base. So, as you saw in the evidence report, there are three studies that favored frenotomy over the comparator. Those studies were all very high risk of bias and low certainty of evidence. Additionally, the outcome that those studies looked at were, uh, breastfeeding self-efficacy, which is a measure

of maternal confidence, self-confidence in breastfeeding. There is a validated tool, a survey tool for measuring that um, and that is a legitimate outcome to look at, uh, for breastfeeding success, maternal confidence in breastfeeding, um is associated with, or should be associated with, some of the other outcomes that we would want to see in breastfeeding infants, like exclusive breastfeeding, or duration of breastfeeding, or decreased maternal nipple pain, or weight gain in the infant. And what was concerning for us as we looked at the evidence, is that all though you see those three studies that do favor frenotomy for breastfeeding self-efficacy, which, I think of almost as a proxy measure for the other things that you would really want to see in a newborn baby, like better weight gain, or longer duration of breastfeeding um, none of that translated then, uh, we didn't see any of those other more objective outcomes that are ultimately of importance. Um, as noted at the start of the presentation, you can see that there is both that there's a national increase in diagnosis and utilization of the procedure that seems like it's far outstripping what you would expect from just better recognition of the diagnosis. Um, and more familiarity by providers. And then, when we looked at our states data, the uptick in use in the dental setting, as well as the use of labial frenotomy in both the medical and the dental setting were concerning. Um, and thinking back to the evidence base, the other thing that's of note is that there were no studies that looked at labial frenotomy, um, and indicated that that was a procedure that could help with breastfeeding difficulties, so that was something we took into consideration as well. Then, as mentioned earlier, although risks of harm are low for this particular procedure. Because we have a concern that this is being done, at least for some newborns who are otherwise healthy newborns without any pathology, um, that gave us pause as well. Um, but we did also consider that despite the, um poor quality of existing evidence, the medical societies, as I described before ENT, pediatric dentistry, the American Academy of Pediatrics, all of those guidelines, although they note that they, too, have concerns for overdiagnosis and overutilization, they do believe that there is a subset of newborn infants who truly have difficulty with breastfeeding related to their ankyloglossia and who might benefit from the frenotomy procedure. Next slide. Before ENT, pediatric dentistry, the American Academy of Pediatrics, all of those guidelines, although they note that they, too, have concerns for overdiagnosis and overutilization, they do believe that there is a subset of newborn infants who truly have difficulty with breastfeeding related to their ankyloglossia and who might benefit from the frenotomy procedure. Next slide.

Charlotte Lewis

Well, I just want to say that was a great presentation. I've been working in this field for many years, and it took me a really long time to kind of wrap my head around all the different issues and, um, the evidence. I think the other thing that's happening, uh, in practice is that people are

going to see, typically, a dentist, but sometimes a physician and, um, they're having 3 sets of frenum that are addressed at one time and the other one that we didn't really talk about today, but there is really no evidence that I'm aware of, is the buckle ties. So, a lot of people, um because I take care of babies that have complicated feeding problems, I see a lot of babies where the first effort to try to address those complex sort of feeding problems that are typically more related to things like dysphagia or swallowing, um, problems, dysfunction. Um, the first way that people try to address those is by sending the baby to a dentist to have all three of those ties taken care of. And I, I think the buckle tie thing is, is gonna likely come up, um, but I as you said, I agree, there's really no good evidence for even a labial frenotomy addressing that superior maxillary frenum. There's really absolutely no evidence to support clipping those buccal frenum Um, and, and I think in my hands, I've done thousands of these, but I quote, like, a 2% excessive bleeding rate, and when that happens, it's quite scary. Like I've sent babies to the emergency room. Um, and uh, so I, parents seem unaware, really, that there are kind of some risks to doing this. Um, but they're largely being influenced, I think, by social media and social media, like, raises all these different concepts or conditions that potentially would be treated, obstructive sleep apnea, posture, facial growth, speech issues, and those, those kinds of things, I think, are driving people to pursue this in addition to their breastfeeding concerns.

Janna Friedly

Great, thank you for those comments. Amy?

Amy Occhino

Um, I'm an OBGYN, so I work fairly, well, I work really closely with lactation consultants, both inpatient and outpatient for Providence, because we deliver a lot of preemies, and so we have all of the NICU babies and things, and I'm wondering if part of the uptick in these procedures is because there is less outpatient lactation support than I have ever seen in my 25 years of OBGYN. As we all know, um, there is a, you know, we're all crunched, right? There's a financial crunch on medicine, and for better or worse, lactation does not reimburse, it is just that way. So Providence, Sacred Heart, not to throw them under the bus just closed all of their outpatient lactation services because we cannot afford to keep them open. It is such a money-losing situation at this point, which is a completely other issue, right? That's something we can't solve today. So I'm wondering if part of the reason that these patients are looking for other answers is because they don't have access to the really, you know, aggressive and informative lactation support that should be in every community, because it's not at our quaternary hospital, which breaks my heart.

Charlotte Lewis

Well, I'll just say the same thing happened at the U, at the University of Washington. They eliminated all their ambulatory Lactation support, I agree 100% with additional lactation support, I don't think people would be pursuing this, but they're frustrated, they really want a breastfeed, they don't have access to help, so they're seeking quote-unquote, a quick fix. I think it's a very short-sighted view that is being taken about the role of the lactation consultant, but similar sort of things have happened to me with administrators saying that they lose $40,000 on every lactation consultant that they hire, but my concern is, and, you know, this gets to kind of the bigger picture, is they're really just focusing on a very small piece of that, and there's a lot of evidence to say that lactation support and being able to breastfeed as an equalizing force in population health, and improves a lot of other longer-term outcomes, like In the mom with type 2 diabetes and blood pressure control and all these sorts of things. But people seem to be very short-sighted in terms of their perception of the benefit of low lactation consultant, and I, I think looking to, like, what they've done in New Zealand, where they really also face this quandary of having way overdiagnosis and really tried to look at what would be the role of having speech pathology, which really functions as a swallowing feeding and swallowing therapist in the newborn population, or in infants and lactation consultant, in addition, consultant, in addition to having someone who's going to do the procedure, all of them working together. The problem is, I think that those resources, the lactation and speech pathology, are sort of hard to come by for most folks. Long, long waits at Children's Hospital to see someone who specializes in this area.

Janna Friedly

Great, thank you. Clint?

Clint Daniels

Hi, uh, yes, great presentation, Dr. Schultz, and I have a question regarding safety for Dr. Schultz and maybe Dr. Lewis as well. Um, you know, it seemed like there's sort of medium risk, maybe some bleeding issues. Are there any long-term implications of having these procedures? Presumably, they're there to you know, these tissues are there to stabilize the tongue you know, any palate issues, speech development, dental issues, is any of that a concern with these procedures?

Charlotte Lewis

Um, well, I'll say that I um, one of the exclusion factors for doing a frenotomy as a baby who has Pierre-Robain, so, uh, recessed, very recessed small jaw, because the concern is that the tongue

could, could further fall back into the airway and, like, occlude the airway. Um, which is already present at baseline in babies with Pierre-Robain syndrome. But, that being said, you know, in my experience, and in my understanding of the literature, there that is not something that we see happening commonly, and I have never seen that happen in a baby that does not have Pierre-Robain. Um, I do have some dental colleagues at Seattle Children's Pediatric Dental colleagues who are concerned about, um, the integrity of the periodontium after doing, um a labial frenotomy, and have had cases that they've shared with me. Um, uh, where there was some, um destruction of the, of the periodontium that needed further operative, operative management. That's not something that I've read a lot about, but it's just something anecdotally that the pediatric dentists at Children's have told me that they've had to manage.

Clint Daniels

Thank you.

Janna Friedly

Great. Any other questions for Dr. Schultz? Okay, and I think, Josh, um, we are, uh, into the public comment period.

Josh Morse

Yes, uh, we're at 9:20, public comment period was scheduled for 9:05, so, um Val, do we, do we know if there are any public comments?

Val Hamann

We did not have anybody sign up ahead of time, um, however please raise your hand if there's anybody in the audience today, the attendees, who is wishing to speak. You would have 4 minutes, and we cannot accommodate any slides today. And I am not seeing anyone raising their hand.

Josh Morse

Thanks, Val. Yeah, Janna, so it looks like we don't have commenters today.

Janna Friedly

Okay. Um, should we go ahead and take our break now before we start the evidence report that was scheduled for 10 o'clock, it looks like. Do you want to take a short break?

Josh Morse

Yeah, why don't we do that?

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Janna Friedly

Now? Um, should we. So we're a little bit ahead of schedule, but, um, should we maybe plan to come back at 9:35? Does that sound okay?

Josh Morse

That sounds good.

Janna Friedly

Okay, let's come back at 9.35.

Josh Morse

Okay, I'll put the agenda on the screen as a hold while we do that. Thank you.

Jennifer Middleton

And Josh, just so I can check to make sure you can hear me correct? Okay, good.

Josh Morse

Yes, thank you for checking.

Jennifer Middleton

And Dr. Middleton, I'll stop my share, and you can take the screen. So, Janna, I think when you're ready for RTI? Yeah?

Janna Friedly

Yeah, absolutely. Let's go ahead. Get started.

Jennifer Middleton

Hello, everyone. My name is Jennifer Cook Middleton, and I'll be presenting on the frenotomy and frenectomy with breastfeed support health technology assessment and on the bottom left of the side of the slide are all the contributors to this health technology assessment. So this is an overview of what we will be covering in today's presentation. I also want to mention that none of the individuals involved in the development of this health technology assessment had any conflicts of interest. So, to follow up on the previous presentation, again, frenotomy, frenectomy, frenuloplasty, and related procedures are used to address the congenial condition of ankyloglossia, tongue tie, and tight labial tie. These conditions can lead to difficulties in latching during nursing, or cause other breastfeeding difficulties. Um, this picture, the picture of

a child with tongue tie, and the picture on the right is a picture of a child with a lip tie. Um, I want to mention that there are other types of OR ties, such as buccal ties slash cheek ties. Their frenotomies and frenectomies can be used to address, but this review did not focus on these other tie types, because they are much less common, and there is very little data on them that currently exists. The technologies that we are focusing on are lingual frenotomy, releasing of the tongue tie, lingual frenectomy remover other lingual frenulum, frenuloplasty or z-plasty, which is plastic surgery of the tongue, and labial frenectomy releasing of the labial frenum, or lip tie. So going forward, we'll use the term frenotomy to describe the various types, various procedures that can be done with lasers, scaffolds, or surgical scissors, specifically for breastfeeding support. Frenotomies can be recommended and or performed by various provider types, including pediatricians, dentists, ear, nose, and throat doctors, lactation consultants, and others. We also acknowledge that these techniques can be used in older children, whom have other issues such as speech and language issues related to oral ties, but this review focuses specifically on breastfeeding.

So again, this topic was selected for a health technology assessment because of the high concerns around the efficacy of frenotomies for breastfeeding support, the medium concerns around safety, and the medium concerns around the cost of the procedure. To give a clinical context, estimated tongue ties varied from less than 1% to approximately 11%. Reasons for this wide variance is linked to the absence of validated diagnostic methods. Diagnosis usually includes visual inspection of the oral anatomy, assessment of functional impairment, and decreased mobility and the effect on mothers during breastfeeding, such as nipple pain. Tongue tie may be most commonly anterior weather frenum attaches in the tip of the tongue and is visible or less commonly posterior, where the frenulum is attached further back on the tongue and may be harder to see. Of note, there is no consistent, no consensus as to the definition of posterior tongue tie, including whether this represents a distinct clinical entity. So there have been several articles in the New York Times, Atlantic, and peer-reviewed journals that have discussed why the number of frenotomies in babies have gone up, questioning whether procedure is necessary for breastfeeding success, how tongue posture is a big business with little evidence, stating pediatricians' warnings against overuse of tongue tie surgeries, the booming business of tongue tie releases, and how the public interests, such as Google searches on tongue tie seemed to be related to the medical claims data.

So on to the methods for this health technology assessment. So here are the key questions for the review. For the effectiveness, um, question, we looked at the effectiveness of the comparative effectiveness uh, the procedure for tongue tie and or lip tie on breastfeeding outcomes. Um, we also looked at the safety and the cost effectiveness of the procedure. This is

our analytic framework for the review. Going from left to right, starting with infants, with tongue tie and or lip tie, having a frenotomy, which may result in harms or adverse events. The effectiveness and or cost-effectiveness of the intervention on the outcomes in the far right box. Our PubMed and Cochrane Library database searches were from database inception through August 2024 and these next three slides provided details of our study selection criteria, slash our PICOTs. So the left side of the table includes everything that met our inclusion criteria, and everything on the right shows everything that was excluded. So for the population, was breastfeeding infants up to 1 year of age with tongue tie and or lip tie. And please note that we excluded infants with physical and anatomic comorbidities, and we excluded infants who were born at less than 37 weeks gestation. The interventions of interest included frenotomy and all related tongue tie and lip time release procedures, using all methods, scissors, lasers, etc. The effectiveness core studies were required to have a comparator. And therefore, only RCTs, cohort studies and, of course, with comparison, crossover studies and case control studies were included. Comparators could have been active, such as breastfeeding support, placebo or no treatment. All study designs were considered for the safety question and safety studies were not required to have a comparator. Cost-effectiveness and cost utility studies with any comparator, we're considered for the CQ. Outcomes of interest included all breastfeeding outcomes through 12 months of age for the effectiveness question. Any harms or adverse events were considered for the safety question. And the outcomes of cost effectiveness or cost utility were considered for the cost effectiveness question. For the effectiveness question, outcomes through 12 months of age were considered. No time limitations were set for the safety question or the cost effectiveness questions. All patient care centers were considered. Only study from countries categorized as very high were considered. We used the Cochrane version 2 to assess the risk of bias of RCTs and the Robin's eye to assess the risk of bias of non-randomized comparative studies. Each of these study types were assessed as having high risk of bias, some concerns for bias, or low risk of bias, and to the right are the risk of bias domains that were considered. We included single-arm studies to allow a broader set of evidence to consider for safety and due to these studies not having a comparator, we had to find another tool to assess their quality. All safety single arm studies were assessed using a modified version of a tube developed by Murad. The tool assessed the representativeness of study samples, the adequacy of ascertainment of exposure and outcome, whether the design featured supported causal inference, and whether reporting permitted replication or generalizable inference. This slide gives an overview of the certainty of evidence grading. We graded the certainty of evidence for each comparison using the grading of recommendation, assessment, development, and evaluation grade approach, which requires ratings for risk of bias, consistency, directness, publication bias. Additionally, when we noted errors in reporting, and we attempted to contact

study authors, we downgraded the body of evidence for those outcomes when corrected data was not obtained. Bodies of evidence started at high and certainty level may be downgraded based on, um, domain assessments. Um, so no concerns. Serious concerns, very, very serious concerns, extremely serious concerns, and observational evidence may be upgraded based on large effect, dose response, plausible confounding, and bias accounted for.

Our database searches capture a little over 1,100 unique citations, and at the time of abstract review and full text review, we included a total of 60 studies and 59 articles, so that was one publication that included two studies. 13 studies and 12 articles were captured for the effectiveness question. Um, this included 7 RCTs and 6 NRSIs. We had 58 studies and 57 articles were captured for safety, which included 7 RCTs, 4 our, 4 NRSIs and 47 single-arm studies, which were mostly pre-post studies. For the safety studies, I must note that even though some of these studies were designed as RCTs and NRSIs, all of the safety data was reported as single-arm data, therefore, these studies only provided safety data for the overall sample and not by intervention group. And no studies were captured for, um, that examined cost effectiveness. Okay, so this table, um, that spreads over the next three slides give a, gives a brief overview of what we found for the effectiveness outcomes. We will get into the details more into the upcoming slides. So, the table presents the outcomes, whether the evidence favored frenotomy, if there was no difference between frenotomy and a comparator, if the evidence favored the control, and if a difference could not be determined between frenotomy and the control. The color legend is at the bottom right of the screen for the certainly evidence ratings, red for very low, um, yellow for low, light green was moderate, and green for high. So, when looking at the table, what stands out is that the majority of the outcomes in the table are red for very low certainty of evidence, and for most of the outcomes, that difference cannot be determined. There is one outcome where frenotomy was favored and another where the evidence was inconsistent. For this set of maternal outcomes, most were rated as very low certainty of evidence and a difference could not be determined, and then it was one outcome where the evidence was inconsistent. And for the infant outcomes, differences could not be determined and everything was rated very low certainty of evidence. Evidence for safety. So the majority of the adverse events were not severe, or they were related to the procedure. Adverse events rates also varied across studies due to how they were measured. More serious complications were sometimes reported, including damage to other structures in the mouth, weight loss, and increased feeding difficulties following the procedure and hospital readmission. Again, even though we captured studies that were designed as comparative studies, they only reported data from the overall sample. So everyone who had received a frenotomy, or after crossover, therefore since we did not have any comparative studies, we did not grade the evidence, so there are no COE ratings for the safety evidence. And as a reminder, no evidence was captured

for the cost effectiveness question. And before I go, start going through the detailed results, I must warn you that the data is not, um, the best.

So, for the 13 effectiveness studies. Um, that were captured 7 were RCTs, and 6 were NRSIs, non-randomized studies of interventions, and all include effectiveness studies were in infants with tongue tie only. The interventions included various provider types, including midwives, dentists, ENTs, general practitioners, lactation consultants, surgeons, neonatologists, nurses, pediatricians performing frenotomies using various methods. Comparators included, um, breastfeeding support, sham, time variations, or no frenotomy, and these comparatives were not mutually exclusive. Of the included studies, 3 were rated low risk of bias, 10 were rated high risk of bias. The majority of studies were conducted outside of the United States. So, these, um, outcomes were shaded as red in the table a few slides back. We're not going to go over these outcomes in detail, because they were all rated as very low, meaning we did not have much confidence in the findings. Um, the results of these outcomes showed mostly no differences between those who had a frenotomy and those who did not. They were, um, low-quality studies due to failing to account for baseline differences, randomization issues, high rates of crossover, poor outcome measurement, confidence intervals spanning the null or being inclusive of appreciable benefits and or harms. Addition to information is available for these outcomes in the extra slides at the back of the slide deck.

So now we're going to focus on the outcomes that were graded as at least, um, low for certainty. So, breastfeeding and self-efficacy was the only outcome that the data favored frenotomy. It was measured by the Breastfeeding Self-Efficacy Scale short form, and measured mothers' breastfeeding confidence, in addition to an external observer's evaluation of breastfeeding effectiveness. There were 3 RCTs that compare frenotomy to delayed frenotomy, delayed with breastfeeding support, or no frenotomy with breastfeeding support. All three studies had crossovers, 2 planned, and one unplanned. And this is important because unblotted assignment coupled with the expectation of crossover may have biased outcome measurement. Of the three studies, one RCT specifically used lasers, while others did not specify the frenotomy method. The two studies with plan crossover reported outcomes before the crossover occurred. Um, and both report a statistically significant differences favoring the intervention arm. Um, the Frosight study reported no statistically different significant differences at 3 months, but most had received it frenotomy by the time they were evaluated. With breastfeeding self-efficacy being the only outcome where frenotomy was favored, we thought it would be helpful to provide some additional details on the studies that were included for this body of evidence. Again, the evidence included 3 RCTs with tongue tie only. The sample sizes range from 47 to 166. Frenotomy method was unclear in two studies, and one study used a laser. The procedure

was conducted by various providers. Two studies were conducted in a hospital, and one study was conducted at a private practice. There was one U.S. study and two UK studies. And here are some of the sample items that were included on the breastfeeding self-efficacy, um, scale.

For the outcomes of any breastfeeding at greater than 2 months, we found inconsistent evidence. For the one RCT, there were no significant differences between groups. Also, the study only reported outcomes after most, um, control group participants had received a frenotomy as unplanned crossover. The four cohort studies reported similar results between arms. Reasons for the very low rating included a lack of controls for confounding, potential attrition bias, and potential bias in outcome measurement, and confidence intervals spanning the null and being inclusive of appreciable benefits and or harms. The evidence was also inconsistent for the outcome of exclusive breastfeeding at 2 months or less. For the two RCTs, no significant differences were found between frenotomy and control. And for the one cohort study, no differences were found. The RCTs were rated very low because they failed to account for baseline differences. Randomization issues, rate of crossover and outcome measurement, and confidence intervals also span at the null and were inclusive of appreciable benefits and or harms. The cohort study was rated low due to confounding, outcome reporting, and attrition.

We had 58 studies that reported safety data, so that was 58 studies and 57 articles. 7rcts, 4 NRSIs, and 47 single-arm studies. And as a reminder that even though they were designed as RCTs and NRSIs, the safety data was reported for the sample overall for everyone who received a frenotomy, often have to crossover and looks similar to the data that was reported for the single-arm studies. These included safety studies included infants with tongue tie and other ties, other ties. Frenotomies within these studies were performed by various provider types, using various methods. The majority of the safety studies did not have comparators, and therefore they were not assessed for risk of bias. The majority of studies were also conducted outside of the United States. So the safety results were organized by frenotomy method. The majority of adverse events that were reported were not severe, but were related to the procedure, such as bleeding, crying, and pain. There were some serious complications that sometimes occurred, including damage to structures in the mouth, increased feeding issues and hospital readmission. Adverse events rates vary significantly across the included studies mainly due to inconsistencies in how they were assessed and reported. So, studies provided very little detail on how adverse events were measured, some considered things such as bleeding as an adverse event when other studies did not, but we reported, um, them as the studies reported them. So this table gives a quick breakdown of the number of studies that reported on the adverse events of frenotomy using scissors by indication. So there were 7 comparative studies and 28 single-arm studies in infants with tongue tie. And 5 single-arm studies in infants with tongue tie and or lip

tie and one single-arm study where the tie type was unspecified. In the 7 comparative studies of frenotomy of scissors for tongue tie only, the re-reported no adverse events, and others reported adverse events, including small percentages reported unto entire reoccurrence or the need for a repeat procedure to up to bleeding. In the 28 single-arm studies, adverse events included small percentages of infants feeding deteriorating, or infants needing to be fed by a syringe after the procedure, up to all participants having bleeding after the procedure. 14 of these 28 studies also reported no adverse events. There were no comparative studies of citizens in tongue-tied and or lip tie. In the single-arm studies that were found, adverse events ranged from needing cauterization, to stop ooze into pain, and two studies reported no complications, uh or adverse events and there was one single-arm studies of scissors for unspecified ties reported no complications or harms. This slide gives an overview of the number of studies that examine frenotomy with lasers. So there was one comparative study that looked at infants with tongue-tied only, two single-arm studies that looked at, um tongue tie only, and five single arm studies looked at tongue tie and or other specified tie types. For frenotomy with laser for tongue tie only, one comparative study reported no adverse events, and two single-arm studies reported adverse events ranging from needing a repeat procedure to crying. Studies that examine the use of laser for the tongue and or other ties, including lip and buccal ties, reported adverse events ranging from a small number of participants report a hypergranulation of the wound, to large percentages reporting experiencing pain. Two studies also reported no complications.

This slide gives an overview of the number of studies reporting on unspecified methods of frenotomy. So, for unspecified methods, the studies only said that a frenotomy procedure occurred, the studies did not report if scissors, lasers, or scalpels were used. So there were 3 comparative studies and 3 single-arm studies that looked at tongue-tie only. Two single-arm studies that looked at tongue tie and or other tie types in one single-arm study that did not specify what type of tie the participants had. For unspecified frenotomy methods for tongue tie only, three comparative studies reported small percentages of participants experiencing adverse events, such as salivary duct damage to large percentages experiencing crying and bleeding. For the three single arm studies, two reported no complications, and one study reported that 4% needed a repeat procedure. One single arm study and one case series reported on the adverse events of frenotomy with unspecified methods for tongue tie and or other tie types, including lip tie, buccal tie, or two or more unspecified types. One single-arm study reported that 99% of the sample reported no complications. The case series included a sample of participants who had all experienced adverse events from a frenotomy. The study described the harms experienced by the 16 participants, including issues related to feeding, breathing, bleeding, pain, and weight loss. Only one, um, single-arm study was captured that reported on adverse

events for frenotomy with an unspecified method for unspecified tie types. 27% had an unplanned visit, reasons for visits include infection concerns, bleeding, continued poor feeding, continued nipple pain, and concern that tongue tie persisted, and 23% of participants had a repeat procedure. And again, no cost-effective studies were identified.

So, for the discussion. So this is the summary of the evidence as a recap of the results for the maternal outcomes. There were 6 studies reporting on breastfeeding pain, and one that reported on breastfeeding effectiveness, but a difference could not be determined between frenotomy and the comparator. As a reminder, um, breastfeeding self-efficacy was the only outcome that the evidence favored frenotomy over control, and the evidence was rated as low certainty of evidence. For any breastfeeding at less than 2 months, we found no difference between frenotomy and control and the evidence was rated as very low. The evidence was inconsistent for breastfeeding at greater than 2 months, um, one RCT reported no difference and the other could not determine the difference, the other studies cannot determine the difference. For exclusive breastfeeding in less than 2 months, the evidence was inconsistent. Um, one NRSI reported no difference, and two, RCTs could not determine a difference. For all other all others, exclusive breastfeeding greater than 2 months, improvement in breastfeeding and breastfeeding problems, a difference could not be determined between those who had a frenotomy and the control, and they were rated very low surge of evidence. And for the infant outcomes of infant weight gain, infant breastfeeding assessment, and GI symptoms, a difference could not be determined between those who had a frenotomy and the control, and they were all rated very low certainty of evidence.

The overall limitations of the evidence base included small sample sizes, the inability to maintain randomization and concealment, and poor outcome measurement. For the effectiveness studies, limitations included short follow-up times due to the potentially small window of time for mother and infant dyads to achieve breastfeeding efficacy, and the difficulty of determining the level of exposure to other interventions that could impact outcomes in longer-term studies. The limitations of the safety studies included that the majority were single-arm studies and that the comparative studies only provided overall adverse events data. There was also a lack of consistency in how adverse events and complications were classified and measured. We only identified one ongoing trial that may already be completed, but does not appear to have any published results. The study is an RCT of lingual frenotomy, sham frenotomy, followed by label frenotomy in Florida. The goal of the study is to determine when lingual frenotomies, labial frenotomies, or both are required to improve outcomes. Future effectiveness, safety, and cost effectiveness studies should seek to address the limitations of the current evidence-based due to the ethical concerns of randomizing mother and infant dyads to

individual versus control, the difficulty of blinding and lack of equipoise, because most mothers likely believe that frenotomy will be helpful, as evidenced by high crossover rates. Future studies should focus on comparing frenotomy methods timing, including assessing improvement in breastfeeding over time after frenotomy and whether the benefits are for not may vary based on contextual factors, such as the availability of intensive and comprehensive breastfeeding support. Future studies should also attempt to report on longer-term outcomes, and should consider using large healthcare system data in an effort to include larger sample sizes. For effectiveness, future studies should look to explore the impact of frenotomy on the outcomes of nipple infection, swallowing function, failure to thrive, milk transfer, low milk supply and other feeding issues that may that appear to be absent in the literature based on the current review's inclusion criteria. For harms specifically, future studies should use more intentional approaches for collecting and reporting harms data, including using predetermined and well-defined measures, and collecting data from various sources.

So, these next three slides give an overview of the clinical practice guidelines and recommendations from other groups. Um, the American Academy of Otolaryngology stated that frenotomy in infants with tongue tie can lead to an improvement In breastfeeding, but not all infants with tongue tie need a frenotomy. The Academy recommends further study to refine the evidence. The American Academy of Pediatrics of Dentistry stated something similar, and that all infants with tongue tie require surgical intervention and supported further research. The American Academy of Pediatrics says it's unclear if release for a tight lingual frenulum improves breastfeeding um, and that further research is needed. The Academy of Breastfeeding Medicine says that the procedure can be an effective way to increase maternal comfort and milk transfer, and may prevent premature breastfeeding cessation, but recommends more research. The International Board of Lactation Examiner stated that its members should not diagnose, um, tongue tie, but may refer parents to a clinician who can diagnose. The Canadian Pediatric Society does not recommend the procedure for all infants with tongue, but stated that infants who experience significant breastfeeding difficulties may benefit from frenotomy, and that if it is performed, it should be by a clinician experienced with the procedure and using appropriate analgesia. The Canadian Agency for Drugs and Technology and Health states that it is a safe procedure with demonstrated short-term breastfeeding effectiveness, but there is less evidence on objective and long-term breastfeeding measurements.

So this slide provides an overview of the procedures that are covered by these pair of groups. Um, Aetna, Washington Apple Health, Regence Blue Shield Dental appeared to cover the procedure for tongue tie and lip tie. Premera Blue Cross and United Dental, United Health

Dental appeared to have some limits, they appeared to only cover the procedure for tongue tie and not lip tie.

So, this health technology assessment has several limitations related to the scope and the analysis. In regard to the scope, the limitation only included English language articles from very highly developed countries. Other limitations included limiting our study our search only to two databases, not including unpublished data or data presented-only conference abstracts. We also excluded, um, effectiveness outcomes from uncontrolled studies, therefore, we excluded studies that did not have a comparative group. And in regard to the analysis, limitations included not grading the body of evidence from uncontrolled safety data. So, in conclusion, we found limited evidence that evaluated the effectiveness and safety of frenotomy for breastfeeding support in infants up to 1 year of age with tongue tie and or lip tie, and no evidence of, um no evidence reported on cost effectiveness. And that is it for me. I don't know if there's any questions or any slides you'd like me to go back and review?

Tony Yen

Ms. Middleton?

Jennifer Middleton

Yes.

Tony Yen

May I ask you, what is the difference between breastfeeding effectiveness and breastfeeding self-efficacy? I'm trying to understand those definitions.

Jennifer Middleton

Yes, and so that's why I put up those, um. The way that scale was measured, they described it as it's basically measuring, um, mothers self-confidence, almost, in terms of breastfeeding. So that's how that was measured.

Tony Yen

So it's one. Are they both very subjective sort of scores, or is what the self-efficacy, I don't know, more subjective in terms of, like, hey, this is really working well, from a mother's perspective?

Jennifer Middleton

It sounds like, so based off what I'm saying, you know, being able to determine my baby is getting enough milk.

Tony Yen

Okay.

Jennifer Middleton

Keeping wanting to breastfeed and being, you know, being satisfied with my breastfeeding experience um, it is more subjective than what affects… so maybe effectiveness may be more tied to how much milk the infant is actually getting. Um, maybe might be tied more, like, to, I guess, like, ounces. I probably need to pull, find that, um that scale, but that was how. So this was the actual scale for self-efficacy, and then effectiveness, I will probably have to see exactly how that was measured, but it seemed like it was more maybe tied to weight or a real measure, versus this is tied to more the mother's, um, experience.

Tony Yen

Thank you, appreciate it.

Jennifer Middleton

Mm-hmm.

Clint Daniels

Dr. Middleton, is this confounded by the high crossover, where the moms already believed it was gonna work and that's maybe why this showed such a positive benefit?

Jennifer Middleton

Yes, and that's why some of the studies, yeah, and that's why we rated so many things as, um as low, because a lot of times the, the follow-up was very short. And so, if you already know that there is a plan, at the end, you're going to get the procedure, so that's what we're in a way to be confounded by or poor measurement, because you would think, oh, I'm going to get the procedure anyway, so let me go ahead and say, you know. It may not be as great now and then I'm going to have the procedure done, and then it's going to get better, you expect for the procedure to work.

Jonathan Sham

Um, it's been kind of mentioned several times that this is a really hard diagnosis to make, this ankyloglossia, because there's not, like, a really good standard definition. But on that ongoing study in Florida, you mentioned that they're limiting it to Class 3 and 4 ankyloglossia. Is that a

relatively new classification that's being used, or do you know why the other studies perhaps didn't enrich their population to, to look at just those higher risk patients?

Jennifer Middleton

I'm not sure why they would, um, limit it, but the way that some of the studies it was, like, real general, so some of them they didn't, they could say if they had a procedure or they did not. They wouldn't necessarily get into a strict criteria of everyone who actually had the procedure. So I don't know if it was just in terms of, like, numbers, why they didn't necessarily, like, limit it to those certain grades. Um, but again, like that study, that was what their plan was, and it should be complete, but we weren't able to find, um any published results, so I'm not sure how that recruitment went.

Jonathan Sham

Dr. Lewis, maybe, do you have any perspective on that?

Charlotte Lewis

Yeah, I think that, that, um, this is kind of a huge issue in the research in that we don't have a really comprehensive way to evaluate, um, the severity of ankyloglossia. I use a tool, um, called Tabby, um, which is similar to, um, what's called BTAT. And that's something that comes out of Bristol, England. And that's something that, um, it's a four-category, um assessment, and you have between 0 to 2 points that you can assign to each of these categories, like where is it attached on the inside of the lower alveolus, because more severe tongue tie, if it's attached, um, not at the floor of the mouth, but on the alveolus, that just makes that freedom shorter, uh, and, and tighter, um how far can the baby extrude the tongue, how well can the baby lift the tongue, and then what is the tip of the tongue look like? Because if it's a significant ankyloglossia, you likely will have a divot or, like, a heart-shaped, um, tongue. So, it's not a perfect it's far from perfect. And the biggest problem with these various different tools is that they kind of lack any sort of functional, um, assessment, like, there's, there's no real consideration of pain, maternal nipple pain, um, bruising or trauma, um, there's no sense of, like, how much the baby is transferring, and so I think the problem with a lot of studies is that they're kind of taking all comers, more or less, sort of mixing apples and oranges kind of thing, with people that have more mild degrees of tongue tie that are likely not going to benefit from frenotomy with people that have significant tongue tie that's anterior, that's very restrictive, like that first picture that was, um, shown with the medical director's review. Um, uh, the other thing is, is that there's many factors that influence breastfeeding efficacy and, you know, if you're a prima, a first-time mom, you're gonna struggle a lot more um, than if you are an experienced breastfeeder. Um, and I think these studies haven't taken into consideration those

other various factors, but they also we don't have a great way to define who really has ankyloglossia, and I think that's partly why we haven't seen really. Well, partly it has to do with poor design of these studies. But, um, but I think part of the reason we haven't seen, like, really compelling findings is because these are small studies that have mixed populations, where we're not really good at defining who might be an appropriate candidate for the procedure.

Janna Friedly

And just to be clear, in these studies, um I think I already know the answer, none of them clearly, we're able to show subgroups that benefited. We weren't able to parse out, um, or clearly identify those.

Jennifer Middleton

No.

Janna Friedly

Those, um those feeds that word would be more likely to, um, to benefit.

Jennifer Middleton

No, definitely not out there, the 13 that we were able to, you know, find date, yeah.

Janna Friedly

Yeah. That's, That would have been nice, if we could. Would have been very helpful

Charlotte Lewis

One thing that I think is driving the labial frenotomies, um, uh, which I don't do, because I don't, I don't see that there's evidence there, but, um to be completely honest, I feel like the referrals that I get have dropped significantly because it's known that I don't do labial frenotomies, and that's what people are looking for because, um, what I think is happening is that If you look at the superior maxillary frenum on a newborn infant who doesn't have teeth, right? That appearance of that frenum, if you saw that in, like a 12-year-old, let's say, you would think, oh, this, this patient is going to have orthodontic issues because that frenum is so prominent, it's causing, like, the space between the two front teeth, but what happens is that that frenum changes over time. And it's very unlikely that what you're seeing in a newborn baby of that superior maxillary frenum is going to end up causing orthodontic problems later on, because that changes over time. But I think a lot of people and I would say in that group would be dentists, and increasingly more lactation consultants are, like, saying, oh, this baby has a lip tie, um, and it's because they're not recognizing what is actually normal uh, in, in a newborn, um,

infant for that superior maxillary frenum. And there is, as I'm sure you know, tons of misinformation on social media and, um, a lot of people doing the procedure on a newborn to try to prevent orthodontic problems later on, like a space between the two front teeth um, and then the other thing is that dentists that dentists use to try to promote, and I, I at one point, had done a lit review on this and had found very little evidence that um, that incising that superior maxillary frenum would prevent, um, dental decay in the two front teeth um, which is a side of dental decay in younger children with early childhood caries. But that if that was so tight that perhaps you may not be able to do appropriate dental hygiene or something like that. Uh, and so that maybe you'd be more likely to get cavities in those teeth. Um, and I think the evidence there is, is very, very limited to nothing. Um, but those are the kind of things that are that dentists are bringing up, I think with families that to encourage them to go ahead and get this labial frenotomy. In addition to this lack of understanding, and I agree completely, there's really the role of the upper lip in breastfeeding is very, very small, and it's, it does not tend to play a role in efficacy of breastfeeding however, tight that frenum is, and in addition to that, it's being over-diagnosed because there's not an appreciation that that's something that's going to change over time, and there's not an appreciation of what's normal in a newborn baby for that frenum.

Janna Friedly

Other questions?

Jennifer Middleton

Anything else? Oh, go ahead.

Janna Friedly

About the report.

Jennifer Middleton

Um, Sarah?

Josh Morse

Janna, we have, um, Dr. Vander Beek, our Dental Director, here for just a few more minutes. I don't know if she has a comment. She does have to depart at 10:30.

Janna Friedly

Great. Yes, I see her hand up. Perfect.

Washington State Health Care Authority

Sarah Vander Beek

Morning, can you hear me? Great, good morning. I just wanted to comment.

Janna Friedly

Yes.

Sarah Vander Beek

Kind of echo what Dr. Lewis is saying. I think even though I am in the dental profession, um, I think that connection to our physical health providers is really critical, especially when you're talking about um, the other frenums in the mouth, so the that she's commenting on the labial and buccal. So, just wanted to chime in from the, you know, the other profession that I do agree with that perspective um, and also see, um, the trends that she's sharing. So just really appreciate your insight, um and expertise. Thanks.

Janna Friedly

Great, thank you. Any other questions from the committee? Okay. Well, I think, um at this point, um, what's next on the agenda is really, um, question and answer, um, related to the report, and then um, discussion and decision, um do, is there, is there any other discussion about the report, or do we want to jump into um, discussion about our decision?

Jonathan Sham

Um, maybe I can just make a brief comment, at least on my perspectives of the report, and, um, maybe if we're able to bring up just those slides again, page, or slide for slide 49. I'm sorry, it's page 36, slide 49, I'm not sure which one, just to give the overall summary of favors, no difference, cannot determine a difference. Yeah, yeah. Again, and this is just a general comment for the group, kind of from a clinical trials perspective, I think this really highlights how difficult RCTs, clinical trials in general, are to perform and it doesn't necessarily have to do with the efficacy of any particular intervention or not. It has to do with a thousand other things, whether or not it's a grading scale for the disease itself, patient, you know, selection. Well, that has to do with equipoise, uh, between the different treatment arms, uh, um both with physicians and patients or mothers or parents in this case, um, whether it's allowing crossover, like, there's just a thousand things that can, um… make these trials go awry, or just most of the time, prevent them from being done in the first place, which is why there can be an absence of data. And so I guess I just want to highlight that, uh, because I think feasibility is such a broad term and can be underappreciated in our ability to evaluate, you know, because what our really true question is,

is, like, does this help or not? And a lot can get in the way of that. Um, and I think this, this really highlights that point in this slide.

Janna Friedly

Yeah, thank you. I think that's a really important point, and it does, it's, uh, it's clear that this is, um, uh, as Dr. Lewis has pointed out a very difficult to, um characterize, um, issue, and there's so many different factors that are playing into, um, identifying the right um, the right babies in the right context to provide the intervention and the right combination of interventions, um, uh, that it's, um, to capture that into a clinical trial, and capture the outcomes is difficult. Um, and so that it makes, makes it very hard, um, to evaluate the evidence and, and to also look at this in isolation, is also what is, um is clear from the discussion to me.

Laurie Mischley

I have a couple thoughts I'd like to add, um I think that was really articulate about the, the difficulty of doing randomized controlled trials in my own field. We're seeing that we can build patient-reported outcomes that are much more sensitive than the tools we've been using for research studies, and so um, I don't think, I'm not quick to dismiss a mom saying this is working better um, as, as placebo. Um, I think it's very possible that the self-efficacy scale might even be superior to some of the study designs we're setting up, and anyone who's breastfed or helped new mothers breastfeed know that time is so critical. I mean, every attempt at breastfeeding is either a stress response or a solution, and um. So, anyway, the time delay, I think, makes studies really, really hard here. Um, I think this looks relatively cheap and relatively safe in the grand scheme of things. I mean, in terms of the dollar amounts being assessed here, I think um, you know, whether or not it really helps breastfeeding. I mean, I'm kind of on the fence, just with the data that we're seeing here. I mean, obviously, we see what we see here, um, but my question and concerns really relate to, is breastfeeding just, um, step one hurdle in these kids' lives, right? You know, we see speech impediment issues, we see increased risk of sleep apnea, um, certainly some chewing, eating, swallowing, dental concerns might be coming up. Like, we are talking here today about breastfeeding, and that's our charge, but could we, for $400, not only remove the breastfeeding question off the table, we've done what we can here, but what we're also doing is saving speech therapy and this, especially with kids with a more severe degree of this. So, that's my question and thought.

Charlotte Lewis

I think we, um, we have already noticed, like, for these very short-term trials, um, how flawed the evidences, and we really lack any longitudinal data. I think what compels a lot of parents to do this procedure is the concern for speech problems later on. Um, that seems to be what is

compelling a lot of people to pursue this, even in a newborn. But I always try to point out to families that we really don't have longitudinal data that helps us to say that if you have this appearance to your sublingual frenum at two weeks of age, you're gonna have articulation difficulties at 4 years of age. When I've spoken to my colleagues in speech pathology, not the ones who are dealing with the feeding issues, but the ones who are dealing with, um, assessing and managing articulation issues in preschool-aged children, what they tell me is it's very, very unusual that, um that the, that ankyloglossia is the source of a speech problem. I don't think we, we really have any evidence, um to speak to things like facial growth or obstructive sleep apnea, or those kinds of things that are other reasons why families pursue um, frenotomies is because of information, mostly, that they're obtaining from other parents and on social media that is encouraging them to pursue this for to prevent other problems in the, in the future. I'll also add, and I know this isn't the scope of what you guys are doing. Um, I, there's a lot of out-of-pocket payment for, um, these procedures, um, and many, um, dental providers um, ask for out-of-pocket payment as opposed to submitting, um, a dental claim or, um It's most, mostly, I think this is happening in the dental world, though I don't know that for sure. Um, and so many families report to me that they're paying Um, over $1,000 for this procedure out of pocket in an effort to try to address their breastfeeding problems, because they're sort of desperate to find something that's going to help, because that was a big part of their intention and they're not able to get support anywhere else. And so even though I know that's not the scope of what we're talking about here, I do have concerns about sort of vulnerable population, not vulnerable, but, you know, the people that are vulnerable to, sort of overdiagnosis because they're they really want to be able to breastfeed, and they want to find why it's not working for them.

Jennifer Middleton

And I was gonna also say that even though it wasn't within the scope of this review, there is a body of literature that focuses on the procedure for speech, but we did not focus on that, we just focused on breastfeeding. So, it may be some study that exists that will answer that question, but they weren't included in this, uh, review.

Clint Daniels

Uh, maybe Dr. Occhino as well. Uh, I'm curious if you could maybe, uh, expand a little bit on the value of the self-efficacy side for the mother. And, uh, I think Laurie touched on this briefly, you know, saying placebo, but I think maybe the contextual factor benefit that could come from the procedure, and just reassuring them that maybe something is being done. In a situation that I assume is very frustrating for them.

Charlotte Lewis

Mm-hmm. Well, I think it's a tool, right? And it's a validated scale, and so that's something that people will choose, and other ways of evaluating breastfeeding effectiveness are likely to be more subjective. Um, I would say there is this the possibility that you could do something like what we call weighted feeds, which means that you feed a baby right before they go to the breast, I mean, sorry, you weigh a baby right before they go to the breast then, um, they go to the breast, then you weigh them out after, and as long as you're using a precise scale, you know, you can monitor for amount of milk that was transferred, because at the change in weight, as long as you're using a precise scale, corresponds to the number of milliliters of milk that was transferred. So that, you know, is something that could be done. It's, the problem is, is that we're also dealing with temporal factors, like somebody else was alluding to in that, you know, in the first few days of life, you're making hardly any milk, and then you're, you know, making more milk, and, you know, that increases over time as breastfeeding self-efficacy and effectiveness, all these things increase over time, so all these studies that, um, you know, relied on crossover or differences in time and things like that are very flawed because that's something that, if you continue with breastfeeding, those things are going to get better over time as your baby gets bigger and older and stronger and those kinds of things. So, I think it's just another limitation to the data that's available.

Amy Occhino

Oh, hey, this is Amy Occhino. Can you guys hear me?

Janna Friedly

Yep.

Amy Occhino

Uh, the other thing that I think is, uh, part of, you know, this whole perception with the parent is, when, when there is a patient that has breastfeeding concerns, and they do get support through lactation, or through their provider, or even through the internet, I will tell you that these mothers come at it from every angle. They are not just trying one thing. So they're power pumping, and they're using supplements, and they're calling their neighbor, and they're getting in with whatever, and they're trying to get their tongue untied on their baby. So, I would wonder if some of the perception for why things are better might not be complicated by the fact that I, most of the time that one intervention is not the only intervention.

Charlotte Lewis

Mm-hmm, I agree.

Janna Friedly

Yeah. And, um, I know this is not, uh, evidence-based, this is N of 1 experience, but I was one of those mothers and had this procedure done on my daughter, um, and, and so I am interpreting all of this through my own lens and experience, and trying to um, and think about it from that perspective, and I can tell you that that's exactly, that's exactly trying to think about, was it the procedure, or was it, uh, all of the other things, because I was desperate, um, uh, with all of the other things, and tried every possible thing. Um, and looking back, was it necessary? I don't know. And was it helpful? I was able to successfully breastfeed after that, so I don't know. Um, but, um, but it was a very, it's very complicated. There are lots of different factors, uh, involved, um. Any other comments, or questions? This has been a good, good discussion. I think, um, if there are no um, additional comments or questions, I would suggest we take a short break before we move on to talking about our, um our, uh, going through our, uh, decision. Um, so I would propose that we take a maybe a 10-minute break, come back at 10:40, or a 9-minute break, come back at 10:45. Does that sound reasonable? And then we'll start, um, uh, with, uh, focused discussion on the decision. Does that sound okay, Josh?

Josh Morse

Sounds good, yeah.

Janna Friedly

Okay, great. We'll come back at 10:45.

Josh Morse

10:45, thank you.

Jennifer Middleton

Josh?

Josh Morse

Yes.

Jennifer Middleton

I forgot I had to slide in the back of the, um with the different measures, because somebody was asking about how breastfeeding effectiveness was measured, and I forgot that we used a latch. Um, so I'm not sure if that's helpful.

Josh Morse

Was that Dr. Sham who was asking?

Jennifer Middleton

Yes, mm-hmm.

Josh Morse

Yeah, there's, okay, he's here. Thank you.

Jennifer Middleton

Mm-hmm.

Charlotte Lewis

I think the latch score is, um, a really helpful score We use that frequently in the nursery to evaluate how breastfeeding is going, um so it's a tool that I use a lot.

Janna Friedly

Do we have everyone back? Just about. Okay. Looks like it. Okay, great. Um, so let's, um I think we're just missing Chris. But Josh, um could we, um, maybe project, uh, or Val, um, project the, um the decision aid?

Josh Morse

I think Val will be sharing that.

Melanie Golob

And I'm happy to walk you through any of it, um, Janna, if that…

Janna Friedly

Sure, yeah, that would be great, if we could get started.

Washington State Health Care Authority

Melanie Golob

Okay, so, um, just as a reminder, this is essentially a slide deck representing the decision aid that was posted that you all should have access to, but this is just to help you kind of walk you through the decision-making process. So if you could go to the next slide. So this is steps 1 through 4 are what you have done so far, and we're moving on to 5, um. So if you can go to the next slide. And so this is just showing, kind of, everything that's going into this decision that's being made, uh, and the idea is to give the greatest weight to the val, the most valid and reliable evidence. Uh, go ahead and go to the next slide. And so these are the next steps that you're going to go through as a committee. We're going to start with a straw poll vote on the sufficiency of the evidence, uh, and then after that, just to kind of get a temperature check, uh, and that'll be separately on safety, efficacy and cost-effectiveness. And we'll preview each, or begin each vote showing kind of an evidence map, or, like, where the evidence was from the report, uh, and then you'll discuss the evidence as a whole, as a committee, and then you'll do the straw poll vote for coverage. And then if needed, you'll draft those coverage conditions, and then do your binding vote for draft coverage.

So if we can go to the next slide. So this is the evidence summary for safety, and if you could just jump ahead one slide, I just wanted to show you, there's no evidence map for safety, but this is just an example of what that evidence map looks like. Jennifer from RTI presented this, uh, so this is an evidence map, but if you could go back one slide. There is no, uh, evidence map for safety, uh, and again, Jennifer pointed this out in her presentation, but that was due to inconsistencies in how those adverse events were reported and assessed. And so, just as a reminder, kind of the brief summary is that the majority of those adverse events were not severe or related to the procedure, um, and the rates of adverse events varied, uh, across the studies.

Can go to the next slide. I think that's. Thanks. And then, as a reminder, this is, uh, what you'll do is, do a straw poll vote on the sufficiency of evidence. So, is it safe for the indications considered, and what is that risk? Is it low? Is it high? And then what's your confidence in that. So, uh, Janna, if you're ready, we can go ahead and go to the straw poll vote for sufficiency of evidence for the safety.

Val Hamann

Yeah, so if everybody wants to jump over to TT Polls and put in that session ID that you were emailed last night. Again, please do not share that information. And once I see the 9 connections, I will jump into that straw vote.

Washington State Health Care Authority

Laurie Mischley

I can't find an email that email from last night. This is Laurie. Could you please resend that to me?

Val Hamann

Yep, no problem. Just sent that. Right now, I'm seeing 6 connections, so if anybody else is having any issues, just let me know. Okay and we have 9. And we are waiting on one more response.

Melanie Golob

Okay, um, should we go ahead to the next vote on, uh efficacy?

Janna Friedly

Uh, yes. Yeah.

Melanie Golob

Okay, so it's a reminder, here was the evidence map, uh, showing that the majority of studies were unable to determine a difference, uh, with very low certainty of evidence. If you go on to the next one, and as a reminder, you just did this, so I think you'll be good. But, uh, your sufficiency of evidence vote is your confidence, and if it's more effective or less effective.

Janna Friedly

We are very split.

Melanie Golob

Yeah, and you can come back and discuss these. We'll, we can go on to the next, cost-effectiveness one. So, there was no evidence map for cost effectiveness, because there were no studies, uh, that met criteria for the cost effectiveness. Um, so we can go on to voting.

Val Hamann

I'm waiting on one more response.

Melanie Golob

Okay. Uh, so, Janna, you can take it from here. I think these were the discussion questions you wanted to, uh, address with the committee

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Janna Friedly

Okay, um, great. Um, so I, um, I thought it would be helpful for us, um, given that we are looking at, um, safety, efficacy, and cost effectiveness, um, we, we typically will, um think about what the most relevant outcomes are, um, for, for each of these, um, and, um, sometimes we're limited by what outcomes are presented in the data, but I thought for this discussion, and we've talked about this a little bit in terms of what the outcomes are that are presented, um, but, um, I thought it would be helpful for us to just talk a little bit about what the relevant outcomes are, um, and to hear from the group about, um, what in the, what in the evidence, um, prompted you to vote, um, in the way that you did, and what the important gaps are, um, in the evidence as uh, sort of, uh, discussion, especially in this, in this case, because there, um, were, uh, some, um, mixed, um, mixed results with the straw poll voting. Um, so, um, I'm, I'm sort of happy to start, um, the discussion, and I think, I think with these, um, we can, um, we, we can each, um, kind of go around, um, and answer these. I don't think we need to separate them out, we can sort of discuss each of these questions to together. Um, but I can, I can start for, from my perspective. Um, um, you know, and we've, we've talked a little bit about the relevant outcomes and, um, whether or not self-efficacy, um, breastfeeding self-efficacy versus, um, some of the some of the other, uh, breastfeeding outcomes are, are more important, um, and I, for my, for myself, I think I, I do actually think some of the more objective, as much as even for myself as a person who has a recipient of the, the procedure, um, and, um, having experienced, uh, that, um, uh, can say I probably would have scored higher on the self-efficacy scale, but may not have seen, um, necessarily improvements on some of the other objective scales. I still think that those other objective, uh, short-term and long-term outcomes, uh, probably are more important, although the self-efficacy, obviously, is important as well. But certainly what we're really looking for is, um, uh, I think, um, sort of, uh, the, um, the outcomes with the, um, with the baby, um, as well as, um, as well as with the, with the mom, but probably more, more importantly for me was, um, uh, some of the objective outcomes with the, um, with the, the feeding with the baby. Um, which we didn't really see, um, in any of the, um, in any of the data.

Um, so for me, I, um, the way I, uh, voted, uh, I thought I, I just didn't have any confidence in any of the data. Um, but I felt that there was, uh, really no cost-effectiveness data. Um, I felt that there was um, uh, that the procedure had a little bit of evidence that there was some mild, um, safety, uh, issues, minor safety issues that there were not really significant safety concerns, but minor safety concerns. Um, and then with the efficacy, um, uh, that it's, for the most part, the data is showing that they, uh, are, uh, that the, that there's, uh equivalent, uh, data, uh, that there's aside from the three studies that show the difference in the self-efficacy, um, I'm just not seeing any differences in the data, uh, but, but again, recognizing that there's all sorts of

limitations in the way that the studies are done, and that there are important gaps. That's, um, that's how I'm viewing things. Uh, but I would love to hear from the rest of the committee.

Tony Yen

Hey, Janna. Um, I agree with your assessment of the data. I think that there is really very little to any data that shows objectively that this actually improves uh, any outcomes for the child. Uh, but it seems like, at least from the data that we have within the evidence report, is that there is some improvements in terms of self-efficacy. Now, um, as not being a mother, I want to just be clear about that, uh, but it seems like that's actually pretty important as well. Um, I see this as being one of the many, many, many tools that we have at hand to improve breastfeeding as a bottom line. Um, I really appreciate Amy's comment and Dr. Lewis's comment about the lack of lactation support within the ambulatory setting. That's well outside the scope of our discussion, but it seems like that is actually a big part of the of what's, what's kind of going on as well, um, in addition to the rise of social media, uh, which we unfortunately have absolutely no control over, um, but it seems like this is get one more tool. That could be helpful in terms of self-efficacy, which I think is a big part of, you know, being successful.

John Bramhall

Yeah, Tony, I was impressed with that early comment from both, um, Dr. Schultz and Dr. Lewis, uh, about the, the lack of sort of formal support. Uh, and given the turmoil that we can predict over the next months and years, that's not going to get better. So I was really, um, quite distressed to sort of hear that um, the lactation support, uh, for new moms is, uh, is being withdrawn, even in urban areas, and we all know, to pontificate, we all know that there are maternity deserts now in, you know, Yakima Valley, eastern Washington and, and functionally in urban centers. I think it's a catastrophe, and what do we expect as a group of, of intelligent medical professionals what do we expect, uh, citizens to do when they can't get the services that we would like them to get within the formal medical system? Maybe go somewhere else, and, and pay out of pocket. I think it's really distressing, and I think we've seen this with certain other technologies that we've looked at, and we certainly see it as human beings who read the newspapers, so um, it's a real problem. A real problem. And it seems to me that, um. Yeah, okay, so I do have, I've personal experience of lactation. 75 years ago, I think. I don't remember it. And, uh, we raised a couple of kids, and uh, went through some of these issues, just like you did, yourself, uh, Janna. Uh, so here's a couple of thoughts. So, one is, if we, if, if we had an objective determination of ankyloglossia, that really we were comfortable with and I know, I know there are within specialty fields, there's grades and what have you, but, you know, if you could take a child, a baby, and say, this baby has ankyloglossia and needs a lingual frenotomy,

um, that, that, that would sort of get rid of a lot of the, sort of, you know, nebulous concerns that we have about the functional outcome that we're concentrating on here. And so, I just wonder, I mean, maybe it's not even within the scope of our discussion, I don't know yet Um, when I was a kid growing up in England, it was really, really common for children to be given a tonsillectomy, an adenoidectomy I mean, it was, it was just totally common, and, and he got tonsils, they need to come out. Uh, and I think that probably there was a population of kids that had, you know, kind of speech impediments, or sleep apnea from it. But, you know, I don't think there were a lot of studies, and the kids just got these things ripped out. And then, you know, the conventional medical sort of thinking changed over the years to think, well, you know, these structures are, they're there for a purpose, and maybe it isn't good to just rip them out. So, I think you'd have the same problem, perhaps, with uh, ankyloglossia, you'd say, well, this baby has a tongue tie, I can see it, it's right there, and if I snip it with scissors, it's gone, and we've solved a problem, but, um, but we don't have the data on that and what we're looking at is this functional set of data that relates to the breastfeeding. Mom's anxious, I haven't experienced it as an individual, but I think it's uncomfortable and sometimes painful the first few hours and days of, of breastfeeding, uh, and mums, they don't have the support that they need. Of course, they go to social media. Of course they do. It's right, they're on the phone. Um, I don't know whether we include the Atlantic Monthly and the New York Times as social media. I tend not to in my own mind, but I did read a couple of the articles that were suggested from the Atlantic Monthly and from the New York Times, and I was very impressed, actually, with I hadn't realized the, the two things that come to the fore is the social pressure and medical pressure to try to breastfeed a baby. And I, I'm of the opinion, I don't know if it's true or not years ago, 20 years ago, uh, what would happen is mom would run into some difficulties with breastfeeding and switch to formula, and go to a bottle and my understanding is that breastfeeding the baby has to suck, and with the bottle, they sort of you know, gum it um, it's a different mechanism. So they get nutrition, but they've moved away from breastfeeding and we, as medical professionals, have been, sort of, starting to understand the importance of breastfeeding from a whole variety of immunologic, of social bonding, all the things that we know about. So we want moms to breastfeed, but again, we're not supplying them with the support that they need to do that conundrum. Here's an issue that's going to be discussed in the newspapers and magazines and on all kinds of, you know, TikTok, whatever. Um, and I do think that we have to rein it in and I think, I think if we were a committee that, um, a part of our responsibility is to see that the, uh, that, let's say Apple Health, that the HCA provides services that we think are necessary, and one of the reasons we think they're necessary Uh, is to be, sort of, regulated is because if they're unregulated, then damage is more likely to be done. So, sorry to be long-winded, but I don't, we don't have any evidence. We don't have any data. We don't have the, the objective

information that we would like as a committee to make a decision, and we can either put our hands up and say, we can't say anything, you know, we, no comment, or we can sort of think a little bit more broadly and, and go to the idea that, as a committee, as a group, we're looking for safe, effective, cost-effective mechanisms to help, uh, citizens, help patients, help people. Uh, and that if we do not make a determination here of some sort that's, that's acceptable. Uh, there's gonna be, it's the Wild West. Uh, people are just gonna go off and get these things done, pay $1,000 to a dentist and away we go. And that might have untoward consequences that we were unhappy with. So, I haven't sorry, I haven't moved the ball very much, I understand. Uh, but I just wanted to vocalize the sort of the, the personal, sort of, feelings of discomfort with the lack of medical support for new mums, apparently, in a variety of communities, uh, and then to, sort of, regular against unregulated, completely open, open-ended exceptions of technology and techniques that, that really don't have a lot of data to them, but may very well have it actually may have important social consequences. Sorry, bit long-winded, um, that's where our thinking is.

Janna Friedly

Thanks, John. Amy, I saw your hand up.

Amy Occhino

Yes, thank you. He said everything that I was going to say. I am 100% in agreement with everything, and when you said reining it in, that resonated with me, because in my professional opinion, the number of these procedures is only going to increase, because we do not have the support in place. It is going to be a long time before our lactation services are what they need to be. And in the meantime, I don't want this low-risk procedure to turn into something that actually is more risky than we thought, because it's being done more commonly, and we are creating more risk and more consequences for these little babies. So I'm, I am really worried, same as you, uh, John, that this is going to get out of control, um, if we do not you know what I'm saying, kind of rein it in at this point in time. And the whole breastfeeding, paucity of support, that's a whole other issue, and I appreciate that you guys see it, um, but for the moment, you know, this is not the answer. To what is happening with the lack of breastfeeding support that we're seeing today.

Charlotte Lewis

And one thing that I alluded to that I think is important for us to think about is um, what, what training do dentists have to, well, and I'll just say, what training do all of us have in medicine, either to evaluate babies with feeding problems, I think it's pretty limited. And even though this is anecdotal, because I run this team at Children's for babies that have complex feeding

problems, it is impressive to me how many of these babies have undergone procedures in an attempt to try to fix some vague feeding problem that ultimately ends up being something pretty severe that requires nasogastric tube, gastrostomy tube, these kind of things. And what's the impact, um, on delaying diagnosis and seeking care by encouraging people with any sort of feeding problems in infancy to, to pursue a frenotomy, because maybe there's something there.

Clint Daniels

Amy, I'm curious, are you leaning towards non-coverage, then? It's sort of how I'm interpreting your statement.

Charlotte Lewis

Um, with caveat, I would say with caveats.

Amy Occhino

Um, oh, me? I, I, that's exactly what I was gonna say as well. I do think that there are some times when it is When it is a reasonable approach, but it is not the first thing that people should go to. It is not the thing that they should be pulling out, you know, money for and paying out of pocket for as first-line therapy. And I don't know how to get that into our qualifications but, um, I think that in and of itself, um. Yeah, I don't know. I would like to be covered with qualifications.

Janna Friedly

Other, other members of the committee we haven't heard from?

Clint Daniels

I voted, I think, really, the question we're only considering, really, is efficacy. Um, I voted equivalent on that. Um, however, I'm also kind of leaning towards coverage with conditions, and largely because I'm thinking of the dyad and not just the baby, and I think… this self-efficacy is, uh, compelling, and I think clearly in high demand. Um, but I agree with everything Dr. Occhino and Lewis said as well.

Janna Friedly

Great. But Evan, I haven't heard from you.

Evan Oakes

Yeah, a lot of really, really good comments, so I've, and mostly echoed what I was or have said what I would be adding. The one, two questions I kind of had in my mind. One is, is there anything about this conversation that gets to Medicaid around the lactation services out there?

So we're, that's not in our scope, but I'm just kind of curious if people can comment on that, who are with you, you know, maybe Josh or somebody about how our conversations catch the ears of, and how does the state then hear these conversations and then respond in a way that might actually improve those kinds of services? Um, and then, uh and then I'm curious to hear with and I'll be I'm just listening, like, with qualifications, what would that look like, and that kind of a thing. I feel like the evidence is pretty limited in terms of what the benefit is of this at the uber all, uber level, but, um, I'm also hearing that there may need to, that there might be situations where our physicians will need to make a decision about that, and how does that, how does this decision affect that, or what are the tools for us to allow that to happen? Seems to be a common theme that I have often had with the committee, is how do we provide the tools in the right way, but then I'm following, um, Dr. Occhino's comments, and I appreciate those very much about the solution is not to approve something that doesn't have evidence. And so that's kind of where I'm going.

Janna Friedly

And just to follow up on that, we've had this conversation before, Josh, where there have been times where we have wanted or thought about putting into coverage criteria, um, as a condition, um, that you need to have, um, tried something else um, uh, before going to a specific treatment, and then wondering if that other thing that we have required is covered, um, uh, is a covered, uh, you know, treatment. So for as an example, not saying that this is what we would do, but if we were to say that you must be seen by a lactation consultant or have those services, but yet those services are not available or covered, um, how does that how does that work? Um.

Josh Morse

Yeah, um, maybe Dr. Schultz can comment on, on that, Doctor, I'm looking at the recommendations that the AMDG, the AMDs put forward, which are very much aligned with what you're talking about, I think. So, Heather, can you speak to that?

Heather Schultz

Yes, I can speak to lactation services are, um, covered under the preventive benefit, um, for UMP. Um, I cannot say off the top of my head what the coverage is on the Medicaid side, and I don't know if Chris um, Chen is still on the call and knows the answer to that question? Is that helpful? Is that the, what you were looking for? Like, whether there's coverage for that? And I will also say, noting that any coverage that UMP or Apple Health is not going to pay, um, for a lactation specialist, right? Like, the reimbursement. The support for lactation specialists is not going to be able to come from any health plan reimbursing, there's gonna have to be decisions

made at the healthcare system level to prioritize things that aren't revenue generating, which is an entirely different discussion, um, but I think worth noting.

Christopher Chen

And sorry, Heather, this is Chris, I don't know the answer off the top of my head, but I can look into it during the meeting.

Josh Morse

Chris, I've reached out to Beth Tinker on that question, just FYI.

Christopher Chen

Okay.

Janna Friedly

The other Is there anybody that we have not heard, heard from on the committee?

Jonathan Sham

I spoke earlier, but again, I'm happy to give a little more granularity. Again, I'm leaning towards covered with conditions primarily because of the points I brought up previously of how hard it is to generate data in this space. You know, I just, I don't want to conflate um, the lack of evidence with the lack of efficacy in this particular situation, you know, it's really hard when you have like, something like 70% crossover with one arm to another in a trial to generate any effectiveness data, because just the nature of this disease, if you will. I mean, this is you're not going to have your kid not eat for 2 weeks, right? Like, you have to cross over, try something different. So, um, I think it might be helpful to bring up the slide with the AMDG recommendations as a basis for discussion, because they have, um, you know, three discrete coverage recommendations here, um, and it might be something more concrete for us to work off of.

Janna Friedly

Yeah, just in, um, taking the temperature, and maybe we can do sort of a straw poll, but I'm what I'm hearing from the discussion is that it seems that most people on the committee are leaning towards coverage with um, with conditions from what I'm what I'm hearing. Um, is that, maybe we can take a straw poll on that, is, is there anyone who is, um, leaning towards no coverage or cover completely with, without conditions.

Jonathan Sham

I mean, I'm certainly in line with the recommendations of no coverage for labial frenotomy given the discussion and evidence, but just to be clear of what we're talking about.

Janna Friedly

Sorry, I should clarify, for lingual, um, frenotomies, is let's stick with that. Is anyone, um, is anyone let's see how to phrase this, is anyone not leaning towards cover with conditions for lingual frenotomy?

Evan Oakes

I'm still right in the middle.

Janna Friedly

Okay.

Evan Oakes

So, just, I mean, I'm leaning towards I appreciated those comments, Dr. Sham, um, but those that's where I am. I still would have that on the table, not coverage, just based on the evidence we're looking at, but I'm really I'm kind of leaning the other way, for sure.

Janna Friedly

Yeah.

Evan Oakes

Just to share.

Janna Friedly

Okay.

Melanie Golob

Janna, we have a straw poll. If you want to kind of take the temperature of um, coverage, separated by lingual and labial frenotomy.

Janna Friedly

Sure, why don't we, why don't we just go, go ahead and do that formally, then?

Melanie Golob

Okay. Oh, and then, uh, discussion about special populations, probably, before you do that if you want. Yeah.

Janna Friedly

Yeah, I'm not sure that this really applies in this case.

Melanie Golob

Because, yeah, that makes sense. Okay. That was just kind of the logic for coverage, as a reminder.

Charlotte Lewis

I think age could be, could be a factor to consider. Um, I, I think people seek frenotomies after the age that you might expect them for, for, to, um, facilitate improve breastfeeding, because of some of the things that they have read about on social media. So, in my mind, like, I only offer this procedure up to about 5 months of age. Um But if you're seeking this procedure for a 9-month-old or a 12-month-old. First of all. I wouldn't do it, but they would do it in the operating room at Children's. Um, and then that just adds all these other sort of components to it, you know, and other risks and things like that, um, so I think we should think a little bit about age. Um in my mind, the older the child is, the less likely it's going to be helpful with breastfeeding.

Janna Friedly

In the, can you remind us, in the studies, were there um, age?

Charlotte Lewis

What I saw was under a year, but I mean, I think even a 3- or 4-month-old, it's a very different procedure, I'll just say, when you do it on a 3- or 4-month-old compared to, like, a 3-day-old. It's like, in terms of the amount of distress it causes the child, and the length of the recovery, um, and the, the likelihood that they're going to go on, like, a feeding strike, or, you know, have these other kind of complications is really different, just if you're separated this by, you know, a few months, because For everyone who's familiar with kids and how they develop, it's just when you're a newly born baby and you get this done, sometimes you sleep through it. I mean, that doesn't happen super often, but it's a very different procedure than if you're doing it, for example, on a 3- or 4-month-old, or it's just much more likely that you're going to have a prolonged recovery that's going to require analgesia, that's going to require, you know, adjusting how you're feeding the child and things like that.

Jonathan Sham

Yeah, um, just for the studies, at least the three that did show, obviously. Um, one was less than 10 weeks, the other one infants after 10 weeks was one, um the other median age is 39 days. Um, and the other just says infants. It doesn't specify. Um But yeah, pretty much less than a year for this data.

Janna Friedly

Dr. Schultz?

Heather Schultz

I was actually gonna, I was just gonna say the same thing. I was just gonna note that the three studies that um, favored frenotomy just as Dr. Sham just pointed out, did look at, um, as would be expected, the younger age range.

Janna Friedly

But they're, um was there, uh, trying to see what the, if there was a specific um, natural cutoff age that

Jonathan Sham

One of them limited at 10 weeks, is that you had to be less than 10 weeks. Um the other one, it just reports the median age of 39 days. I don't, it doesn't give a cutoff here, but um it may be hidden somewhere in the paper.

Charlotte Lewis

Not that I want people to do more data analysis, but I would be very curious to see, sort of, what those ages were. um, for the claims data that was initially reported. Was that, was that a limited group, like, they only looked at kids that were under a year of age, or?

Heather Schultz

Yeah, are you referring to the like, that first slide that I had of the that was in the AAP?

Charlotte Lewis

Yeah.

Heather Schultz

Yeah, I mean, I would assume that those were all very young infants, because it was um, inpatient database,

Charlotte Lewis

Oh, yeah.

Heather Schultz

So it wasn't looking at outpatient, so it would be capturing those newborns during their hospital stay, birth hospital stay.

Charlotte Lewis

Right, right. And I mean, at least in Washington State, or at least at the UW, I guess that's the only place I could really speak to, that's a relatively unusual thing, that we would do it in the hospital. Um, what I meant, though, was, like, the data from Apple Health and the data from Uniform Medical, I'm curious.

Heather Schultz

Yes, we looked up, we looked up to a year.

Charlotte Lewis

Okay. I wish, I wish I knew kind of what some of the ages were there.

Heather Schultz

Right? We did too.

Charlotte Lewis

but It's okay.

Heather Schultz

Yep, we were also, we didn't have the ability to shrink it anymore.

Charlotte Lewis

Yeah, no worries.

Jonathan Sham

I just found out that the median was 11 days for the final paper for intervention.

Janna Friedly

So, definitely less than 3 months for all three. Okay, let's move on to the straw poll.

Val Hamann

Again, if you can jump over to TT poll, um, you may have to sign in again if it has uh, lapsed. And waiting on one more response. And we'll go on to labial.

Janna Friedly

Okay, great, thank you. So let's, um, let's, uh, could you go ahead and pers, um, show the screen with the agency medical director's, um, recommendations for the coverage conditions.

Josh Morse

Uh, Melanie, would you like me to do that?

Melanie Golob

Uh, yeah, do you want to do, um, like you do with the Word document? Uh, just using what the AMD recommendations were, we can start that use that to start. Yeah. Thanks.

Josh Morse

Yeah, it's got some formatting issues, but these are taken from the agency medical director presentation.

Jonathan Sham

Gotta ask a question, um perhaps to I don't know, Chris or, um Heather, with this first potential condition of lactation support. Um, is that, could that be sufficiently vague, such that that support could be provided by, I guess an OBGYN, uh, or some other physician, and not necessarily being separately evaluated by a lactation specialist, per se, like, at an outpatient visit, if that's not available to them. Could it be interpreted that way, or were you really they need to see a specific?

Heather Schultz

Yeah, I don't think, yeah. I hear your concern, and the rest of the committee's concern with, like, a decreasing work supply of lactation consultants. Um, making that a hurdle, um, doesn't seem

reasonable. So, um, yes, that we could absolutely implement this without a requirement that a lactation consultant is involved. Um. Yeah.

Jonathan Sham

I don't know if there's, like, a written rule, like, how it's implemented, and obviously that gets into the weeds, but, but I presume, and maybe Dr. Occhino can correct me that obstetricians could potentially give some sort of, some level of, uh support or guidance, um that could qualify for that first bullet point if they couldn't necessarily get into, uh separate, uh, specialists for the purpose of this decision.

Amy Occhino

Yeah, yes, that's true, and, and, you know, I think that someone who takes care of newborns who is a provider of newborns. That is quite a large group of people. They are advanced nurse practitioners, um, pediatricians, family practice providers, even OBGYNs, because we see people back in the office a couple of days after delivery because we're evaluating the mother. So I think as long as we keep that third bullet point of having the expertise of someone who is you know, proficient with newborns being part of that referral process, I think that that is going to help quite a bit. And then, um, yeah, that I don't know, what do you think, Dr. Lewis?

Charlotte Lewis

Um, well, given that, I agree with what you said, but, um I wouldn't want, for example, an obstetrician who is sometimes considered a primary care provider, but I think, like, for example, my colleagues in MFM wouldn't necessarily think of themselves in that way, that, that I wouldn't necessarily want to limit it if somebody who wasn't necessarily considering themselves a primary care provider felt like it was indicated. I don't know if that makes sense. Like, are we limiting ourselves too much by saying primary care provider? Could we say, performed or referred by a by, um clinician, or um, healthcare provider, I, I'm not sure, but I just wouldn't want that to be, um, something That we kind of excluded people who really could be qualified.

Amy Occhino

What.

Janna Friedly

I think the concern is that you that I heard was that you wanted to make sure that it wasn't a dental you know, just a dental provider that would seem. Right? Wasn't that the concern?

Charlotte Lewis

Yeah, yeah, no, that's another really important point. And, you know, I will say that there's some dentist in the Seattle area who have really made this their entire focus of their of their career. Um, and they have tried to build sort of a support system there that includes other things, like lactation support and things like that. Um So, yeah. I think the public comment is gonna raise some additional issues once people review it. Um, but yeah, I, I do think somebody I'm not sure exactly how to say it, but yeah, I do think that Somebody with expertise caring for, you know newborns who understands. Um, yeah, I maybe I wouldn't go any farther than that, but yeah. I'm not exactly sure how to say it, to be honest.

Janna Friedly

Dr. Schultz?

Heather Schultz

Yeah, I don't know if that third bullet point is worded in the best way it could be worded, but what our group was getting at was just making sure that there is someone who is able to follow up on that baby, right? Like, when you think of, sure, a dentist can do a frenotomy, but is the dentist going obviously, the dentist is not going to be the provider who is able to then do weight checks for that baby, or see how things are going. So that's the piece that we were we wanted to make sure that someone who is going to ultimately be responsible for the follow-up of that baby, and the ongoing medical care of that baby is involved.

Janna Friedly

Yeah

Charlotte Lewis

And I think right now. I think.

Janna Friedly

Mm-hmm. Is the role of a primary care provider. I mean, that really is the role I mean, to me, it seems like the newborn um, really needs a primary care provider, um.

Charlotte Lewis

Right. Right now, though, I'll say that, um, it is kind of like, to use the expression somebody else used, kind of like the Wild West out there. You don't need a referral to come to see me, you don't need a referral to go see um, a dentist, as far as I can tell. So what comes through on

social media, um is that pediatricians don't know what we're talking about. We don't recognize ankyloglossia the way that dentists do, and thus you shouldn't trust your pediatrician to assess this, because we don't know what we're talking about, but dentists do, and so that's why you should pursue this with a dentist without going through your pediatrician, because we don't understand what ankyloglossia really is, kind of thing.

Clint Daniels

Should we change primary care to medical provider with expertise in caring for newborns? Would that fix it? And then even the clinical practice guidelines, the dentistry one recommends a team-based approach as well. Um, so I think that's important to note.

Charlotte Lewis

I think in an ideal world. That a team-based approach is how it should, it should be, and, like. You know, I think a lot about that study that came out of New Zealand, you know, when New Zealand felt like they were when you have a single-payer healthcare system, and you're feeling like this is being overdone, you know, and that was kind of the approach that they ended up taking, an part of the reason I like that Tabby score is because that's what they ended up using, is, like, the score of 4 or less, um, but they also had a team-based approach where they had lactation and they had feeding therapy, um, and I think that is what's really needed. To be able to, um do the right thing for babies and for moms. But I think we face this sort of limitation in available resources.

Evan Oakes

Yeah, I have a question. How, um I think this, um, the sentiment of this makes a ton of sense. I'm curious from our HCA colleagues, how the heck do you identify or define expertise or primary care. That's what I think the discussion is right now, and I, I don't know how the heck you do that. Like, what do you do on the coverage side to just say, this person does meet that criteria? That seems to be something we need to understand if we're gonna put a condition in place around that.

Heather Schultz

Yeah.

Charlotte Lewis

I don't think you really can. I think you probably, you probably, um the best you could probably do, um, even though I think there is some real shortcomings in terms of pediatrician and family physicians capability to evaluate how breastfeeding is going, to evaluate how infants, newly

born babies are feeding. Um, we rely a lot on colleagues, like in lactation, to inform us, because it's not a huge part of our training. And just as an aside, I think one of the other really sad things about this elimination of lactation support in the outpatient setting is that's limiting trainees' exposure to lactation and their ability to develop an expertise there. Um, but I think the best that you could probably do is somebody who um, it has experience and expertise in caring for newborns.

Heather Schultz

I wanted to clarify whether your question is around the lactation support piece of the bullet point, like, who do we who are we saying is okay to provide that lactation support if it's not a lactation consultant? Or are you getting at the who has expertise in caring for newborns?

Evan Oakes

Um, yeah. Yeah, I'm looking at bullet 3, performed or referred by a primary care provider, which is not a credential. Um, with expertise caring for newborns, and listening to the conversation about the importance of team-based care and, and the fact that it's a true primary care person and, um, you know, so how do you at the HCA sort of say, this person meets that criteria? And one way would be to say a lactation specialist, because that, I assume, is either a credential or a specific certificate or training of sorts, which I don't know that much about, but on the details of. Um, so that's what I'm wondering. Yeah.

Heather Schultz

Yeah, and it would, it would likely be attestation-based. And then the way that we get at that is if we have additional concerns, we audit and see.

Evan Oakes

Okay.

Heather Schultz

What is actually being done. I think we would be concerned about it I mean, my concern, at least, about like I said, that third bullet point was really about the follow-up care, um, because you could picture a scenario where you have a dentist and a lactation consultant just doing their own thing off to the side um, and you still don't have that person who is ultimately responsible for taking care of the newborn. Um.

Evan Oakes

I'll just Heather, sorry to interrupt.

Heather Schultz

Oh no go.

Evan Oakes

I didn't want to lose it. I think the other thing so, just to share with the committee, I just and this is totally anecdotal, but when, when all the work was going on around the patient-centered medical home, how many different specialties spoke up and said, we're a patient-centered medical home. And it included, you know, eye doctors.

Heather Schultz

Yeah.

Evan Oakes

So I think that's where we need to be a little bit cautious about what that means, but I'm appreciating what you're saying there, Heather. Thank you. I think that sounds, you know, that makes sense that you have a I'm just glad to know you have a process for that. But I those are the kinds of things that worry me when we, when I hear how important it is to have team-based care and follow-up, and that kind of thing, then how do you then translate that into actually happening by us putting a condition on this?

Janna Friedly

Yeah, because and I agree, as worded here, really, anyone could say that they qualify. Anyone doing these procedures could say that they qualify as someone who, um, is a provider with expertise caring for newborns. I think that's, that's a very vague statement that doesn't really limit it, I think, in the way that you are trying to achieve this ongoing care um, in a team-based approach.

Charlotte Lewis

And even though I would say that I do get referrals directly referrals, meaning, like, someone gave a family my name from lactation consultants, I think if you really spoke to lactation consultants, they're pretty clear that they're not supposed to be making diagnoses um, so, even though they do, um, that they, they do understand that that's not within their scope and there are limitations to who can perform this procedure I'm not really sure how it works outside of the UW, since that's the only place I've ever worked, but you have to be you have to have privileges to do this procedure, and you have to prove that prove that you've done enough. Um, and that you're competent in it. But that, you know, that's more likely to be, like, in an academic

setting. It also happens at Children's, that you have to have the privileges to do the procedure, just like if you were doing CERCs or something. It's not something that a lactation consultant who is an RN, that's the most common other, um, credential that they have couldn't do this procedure, but a nurse practitioner or a PA, Um, uh, who is also a lactation consultant, or also has a special interest in lactation could do this, could do this procedure.

Josh Morse

In lactation, uh, some information I received from one of our colleagues who's not here is that lactation consultants are not regulated in Washington, they don't have a DOH credential, um, that has, she pointed out that has been debated. There was a what's called a sunrise review done by Department of Health Um, so they're not separately payable, uh, at least by Apple Health, um in the outpatient setting.

Charlotte Lewis

Yeah. And I think there's been I think there's been, uh, legislation uh, that's been proposed. I don't know all of the details, but I don't think it's made it to whatever that final stage is where it gets voted on. Um, yeah, I think that's I think that's been something that people have been looking for in the state, because of this, this issue where, um they can't generate adequate income to justify in a very narrow closed-minded perspective, um, their existence.

Jonathan Sham

So, I guess my question then, um just to complete Evan's thought, is um, as worded, this expertise in caring for newborns, is that implementable from the HCA perspective? I think we're all leaning towards. I feel like we get what that's trying to say. Um, does that communicate what it needs to communicate uh, to the HCA, and is that language you could actually implement in policy and practice?

Heather Schultz

I think it might be helpful to have some language that's not currently in that bullet point getting at the longitudinal piece of this, right? Because as people are noting, anyone could theoretically say they had expertise in caring for newborns. Um, but the piece that, that everyone cannot say is, I have a longitudinal relationship in which I'm following this infant, um, for their ongoing care. So, maybe language that gets at that would close that potential loophole.

Jonathan Sham

I see Dr. Lewis nodding. Is there a number of visits that you'd propose, or some other way to define longitudinal relationship.

Heather Schultz

I don't know that it needs to be that's specific. Um

Charlotte Lewis

Yeah, I would agree.

Janna Friedly

Could you just say, referred by a primary care provider? Uh, well, that's saying providing twice, but a primary a clinician, uh, providing ongoing care.

Charlotte Lewis

Something like that, I think.

Janna Friedly

For punishment with expertise caring for newborns, providing ongoing care for That's, that needs to be reworded, but. And then we had talked about the age as well, I think. Were we thinking about adding less than 3 months of age? Infants?

Jonathan Sham

Looks like Dr. Lewis has some thoughts on that, it looks like on that

Janna Friedly

What's your preference?

Jonathan Sham

Yeah, you're muted.

Janna Friedly

Yeah, I'm It's hard to come up with a cutoff other than what the evidence.

Charlotte Lewis

Sorry, I'm a little loath to kind of establish an age, because you know, we have issues with babies that are coming premature you know, and that maybe they're born at 25 weeks or something, and then I might consider, for example, oh, their corrected age is just one month, but they're really 5 months old, or something like that. Um. I guess my It would it's any baby who's older, who comes to see me, I really question like, are we really doing this for breastfeeding? And

that's what I say to families. The reason we're doing this is to improve your breastfeeding experience to allow your baby to more effectively breastfeed, to transfer milk better, or have better latch, all these kinds of things and if you're coming to see me at 6 months of age, you know, and you're already breastfeeding, or you're bottle feeding exclusively, I think it just becomes, like, a sort of a different situation where you're not doing it for that reason for breastfeeding, so I don't know, I don't know now whether I would really say a specific age, but maybe if we're just this restricting this to just for, um, promotion of or improvement of breastfeeding, supportive breastfeeding, like you guys said.

Laurie Mischley

I'll just add, there wasn't any evidence that this it wouldn't be an evidence-based decision to just arbitrarily pick an age. I like the idea of, of not making up what we think is a cutoff, we don't have data that says there's a cutoff where this stops, is more effective before this age and less effective after that.

Jonathan Sham

I mean, I agree with that. In general, we got all of our all of the data that did show a difference was less than 10 weeks. Um, again, it wasn't exclusionary in two of the three trials, but it's just, that's where the data exists. So, I mean, to play devil's advocate, if you had, like, a 5-year-old come in, like, that would just be crazy. We would never think that's right. So, I don't think it's, it's wrong to consider age, necessarily.

Laurie Mischley

Would we include corrected, then, for premature babies?

John Bramhall

I mean, I think it's again, the data we'd be putting a number out of the air, it sounds like, and, you know, we don't want to do that. So, it seems to me like the insistence on this being a procedure that requires a referral from someone who knows what they're talking about, that's not the language we use, but that's what we're thinking. It sort of encapsulates that age issue to, to me. I mean, if we are putting reliance on the referral pathway as involving someone who is knowledgeable uh, and responsible, then you know, in a way, who are we to say what age the cutoff should be? It's something we could probably implicitly accept is, is correct, coming from the referral pathway that we're insisting on. That's what it seems to me. The points of the referral.

Jonathan Sham

I mean, also the indication for breastfeeding will certainly define and aid implicitly.

John Bramhall

Yeah, yeah, exactly. Yeah, well, Judy Caesar breastfed till 7 or something?

Josh Morse

I think the um, maybe Jennifer can comment, but I think the scope of the review also went only goes to one year, I believe?

Jennifer Middleton

Um, yes, and so we, at one point, discussed, we consider a younger age, and the reason we said it's 12 months is because, um, the Academy of Pediatrics recommends breastfeeding up. So that's the only the main reason we went up to you know, 12 months, 1 year, so if that means anything. We didn't want we want to be inclusive.

Evan Oakes

I appreciated those comments, Dr. Bramhall and Dr. Sham. I, the age thing did I'm sorry if I missed it, but the one thing I was thinking is that if we're making these recommendations based primarily on I don't know, the benefit of those three randomized controlled trials, then I was appreciating the earlier, you know, sort of looking at the ages and that is all. And then it's not quite as random, it's some number that is based on, or there's a logic around that. So that's what one of the things I was wondering, and then I was trying to I would want to respect that, the comments about, you know, gosh, are you going to do this on a 9-month-old or not? And is that safe and different, or do we need to know more about that to allow for that? You know, that kind of a thing. So I just was, um, wondering if there wasn't an actual way that we could have a logic around a younger age.

Jennifer Middleton

Oh, and one more thing, um, we also excluded premature infants, so that's another thing to consider. None of the evidence included.

Evan Oakes

Oh, interesting.

Jennifer Middleton

Preemies.

Janna Friedly

Well, so just going back to that point, the data that Dr. Sham the ages were from those trials. So, that's where we came up with the essentially 10 weeks, or 3 months, um, was, was from those three positive trials.

Clint Daniels

Were studies all outpatient, as well? I thought I heard Dr. Lewis said that as the baby gets older, but they might have to be admitted for the procedure, or maybe I misheard that?

Charlotte Lewis

I think if, um uh, I don't, I don't know how things work outside of the UW and Children's um, any child that's over 6 months who is judged to need this procedure for whatever reason, um would receive anesthesia in the operating room. It could be a same-day procedure. Um, but that is what happens at Children's, in part because it's much harder to get adequate analgesia um, and to have an immobile patient, um, that you feel safe doing a procedure on.

So, any, like, small sort of operative, relatively small operative procedure in, in infants. Um, typically requires you know, going to the operating room for something like this.

Clint Daniels

Is that a potential?

Charlotte Lewis

I'm sorry, I didn't

Clint Daniels

Is that a potential limiting condition we can, it has to be an outpatient. I said, uh, sorry, is that a potential limiting condition we could use, then? Like, it's gotta be you know, our scope is the outpatient, because all the studies were presumably in the outpatient you know, that first 10 weeks that showed benefit.

Charlotte Lewis

So, in my own experience, so I'm, I'm pretty much the one who does all the frenotomies on inpatients at the UW. Um, I do some of them at Children's. Um, there are occasions when I um,

do this procedure on a newly born baby who, um, who is still an inpatient. And it's like, you know, one of those for not one of those ankyloglossia situations that's similar to that initial slide that was shown the pre-op, kind of ankyloglossia, where it's all the way at the tip, the mom can't sustain a good latch, there's significant pain. The caveat is, though, that there's a lot of other things that cause pain and breastfeeding difficulty in those first few days. So if I saw that really significant tongue tie with, like, and I gave it a Tabby score of a 1 or something you know, that's a that's and the lactation consultants came to me and said, this baby cannot latch, you know, I that's a baby that I would do a procedure on in an inpatient. It seems like from that slide that those inpatient procedures have really taken off, but I don't know what happens in the rest, the rest of the country when people are seeing, um ankyloglossia, whether they're just saying, oh, we should just do that here in the hospital.

Jonathan Sham

I would advocate for not getting into the weeds of the practice setting where this is performed.

Charlotte Lewis

Yeah, me too.

Clint Daniels

I agree. Yeah, thanks for that.

Jonathan Sham

I think we get we get what we want. By those other conditions that we've already listed, in my opinion.

Janna Friedly

Yeah, so I, I think it's it sounds like the that we're still a little bit stuck on um, the age. Did we have we come to a consensus about whether or not to include age?

Laurie Mischley

I like the idea of trusting the referring provider to make the decision if we are past the point of where it is likely to help.

Charlotte Lewis

I agree.

Washington State Health Care Authority

Tony Yen

I agree. We should just keep the age out of it.

Jonathan Sham

And, like, again, realistically, again, the first bullet is you have to have symptomatic ankyloglossia, so, like, um or I guess, I guess, breastfeeding problems. Is there even a situation where you'd have a 6-month-old who, like, couldn't have breastfed for the first 6 months of life within could theoretically even have be treated at that point, and then start again? I'm just like, it may be a problem we're trying to solve that doesn't actually exist, you know?

Charlotte Lewis

It exists, but it's rare.

Janna Friedly

Okay, so it sounds like we should put that to rest then? Okay. Are we comfortable with this wording? Any, any other changes to the wording right now of these conditions? Um should we so, at this, this point, I think we're the next step would be to take a vote? Um, do we want to, Do we want to go ahead and take final votes on these, um, decisions now, or do you want to take a break?

Josh Morse

Can I just clarify? These are 3 conditions, right? So, should this read when the following conditions are met, or something similar? These are 3 these are ANDs, right? Thank you.

Janna Friedly

These are ands. Yes, thank you. When the following conditions are met. Josh, do you have a suggestion? Should we, do you want to, should we, um take a take a short break before?

Josh Morse

I'm supportive of a whatever you want to take, 5-minute break, 10-minute break, um, Melanie, does that align with, uh processes on our slides? Are we ready? Or is there a step where yeah?

Melanie Golob

I think we're ready to, to do the final vote for draft coverage.

Washington State Health Care Authority

Janna Friedly

Okay, why don't, why don't we take a short 10-minute break, and then we'll come back and do the final votes.

Josh Morse

Sounds good. I'll leave this on the screen so people can see it.

Janna Friedly

Okay, great.

Josh Morse

Thank you.

Janna Friedly

Okay, I'm starting to get folks back. Um, let's see, I think we have everyone, everyone back that I can see. Okay. So um, I think it's time to get our polls back up.

Val Hamann

Great, and that first poll is live. We're waiting on one more response.

Amy Occhino

You're waiting on me, I'm sorry, I'm gonna be one more minute.

Val Hamann

No problem. And we'll move on to labial

Janna Friedly

Okay, great. Um, so cover, cover with conditions, uh, for lingual, um, and not covered for um, labial.

Val Hamann

Correct.

Janna Friedly

Uh, with the wording, uh, that we reviewed. Covered conditions.

Val Hamann

Correct.

Janna Friedly

Okay. Um, and, uh, so next, um, is whether this is in alignment with Medicare guidelines. There, there is no, um relevant, um national coverage decision for Medicare. Um, we've reviewed the, um clinical guidelines, um, various clinical guidelines that are, um, pretty consistent that there's, um, uh, some indications for frenotomy, but recognition of very limited, uh, evidence, um, from, uh, various, uh, different organizations um, and uh and then we also did review other, um insurers, uh, as well. Um, and in general, I think our, our, uh, decision is in line, uh, with, uh, with other insurers, uh, and guidelines. Okay, um, Josh, what is, what is next?

Josh Morse

Um, I believe we've reached the end of our agenda. Thank you, everyone. Appreciate your work today.

Janna Friedly

Okay. Yes, thank you, thank you, everyone. I think that, uh, that, uh, ends, ends the meeting for today. We were very efficient today.

Evan Oakes

To our experts and our reviews from the medical directors, everybody. Thank you.

Tony Yen

Thank you.

Janna Friedly

Yes, thank you very much, Dr. Lewis. We really, really appreciate your input. It was incredibly helpful, um, today. Um, so I hope everyone has a very nice and safe weekend, and we'll see you in July.

Josh Morse

Thank you, thanks Janna.

Charlotte Lewis

Thanks everybody.

Washington State Health Care Authority

Janna Friedly

Bye-bye.