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Health Technology Clinical Committee Public Meeting

March 17, 2017

Chris Standaert: Alright. We're going to get started. We're waiting for our evidence vendor. So, hopefully, they will show up before we get too far along. Much of what we do initially at least doesn't have to do with our current topic.

So, just for clarification and introductions for people on the phone or elsewhere. So, this is Chris Standaert. I'm the chair of the committee. We're gonna call the meeting to order. This is the meeting of the Washington State Health Technology Clinical Committee from Friday, March 17th, 2017. The agenda is in front of you, and the meeting has been published online for anyone else who is interested or is listening.

This committee is an evidence-based decision-making body. We follow this evidence-based decision process, and we are charged with three things, essentially. We are charged with making sure that health technologies utilized within Washington State are judged based on safety, efficacy, and cost. Our decision is to look through the data presented to us on the technology in question and decide the best policy for utilization or not of that procedure, based on the evidence. We have the committee group, itself. We have Dr. Michael Chang as our clinical expert. Dr. Chang has many years of experience with this particular procedure. He is a physiatrist, formerly at the University of Washington but in private practice in Bellevue now, and we are happy to have him.

We will start with our meeting. So, first Josh, program updates?

Josh Morse: Thanks, Chris. Very briefly here, today's topic is extracorporeal shockwave therapy review. In May, we have a two-topic meeting, and we are scheduled for a review of the treatment of chronic migraine and chronic tension type headaches, as well as a review of treatments for varicose veins. We will have the followup meeting from the May meeting on July 14th, and that'll be a phone webinar meeting to take action on the May 19th determinations. Then, right now, we have scheduled in November a review of computer-aided detection for mammograms. The skin substitute's review we initiated and have withdrawn. So, we will not be holding that one in November. We do have other topics proposed that may soon be available to put in the pipeline. We have to go through a couple of comment periods and see if that changes. Those have not yet been released, but it's conceivable that one of those topics could go into the November meeting.

Thusfar, this year, these are the topics that you have reviewed and will review going forward. So, today, the conclusion of the artificial disc replacement, review of the draft and the comments, the first step of the review for extracorporeal shockwave therapy, and then again, those two topics in May and the one topic, now, for November that is scheduled. So, if you have any questions for me, please let me know. Thank you.

Chris Standaert: So, we also have the topic of pharmacogenomic testing, which we did last meeting, as well, it's just not on that list.

Josh Morse: My apologies.

Chris Standaert: No problem. So, the first step is to go through our minutes from the previous meeting, which, for the committee, are in your packet of information. If you all would take a few minutes to look at them. I did not see any corrections or concerns myself. I don't know if anyone else did. Where are the minutes? I don't have them in here. Oh, they're right there. OK. People need more time? Anybody have any questions or comments about the minutes? Once people are comfortable, I just need a motion to approve the minutes.

Gregory Brown: Move to approve.

Chris Standaert: Do we have a second?

- John Bramhall: Second.
- Chris Standaert: Do we have any questions or comments on the minutes? Anybody? No addendums? OK. So, all in favor of approving the minutes as is.
- Josh Morse: All approved.
- Chris Standaert: OK. And no disapprovals? Everybody raised their hand, I think, yeah? OK. So, our next step is to go through our findings and decisions from the last meeting, and we covered two things, pharmacogenomic testing for select conditions and artificial disc replacement. So, let's start with pharmacogenomic testing. We did receive two comments from the public. One supported our decision, which is appreciated.
- Joann Elmore: That's nice.
- Chris Standaert: That is nice. Yeah. So, one supported our decision, and one is from the state agencies, and Dr. Johnson, in particular, wanted us to specify in the document the actual conditions, because we just used the phrase 'selected conditions' and our whole discussion was based around the conditions that were part of the search and the key questions, which she listed in her letter to us, brief note to us, depression, mood disorder, psychosis, anxiety, ADHD, and substance abuse disorder. Just in the documentation, would clarify that those are the conditions to which our decision applies. I think that's quite reasonable. That should have been in the document, I would think. So, our decision was to not cover, a noncoverage decision for those . . . for pharmacogenomic testing. Anyone have any discussion about our decision, anybody have any questions, concerns they want to bring up? If not, then I just need a motion to approve our decision. Do we have a second? OK. All in favor of approving the decision we made at the last meeting regarding pharmacogenomic testing for noncoverage for the conditions, as defined.
- Josh Morse: Before I record this is that . . . that's with the addition of the selected . . .
- Chris Standaert: Say that at the end, for the condition, yeah, for the selected conditions that are defined.

Josh Morse: OK. All approve? Thank you.

Chris Standaert: OK. So, our second topic was artificial disc replacement, and we did receive comments on this, as well. I think we should address what the letter we received. It is a multi-society letter. It includes several practicing physicians in our state as signatories. It goes through several issues with our decision. I personally think we addressed a number of these at our meeting. From our standpoint, one of the concerns here, and they brought it up again for the lumbar fusion questions was, there was no need for a rereview at this time. That is not within our purview. We don't decide whether something gets reviewed again or not, and we don't determine that. We decide what is brought before us. So, from our standpoint, that's not something we can address. They made a comment about available registry data. I believe we had Dr. Shonnard here, and you all can correct me, but my understanding when Dr. Shonnard was here is that we asked him whether the data had been made publicly available and published, and it had not been. They were waiting until later this year for the data to be available, and then they would, in some form, make it publically available, but that data was not available in any manner that would show up in a search for the data. Therefore, we can't use it. Again, they had the opportunity to submit the data, if they wanted to, as part of the process of discovery for the topic, and they didn't. Maybe it was not ready to, but that's OK, and we certainly can't hold our decision for nine months waiting for the promise of someone to release additional data. So, if that data gets released, and if it is deemed substantive in a way that might change the decision, it can be rereviewed yet again, I would assume. Yes, Josh?

Josh Morse: Yes.

Chris Standaert: So, if they release it, and they publish it, it becomes part of the peer review literature, and then it can, and if it changes, potentially changes the thought process, they can be rereviewed one more time.

Josh Morse: That's right.

Chris Standaert: So, I don't . . . there's no . . . I don't . . . there . . . the comment that we are disregarding it, I think, is inaccurate, myself. The next statement had to do with lack of

nonoperative outcomes data. Again, what we had are data on studies that had a nonoperative treatment arm is what we looked at. Whether they are in, you know, saying they're in Europe and they don't apply, I'm not totally sure I understand that, but that's the data we had. And we had a clinical expert here, and we asked about additional data in some other format that wasn't available. So, I'm not quite sure what's on, you know, we have what we have, and we used the data that was available to us, as far as I'm concerned. Those seem to be the majority of their concerns. Anybody else have any questions, comments, or thoughts on this?

Kevin Walsh: It feels to me like they have process issues, issues with the process. The process that . . . I think the process that this committee follows has been publicized for a long time, and it's now new, and it's not different, and I don't understand the issues that they bring up.

Chris Standaert: Carson?

Carson Odegard: When we discuss these types of letters in our meeting, it becomes public knowledge, and do we, besides including that in our minutes or whatever, do we make any formal replies to these types of letters from our discussions, or do we just discuss it at . . . because I don't remember doing any reply to . . .

Chris Standaert: At the committee level, we don't . . .

Carson Odegard: Yeah.

Chris Standaert: . . . formulate a response. A number of organizations and individuals will communicate with Josh and the program, but that's not our job as committee members to engage in that, particularly.

Carson Odegard: OK.

Gregory Brown: My understanding, Carson, is that we review our comments, and if we failed to follow our process in some way and find their argument compelling, then we would potentially change our decision here today, but short of finding any compelling argument that we didn't follow our

process, you know, our response is vote for approving it, I think.

Chris Standaert: I mean, it's a . . . this is a public process, right? So, everything we do is open to the public and, as Kevin said, it is clearly evident how the process works and what the timelines are, and when data can be submitted, and how you do that, and the process gets . . . the state has had it audited and rereviewed and discussed a couple of times already and will do that on an ongoing basis, and I think it is our obligation to look at, acknowledge, and consider comments from the public to us about our decisions, which is the point of this discussion, but that's our obligation, really.

Josh Morse: In your decision document, which is . . . you don't have the tail end of your decision document for the artificial disc discussion, but if you were to look towards the back of your binder, you'll see the one prepped for today's topic. You'll see that the followup questions that the committee has included in its deliberations from the draft comment are, based on the comment was evidence overlooked in the process that should be considered, and it sounds like you've addressed that question. Do the proposed findings and decision document clearly convey the intended coverage determination? These are the areas for consideration. Our process issues the program can respond . . . I can respond to those questions.

Chris Standaert: And they did send a similar letter regarding the lumbar fusion decision, but that decision has been finalized already, and we've been through some of the issues and discussions regarding that. Questions or comments?

Josh Morse: So, there were two other comments.

Chris Standaert: Oh, wait. Two other comments. Where are they? So, there were two. Sorry.

Josh Morse: Dr. Carpenter is the first comment in front of that one. We should probably color code these.

Joann Elmore: It's an email from Clyde and Patty Carpenter, Clyde Carpenter.

- Chris Standaert: So, Dr. Carpenter wrote a letter regarding his personal use and experience with the technology.
- Gregory Brown: I would actually go back to our previous letter. I would make one comment from Dr. Chapman that he is a board member at large for the Washington State Orthopedic Association, as vice president for that association, I remember no conversation within our board to whether to sign onto this letter or not. So, I would suggest that he's signing on as an individual, not as representing the Washington State Orthopedic Association.
- Chris Standaert: Dr. Carpenter's letter expresses his use of the procedure but does not necessarily present us with any new or additional data or process concerns, and it does not particularly narrow down what he terms are very narrow indications for artificial disc replacement. Certainly, our . . . the surgical community at large who wrote to us was more in concordance with our decision on cervical disc replacement, as Dr. Carpenter appears to be. There's another letter?
- Josh Morse: Go back two pages.
- Chris Standaert: Go to this tab.
- Josh Morse: Go to the next tab.
- Chris Standaert: That's why I couldn't find it. It's at the end.
- Gary Franklin: Can I make a comment?
- Chris Standaert: Yeah.
- Gary Franklin: So, the agency medical directors discussed this a little bit. I just wanted to let you know that we discussed it, which is . . . both Dr. Oskouian who sat at the table here and Dr. Chapman and several others who came sort of downplayed their conflicts of interest, very, very substantial conflicts of interest. I just think . . . and we've been talking about kind of a better way to gather that information when people come and talk to you or join you at the table.
- John Bramhall: These letters become part of the public record, subsequently?

Chris Standaert: They do, yeah. So, now we have a letter from Dr. Franklin regarding our language. Way at the end, right after the agency presentation. No, right after . . . so, the presentation is from the public.

Joann Elmore: Right before the divider at the end after all his slides.

Chris Standaert: So, he asked for a couple of changes in language. We said patients must have advanced . . . this is regarding cervical artificial disc. We said patients must have advanced imaging or clinical evidence of corresponding nerve root in spinal cord compression, and he thinks that should be an and, which I think is probably correct. We're talking about the correlation of imaging to clinical findings being the requisite criteria there. To make them correlate, I think there should be an and there. For the second part, though, he is suggesting taking out the phrase spinal cord compression and just leaving the word myelopathy. So, changing it from a two-level procedure objective . . . radiculopathy, myelopathy, or spinal cord compression at two consecutive levels is what we wrote. Gary, my only comment would be that myelopathy, there's a clinical diagnosis of myelopathy, which is hyperreflexia and spasticity and all that sort of thing, and you can have a clinical myelopathy without abnormalities in the cord that you can perceive on imaging, and you can also have abnormalities on imaging in the cord where it isn't being compressed, and the word myelopathy versus myelomalacia as an imaging finding, myelopathy isn't an imaging diagnosis. That's not the term they use in radiology. They use myelomalacia for cord signal change, maybe edema, maybe compression or something else. So, I don't know. I'm not in favor of . . .

Gary Franklin: I agree with that. I think the first thing is more important.

Chris Standaert: Yeah. I agree with you. I think the and is important. I personally think we should leave myelopathy or cord compression.

Gregory Brown: At least for lumbar, you're dealing below the cauda equina. So, it's really not a cord compression issue for the lumbar issues, right?

Chris Standaert: No, but we only covered disc, because . . .

- Gregory Brown: Yeah. Yeah. No. Yeah.
- Chris Standaert: The indication for surgery really is two-level involvement of some way that can be well documented. So, then I would change, I would see that we would change the word or to and in that first sentence, which I think is appropriate. Questions or comments otherwise? If no more, a motion to approve our decision.
- Gregory Brown: Do we want to add advanced there also then?
- Chris Standaert: We have advanced. Patients must have advanced imaging or clinical evidence of. That's what I said.
- Gregory Brown: Following one or two-level, oh, OK.
- Chris Standaert: We have that word.
- Gregory Brown: I was just looking above where it says by patient findings and imaging, but OK.
- Chris Standaert: We're going to change it to patient must have advanced imaging and clinical evidence for corresponding nerve root and spinal cord compression. That being said, motion to approve?
- Gregory Brown: Motion.
- Chris Standaert: Second?
- Tony Yen: Second.
- Chris Standaert: All in favor of approving our decision regarding artificial disc replacement.
- Josh Morse: All approve.
- Chris Standaert: Alright. So, we move on to our topic, extracorporeal shockwave therapy for musculoskeletal conditions. Dr. Franklin, you're presenting this? So, we will start with the Washington State Agency Utilization and Outcomes presentation. Then, we'll have time for public comment for people in the room or on the phone. Then, we'll go through the evidence report with our evidence vendor.

Gary Franklin: OK. Thanks very much. I'm Gary Franklin. Dan Lessler and I are co-chairs of the Agency Medical Directors group. This is an interesting topic, because it is so heterogeneous, and the literature is extremely heterogeneous. I'm going to have to grab my slides, because I can't really see that well.

OK. So, the background of this is that I got to tell you, when . . . we've used electroshock therapy for renal stones for a long time, and at some point, maybe 15 or 20 years ago, somebody figured out that they could use it for some other stuff. L&I actually got wind of a van going around the state, driving up to primary care offices and blasting people's feet and shoulders and other parts for about \$3000. This is how this stuff first came to our attention. At that time, they were only doing, I think, plantar fasciitis and maybe shoulders or elbows. Now, they're doing all manner of stuff. These shockwaves are high amplitude pulses of mechanical energy. In 1980, the shockwaves were used clinically to break up urinary stones, and in the 90s, the effective treatment for calcific tendinopathy of shoulder was first published. Shortly thereafter, the FDA took a look at it and since then, there have been many studies.

On October of 2000, the FDA approved OssaTron, which was the first device approved for chronic plantar fasciitis in that case, and in 2003, they approved it for chronic lateral epicondylitis of the elbow. You all know that the FDA standards for devices is not the same standard for drugs. Drugs require really high quality randomized trials. In fact, two trials are required to approve a drug. The standard for devices is much lower than that for drugs. One of the problems is that there is no actual definite known therapeutic mechanism, biologic plausibility wise. The effects from direct forces and cavitation from indirect forces causing microfractures or hematoma formation or focal cell death simulating new tissue formation, I mean, there's a lot of words out there and many, many articles, as to why this might be helping inflammation, but to my mind, there's no clearcut biologic plausibility for this technology. Although the therapeutic mechanism for most of these conditions is not fully understood, the application has been expanding quite dramatically.

There are now many published studies, 72 are included in the evidence report, but is the evidence strong enough to

support shockwave therapy being an effective, safe, and cost-effective treatment alternative when, in fact, there are from almost all of these conditions, very effective other treatments and so that is really one question here is, given that there are other effective treatments, you know, how good is this evidence? How compelling is it to make a decision to cover it or not cover it? So, the scope is now, you know, patients with all manner of tendinopathies and tendonitis, heel spurs, shoulder calcific tendonitis, etc.

The agency medical directors group felt that the concerns were high for safety, high for efficacy. These are concerns. Medium to high for cost, although since we haven't really been covering it, we don't really have any information on costs, as far as what we're paying. So, normally we come here with pretty good information on what we pay for, but in this case, since it is not really being covered, we don't have any information for you.

The key questions are typical key questions. I'm not going to go over them again. The vendor will go over these in detail, but I do have some comments on sort of overall methodologic issues that I have from this body of work and reading some of the papers and reading the report. Number one, there is tremendous heterogeneity in the application of it, low versus high energy, etc. There's no standards on what kind of a dose or exactly where to put the shock therapy unit, the frequency and duration of pulses varies across studies. Oftentimes, local anesthetic is used, because it hurts to get, especially the high energy, but also the low energy is associated with pain. So, if you're injecting anesthetic, what's really getting better and from what? It may be difficult to define the focus of maximal tenderness in the tendon, like, where do you apply it. There's a great variety of comparators and outcome metrics, but my question is, what is the most relevant outcome for function for each condition? What thing can't you do the most if you have, say epicondylitis? What is it that is the hardest to do and for me, it was playing tennis, having grip strength. So, it wasn't like so much waking up in the morning with how much pain, or whatever. So, there's all manner of these kinds of outcomes for every one of these studies, but I think one question is, what is the most meaningful functional outcome, and I think my view is that when the meaningful functional outcomes were

looked at in these studies, they were mostly not impressive. There's a consistent difference in outcomes when you use proportions rather than mean change in scores, and that's another kind of methodologic issue that I had.

I think this study, which I had to go online to find this. It ended up in, I'm sure, one of the published studies. I'm not really sure which one, but this was the original FDA study that I found the report of on the FDA website. The reason I like this is, it looked at plantar fasciitis, 12-week outcomes. If you just looked at the VAS, the visual analog scale, there was some difference with more improvement in the shockwave therapy and 50% better thing under significance, that was moved there by mistake. So, really that was significant, but then if you start looking at sort of some combinations of pain things that a lot of pain people like, like did the pain get down under five or under four on a scale of one to ten? A lot of pain people think that getting it down under five or four is an important goal in any kind of pain treatment. That was not significant. Most importantly, walking without distance . . . the walking distance without pain or whether or not you needed pain medication was not even close to being significant. So, this was the original FDA study on which the FDA based its approval. Like I said before, the standard for the FDA to approve a device is not the same as it is to approve a drug. The other interesting thing on this study is that, and I think this is another theme that you see in some of the other studies is, the majority of the treatment effect observed was in the so-called blinded evaluators assessment of heel pain. So, that kind of implies that maybe the blinding is not so perfect in some of these studies.

Now, in terms of some of the active control studies I mentioned before that most of these conditions do have reasonable existing treatments, and in the plantar fasciitis studies, the pain and function outcomes were the same or worse for shockwave therapy compared to steroids, compared to PT stretching, compared to NSAIDS.

Now, I had to . . . I had never done this before, but I had to actually bring one of the studies, because I couldn't believe it. It's like a joke. So, this is the Ibrahim Study, and this study was done in this guy's office, and if you look at the picture in here about how he applied the extracorporeal shockwave therapy, he's got . . . one picture has him

shocking the foot without something over the foot. Then, he puts something on the foot and that's the sham. He's doing the shocking. So, although he says it's blinded or whatever, he comes up with findings that are dramatically improved in the intervention and zero improvement, or 5% improvement, in the controls, and all the other studies here treating these tendinopathies and tendonitis conditions, which tend to improve over time, always had pretty big improvement in the control group no matter what happens, and in this study, there was zero improvement in the control group, or hardly any improvement in the control group. So, this study ended up in the vendor's report, and I just wanted to point out that maybe this is the worst one that I saw. I don't know. I just wanted to bring it to talk about, this is sort of an unbelievable study, and I don't think it was . . . I don't know how it got published, honestly.

Lateral epicondylitis is again an example of which functional outcome is the most important to look at and when grip strength was looked at, it was not significant across four studies.

Safety, there's not a lot in here on safety. There were four cases of fascial tear or tendon rupture. So, the energy from this thing is high enough that you can actually tear a fascia or a tendon. Then, this Gerdesmeyer study in 2003 for calcific tendonitis of the rotator cuff, 36 of 48 people receiving the high energy ESWT had bad enough pain that 8 of 16 required IV analgesics during the procedure or after the procedure, and the same thing in the low energy group. There was a lot of petechiae, bleeding, hematoma, and erythema. So, this thing is not, like, nothing, as far as safety is concerned.

Then cost-effectiveness, it's hard to find this stuff, but I saw some ads on some podiatry centers on the web where the costs were somewhere between \$900 and \$3000 depending, and maybe our expert here can help us figure out what is charged on these things.

CMS does not have any national coverage decision on this.

There are a number of national and international clinical guidelines and payer policies. I think the most impressive one, for me, was the National Institute for Health and Care

Excellency, main health technology group for the UK for their healthcare system, and this was a little bit old, 2010. The procedure should only be used with special arrangements for clinical governance, consent, and audit or research. So, it's basically coverage with evidence development. And then the biggest payers, Anthem, Premera, United basically do not cover it. AETNA only covers it for calcific shoulder problems.

So, given the heterogeneity, the fact that the biologic plausibility, to me, is sort of questionable, if you look at comparisons to real live active treatments that work in general, they don't . . . it doesn't . . . it's not equivalent. It's either about the same or worse. There are safety concerns. There are definitely cost concerns, and I'm not sure that this large body of work actually is very compelling. So, we're recommending that it not be a covered benefit. Thank you.

Chris Standaert: Anybody have any questions for Dr. Franklin? No. You can't walk away yet. Yes, Dr. Odegard.

Carson Odegard: Gary, did you . . . I just happened to run across some other safety issues, and one of them was, besides trauma to tendons and other tissues, was actually periosteal fracture and displacement. I don't know if you ran across that or not, but I thought, wow. That's getting pretty deep.

Gary Franklin: You found a paper on that?

Carson Odegard: Yeah.

Gary Franklin: Yeah. That's pretty deep.

Carson Odegard: Yeah.

Gary Franklin: Wow.

Chris Standaert: You found a paper on, as a complication?

Gary Franklin: Periosteal fracture.

Chris Standaert: Mm-hmm.

Carson Odegard: It didn't single out, it . . . it just mentioned that a certain percentage of people had that one.

- Gary Franklin: Yeah. I don't know if that was mentioned in the report. I don't think . . . I don't think it was.
- Chris Standaert: No, but you don't have any idea how prevalent this is in the community in the Washington State, how widely used this is, how frequently it's used, any of that?
- Gary Franklin: I have no idea, because we don't pay for it.
- Chris Standaert: Yeah, Dr. Chang.
- Michael Chang: So, the . . . it is not uncommon to use in the control group, shockwave treatment without using the gel, which is serving good conduction between the device and the tissue. So, in the control group, a lot of clinicians will use the treatment without the gel to illuminate the shockwave, but the patient can actually hear the shockwave firing, but there is really no energy delivered to the patient. So, we will find out in the literature that people use this as a control.
- Gary Franklin: Are you commenting on my comment on this paper?
- Michael Chang: Not particular that paper.
- Gary Franklin: OK. That's good, because this is a terrible paper.
- Michael Chang: Not particular for that paper.
- Gary Franklin: OK. Thank you, I appreciate it.
- Michael Chang: Because acoustic wave attenuates very quickly in the air, OK? You need conduction gel to deliver the energy into the tissue, but you have to do it. If you don't do it with conduction gel, you will lose all the energy, even you contact the patient's skin.
- Gary Franklin: Great. Thank you.
- Michael Chang: And the other thing is, heterogeneity, because we are here proposing a tool, a clinical tool. So, the clinician has a tool. It depends on what kind of practice they have. They will use a different kind of application. That's why you would see in the literature there are so many people using it for different purposes.

- Gary Franklin: Yeah, but the whole point is that it's not easy to look at a body of literature with such heterogeneity and come to a conclusion. That's my point.
- Michael Chang: It is very difficult, yes. I agree.
- Chris Standaert: Dr. Chang, is there . . . how is this billed? There's a CPT code for it. Is it by session? Is it by . . . how does this, how does this get billed. Since it's not paid for by the state, people might just have a flat cash fee. I don't know, but in the medical world of CPT codes and ICD-10, how is that billed?
- Michael Chang: So, CPT code for low energy or radial shockwave is 0019T. It's an investigational code.
- Chris Standaert: It's a T-code.
- Michael Chang: A T-code, yeah. That code was eliminated starting this year. For high energy shockwave, only for plantar fasciitis, there is a CPT code.
- Chris Standaert: OK.
- Michael Chang: And there, there is also investigational code, I think it's 0101T for high energy focus shockwave.
- Chris Standaert: OK. For those on the committee, the CPT codes, there are codes that have a value attached to them, an RVU, which is a standard CPT code. A T-code is a tracking code, which Medicare makes as a code so they can document what's being done, but as a T-code, it doesn't have a value applied to it. So, it doesn't get reimbursed. So, it's considered an investigational way and in my understanding of the Medicare system, is that's a way for them to track how often a procedure is being done, because one of the ways you advance to a code that gets paid is the procedure has to be widely utilized for them to start to consider it as a regular code. So, the fact that it exists under a T-code means they are considering a tracking code with no actual value applied to it. So, you can't bill for it, essentially. You could put the code on your chart so they know you did it, but Medicare wouldn't pay anything for it. So, you're saying there is an actual CPT code that's reimbursable by Medicare with an RVU for treatment of plantar fasciitis, as a single

event or as, like, if you do this multiple times it's multiple codes? Each time you deliver . . . each time you do the treatment you bill the code?

Michael Chang: Yes.

Chris Standaert: OK. Per session, yeah. OK. Do you know what they reimburse for it?

Michael Chang: You mean, some insurance company reimburse for it.

Chris Standaert: Some do, Medicare.

Michael Chang: Medicare, I don't know specific. I don't think Medicare reimburses.

Chris Standaert: Well, it'd have an RVU, right, if it's a regular code. So, it should have an RVU. So, it should be . . .

Michael Chang: For the plantar fasciitis?

Chris Standaert: Yeah. So, it should pay something.

Michael Chang: I don't have specific experience with Medicare, yeah.

Chris Standaert: OK.

Michael Chang: So, I cannot answer.

Gregory Brown: What did you say the code was for plantar fasciitis?

Michael Chang: I don't remember, yeah.

Chris Standaert: So, for those on the committee, this all does get transcribed. So, you have to use your mics so the transcriptionist can hear you.

Michael Chang: So, it's just another comment for your presentation is, for tendinopathy at the insertion site, it is very difficult to heal by itself. The area has poor blood supply and also that's where the force concentration is. So, insertional tendinopathy, lateral epicondylitis, or plantar fasciitis, or tennis elbow or rotator cuff tendinopathy with or without calcification, of all the tendon, insertional tendinopathy is very difficult to heal clinically, and there are a lot of treatments, existing treatment for it. It either doesn't work

very well, or sometimes it's harmful to inject steroids to those tendon insertion sites. It's not a good idea. It can actually jeopardize the healing. Shockwave is probably the unique tool that can help with the healing. We thinking we understand the physical mechanism, through the study with the physicist, but it is not yet widely known. I can go into more detail, in terms of physics, but probably not at this point.

Chris Standaert: I think Dr. Franklin's point is that there isn't a documented clearly-delineated uniformly understood mechanism of action existing in the medical literature, which seems like a fair statement, yeah.

Gregory Brown: Yeah, I guess I would beg to differ. There's just recently released in the BMJ a meta-analysis of ultrasound for bone healing and when they basically reduced the RCTs down to four studies without bias, there is no effect on healing. So, there's been a theoretical concept of encouraging healing with ultrasound or electromagnetic pulse or other things, but the randomized control trials don't hold out to any improved healing. As a shoulder surgeon that's done numerous injections in the shoulder and everything, tendinopathy is aging. It never heals. If it becomes a complete tear, you excise the damaged tissue and you repair it back to bone. You don't try and get the damage or the tendinopathy degenerated tissue to heal itself.

Chris Standaert: To regrow itself.

Gregory Brown: To regrow itself, yes.

Chris Standaert: Right. So, again, we're not . . . with regards to that comment, we're not talking about the ultrasound, which is a different methodology. Again, my comment was just to clarify the discussion between these two that in terms of documented mechanism of action that has a physiologic basis that is well studied, well understood, and uniformly accepted, it does not seem to exist for this technology. That was my clarification. Yes.

Joann Elmore: I'd like to ask Dr. Chang, our clinical expert, a question. I appreciated your very impressive CV, curriculum vitae, and your filling out our conflict of interest forms. I have a few

questions. Number one, do you perform this procedure in your own clinical practice?

Michael Chang: Yes.

Joann Elmore: OK. And then, approximately how many per year do you do in your clinical practice? I assume you work full time?

Michael Chang: Part time, full time, depends on the patient. For high energy focus shockwave, I do about probably around five to ten per year.

Joann Elmore: A total of five of these per year?

Michael Chang: Yes.

Joann Elmore: OK.

Michael Chang: Because this is a completely from a referral base. Somebody referred . . .

Joann Elmore: Not very frequently.

Michael Chang: Not very frequently, yes.

Joann Elmore: OK. Alright. And then, there's mention of pain with this procedure. When we looked at the harms, they talked about serious harms, but to me, pain is a harm to patient, but I didn't see adequate documentation and description of this. In the five or six that you do per year, which obviously is a limited number, can you describe the pain associated with this procedure, and I'm assuming it varies based upon the technique and the location, but I didn't get a good sense from the evidence vendor.

Michael Chang: For high energy focus shockwave, it is very painful. It is extremely painful, and the pain that you do not experience from a common trauma. It is a very unique pain, because the shockwave energy deposits the energy at the interface, such as the bone. So, it deposits a lot of energy at the bone surface, and that's part of the reason it works very well for the enthesopathy or insertional tendinopathy. So, it is very painful, and they need the local anesthetic. I think the local nerve block would be sufficient for the treatment.

- Joann Elmore: OK. Thank you. To me, we need to look at the harms, and that was an important one that I appreciate your information.
- Michael Chang: You're welcome.
- Carson Odegard: I have one question of Dr. Chang. In the literature, they were speaking of activation therapy. What is the difference between shockwave therapy and activation therapy?
- Michael Chang: I think the . . . I have to know specifically what they refer to. I think there's a . . . the radial pressure wave device, there are some people who refer to this device as activation. So, if the patient . . .
- Carson Odegard: So, that's the same as the radial, equivalent to the radial.
- Michael Chang: Shockwave is not equivalent to pressure wave device. Pressure . . . radial pressure wave device and nonfocus is a pressure wave. There is also an acoustic wave, but not shockwave. So, shockwave specifically refers to . . . so the shockwave has a positive pressure and an active pressure. So, if the positive pressure is less than 10 nanoseconds, in terms of rise time from zero to the peak, you call that a shockwave. The radial pressure wave device does not have that kind of rise time. Shockwave is actually the explosion. It's a sonic explosion.
- Carson Odegard: So, the activation therapy that they mention is somewhat similar to . . .
- Michael Chang: So, pressure wave, I do not think they induce a lot of cavitation like shockwave does.
- Carson Odegard: OK.
- Michael Chang: Because they do not have a large negative pressure, but androgenesis actually relies on the impressions of cavitation actually.
- Carson Odegard: OK. Very good.
- Michael Chang: Yeah. That's where physics start, and we need to understand it. The cavitation is actually very important in terms of the therapeutic effect caused by the androgenesis,

because you have to break the vessel. One of androgenesis effect is, you have to disrupt the basement membrane of the blood vessels, and then they actually used the cavitation to cause the controlled injury in the blood vessel, which is androgenesis by sprouting. Another mechanism is also caused by cavitation is cavitation oscillate within the blood vessels in the acoustic field. The oscillation increases the blood flow, the local blood flow, and that's the androgenesis by intussusception.

Chris Standaert: Dr. Chang, can you get closer to your mic, just so the transcriptionist can hear you.

Michael Chang: Sorry.

Chris Standaert: So, does that answer your question? OK. Any other questions or comments on Dr. Franklin's presentation? So, we're going to move on to public comments. So, we have nobody who contacted us before the meeting. We have nobody who is signed up. So, I will check if anybody in the audience wants to make a public comment and address the committee. They can if they so choose. I see three shaking heads in the audience. So, that's probably not the case. Can we open up the phone lines? So, for people on the phone who may be there, this is the March 17th meeting of the Washington State Health Technology Clinical Committee, and we're discussing extracorporeal shockwave therapy for musculoskeletal conditions, and this is the opportunity for public comment. So, if you're on the phone listening, and you would like to make a public comment to the committee, this is your opportunity to do so. We'll give you a minute to see if you want to respond. Well, maybe not a whole minute. She's looking at the clock. With that being said, we will move on to our report from the evidence vendor, from Hayes. Spectrum? This says Hayes.

Josh Morse: That is incorrect.

Chris Standaert: I thought it was Spectrum. I was, like, you guys aren't Hayes, but my forms, my minutes say Hayes.

Erika Brodt: Good morning. My name is Erika Brodt, and I'll be presenting the results for our report on extracorporeal

shockwave therapy. Can you hear me OK? OK. I'd like to take a minute to acknowledge my co-investigators.

So, beginning with just a little bit of background, a shockwave is a special type of pressure wave that propagates in three dimensions. As has already been said is characterized by a quick rise time of just few nanoseconds to a high maximum positive pressure. There are two types of extracorporeal shockwaves focused in radial, and they differ in two important ways. First is the type of pressure, deep versus superficial. In a focus shockwave, the pressure field converges at a selected tissue depth where the maximum pressure is reached, and on the slide there, the picture starting on the left, the three pictures show focus shockwaves, and as you can see, they are converging away from the source. Radial shockwaves create pressure waves that are highest at the skin surface and diverge, as they penetrate deeper. That's the picture there showing kind of a cone or a funnel shape. The second difference is the speed at which they travel. Focus shockwaves travel faster than the speed of sound, while radial shockwaves travel much slower and do not break the sound barrier. Thus, radial shockwaves are not truly shockwaves. Additionally, focus shockwaves can be generated by three different techniques. Electrohydraulic, piezo-electric, and electromagnetic, while radial is generated pneumatically, when compressed air strikes a projectile in a chamber.

In this report, we have evaluated the evidence for focused and radial separately, given these inherent differences. So, as has already been said regarding the mechanism of action, it is not well understood, but there are three main theories, the first of which is hyperstimulation analgesia. That is where overstimulation of the treated site by these shockwaves leads to a diminished transmission of pain signals to the brain stem, thus providing pain relief. The second theory is mechanotransduction whereby the mechanical load or force placed on the tissues by the shockwave effects the cytoskeleton leading to cellular responses, such as an inflammatory response, the creation of new blood vessels, and increased blood flow, the release of growth hormones, all of which stimulate and accelerate the healing and repair process. Thirdly, shockwave therapy may destroy or break down calcifications in the tendons. This effects is comparable with the way shockwaves are

used in lithotripsy to destroy kidney stones, but again, as has already been said, there is really no consensus regarding exactly how these shockwaves work in treating musculoskeletal conditions.

So, specific conditions where shockwave therapy is utilized include plantar fasciitis, various tendinopathies, such as lateral epicondyle, Achilles, patellar, and rotator cuff tendinopathy, and knee osteoarthritis. Shockwave therapy has FDA approval for plantar fasciitis and lateral epicondyle tendinopathy. The two conditions highlighted in red. The other conditions are considered to be treated off-label.

So, regarding the procedure itself, it's a noninvasive outpatient procedure, in which a probe is placed on the skin over the desired location, and gel is usually applied to help conduct the shockwaves. Again, as has already been stated, techniques for using extracorporeal shockwave therapy for musculoskeletal problems have not yet been standardized, and we've already talked about the two different categories, focused and radial, but there are also a number of instrumental settings that can be varied during shockwave therapy, such as the energy dosage or intensity and the number of impulses, and the exact relationship between these settings and the effectiveness of the treatment are often unclear. I've included on this slide the range of energy doses and impulses used in our included trials, and as you can see, there is a lot of variability. Also, regarding energy dosage, there is no universal agreement, as to the cutoff that separates high, medium, and low. So, in this report, we use the cutoff shown here, which were obtained by consensus from our clinical experts. Also, the frequency and number of sessions can vary, again in the trials we included it varied from one to five applications over days to weeks. There is also controversy regarding the use of local anesthesia. Some investigators suggest that shockwave therapy is less effective when used in the presence of local anesthesia, and there is some evidence to show that anesthesia may alter the biological response of shockwave therapy. Finally, the direction of application, whether the shockwave is directed to the site of the pathology, identified anatomically by some means of imaging or versus to the site of maximal tenderness specified through palpitation.

So, the key questions are pretty standard and address the short and long term efficacy, short and long term harms and complications, differential efficacy in safety of shockwave therapy compared with alternative treatment options, sham, or no treatment, and key question four addresses cost-effectiveness.

Regarding our population, we included patients with musculoskeletal tendinopathies, plantar fasciitis, and osteoarthritis. We excluded conditions, such as kidney stones, fracture, treatment of non or delayed union, wound treatment, and dental conditions. For interventions, we looked at both focused or radial shockwave. Again, these were analyzed separately in the report. We excluded shockwave therapy in conjunction with other procedures or as an adjunct to procedures, such as surgery. As far as comparators, we looked at alternative treatment, sham, or no treatment, and for efficacy, comparisons of different characteristics of shockwave therapy, such as comparing focused versus radial or high versus low energy were excluded, but they were retained for safety purposes only. So, our primary outcomes were physical function, pain, composite outcome measures, and adverse events or complications. We looked for the proportion of patients achieving some kind of success criteria for pain and function, which was most commonly greater than or equal to 50% improvement from baseline. These patients were often called responders in the trials. We also reported the mean improvement from baseline in the scores on the measures. Regarding pain, specifically, this has kind of already been alluded to, the trials reported multiple pain outcomes, depending on the condition. Pain was reported on the visual analog scale, primarily under various circumstances, such as with activity, at rest, first thing in the morning, and at night, again depending on the indication. In some instances, it was unclear under what conditions the pain was being assessed, so we referred to this as pain not otherwise specified or pain NOS. For pain, we considered a difference between groups of 1.5 on a zero to 10 scale, as a clinically important difference. For function, the MCID value varied based on the validated measure, and that information is provided in table one, I believe, of the report, the outcomes table. As usual, we looked at short, intermediate, and long term outcomes, and they were defined as shown there on the slide.

So, regarding the literature search, it ran through November of 2016, and did not place a limit on start date. Regarding the study design, the focus was placed on studies with the least potential for bias, which we consider to be RCTs and randomized control trials, and as you can see, we identified numerous trials that met our inclusion criteria from over 1500 citations. We included a total of 72 RCTs; 59 were included for efficacy, and a total of 65 trials provided data for safety, including 52 of the 59 included for efficacy. We did not find any formal cost-effective analyses.

So, I'll be presenting the results, in terms of overall quality or strength of evidence, which is based on AHRQ's recommendations and our application of grade, which you are all familiar with, I think. We grade the overall strength of evidence separately for each primary or critical outcome after assessing across the studies for risk of bias, consistency, directness, and precision, and the final strength of evidence rating for each primary outcome represents how confident we are that the evidence reflects the true effect. That is, is our confidence high, moderate, low, or do we have insufficient evidence to draw conclusions. For this report, we most commonly downgraded the quality of evidence due to methodological flaws in the included studies and for risk of imprecision that results from small sample sizes.

So, I'm going to turn now to the efficacy results and before I begin, I just want to talk about the efficacy results, in general. I'm not gonna talk about each and every outcome. I just don't have time here. There's so many. So, in this presentation, I'm going to focus on results for which we have multiple data points. That is data from more than one study, and at the end of the efficacy section, as a whole, I'm going to display some summary slides that give an overview of all the data, according to strength of evidence, including some I may not have presented specifics for in the slides previously. My hope is that this will help give you a nice overview of the evidence.

Also, by way of orientation, as I go through these, since there are so many outcomes, I will be discussing focus shockwave therapy first versus sham and then versus active control followed by radial shockwave therapy versus sham versus active controls.

So, beginning with plantar fasciitis, one of our FDA approved indications, this slide shows the evidence base for this condition. As you can see, the bulk of the data is for the comparison of focused shockwave versus sham.

So, over the next five slides, I'll be reporting on five different pain outcomes, pain when first walking in the morning, pain during activities, pain composite measures, pain at rest, and pain not otherwise specified. So, beginning with data over the short term, a total of eight RCTs assessed pain when first walking in the morning, and two different measures were reported. Across five studies, 38% more patients were reported to achieve pain success following focused shockwave therapy, which was defined as an improvement of greater than or equal to 50% compared with baseline. Confidence interval was 15 to 66%. I'm talking about the forest plot at the top of the slide. When we looked at just the three studies that were of better quality, that is lower risk of bias, the pooled results were similar. Some studies looked just at the change from baseline or also at the proportion of patients achieving success, and the pooled analysis, now looking at the plot at the bottom of the slide, as you can see, showed no statistical difference between the groups; however, it resulted in a lot of heterogeneity. The I-squared was 96%, which primarily had to do with the outlier, which was at higher risk of bias. When you look at the higher quality studies, the result did become statistically significant; however, it was not clinically important, or did not meet the clinically important threshold. That difference was 0.69.

Quickly, to orient you to these boxes we move through, originally, we had wanted to stratify by energy level and other variables, but the data became too thin and too sparse to do so. So, we have added three different columns to these slides after the study. Energy, risk of bias, and anesthesia. The energy is the energy level, whether it's high, low, or medium based on how we classified it. Risk of bias, whether it's higher or lower. So, higher risk of bias means a poorer quality study, lower risk of bias, higher quality, and then whether anesthetics was used.

So, moving on to the next slide, a total of five studies provided data for pain with activities. So, we're still talking about focused shockwave versus sham. They looked at this

outcome over the short term. We had fewer studies reporting on this outcome, as compared with morning pain. Regardless of how it was measured, either the proportion achieving pain success or the mean change in pain on VAS from baseline, there was no statistical difference between groups. When we looked at the studies with lower risk of bias, the results were similar, no statistical difference.

So, for composite pain success over the short term, four studies, all at lower risk of bias, reported this outcome, some composite of pain outcome, that is, and they all did vary in their definition; 55% more patients achieved pain success following focused shockwave compared with sham over the short term, according to the pooled estimate. Confidence interval was 29% to 85%.

So, two studies each reported short-term results for pain at rest and pain not otherwise specified. For both outcomes, there was no difference between groups in the mean change from baseline in pain on VAS. Again, when we considered just the better quality study for each measure, the results remained the same. No statistical difference.

So, this slide shows long term data, for which we don't have much. As you can see, most of the evidence for pain for plantar fasciitis was in the short term. Only two trials reported long term pain outcomes. Both trials were at lower risk of bias and reported pain when first walking in the morning at 12 months. There was no difference between groups in the pooled estimate. However, this analysis resulted in a large amount of heterogeneity, and since both are at lower risk of bias, we looked at the study characteristics, and some of them may explain the difference. The study populations differed in mean age and the proportion of males. Furthermore, the population in Rompe 2003 was a group of runners who logged at least 30 miles per week, whereas the running status of patients in the other trial was not known.

So, switching now to function, still talking about plantar fasciitis, focused shockwave versus sham. Function was reported much less frequently than pain for this comparison, and two RCTs, both at lower risk of bias, provided data for functional outcomes using the American Orthopedic Foot and Ankle Society Ankle Hindfoot Scale.

One trial reported short term data only and found no difference between groups in success or mean change from baseline at three months. The other smaller trial reported intermediate and long term data and found a statistically and clinically greater improvement in mean change from baseline with shockwave therapy at both timepoints.

This slide shows our evidence base for focused shockwave versus some kind of active control. A total of five trials were included for this comparison. Control groups included corticosteroid injection in two trials, conservative care in two trials, which was comprised primarily of physical therapy stretching exercises or modality treatment and NSAIDs. One trial looked at endoscopic plantar fascia release, EPFR there at the bottom.

Across all comparisons and outcomes, as you can see both pain and function, the only difference between groups was seen for short term improvement in pain when first walking in the morning in one trial and favored the control group, steroid injections. The difference was both statistically and clinically meaningful.

So, switching now to radial shockwave therapy, and as a reminder, compared with focused shockwave, these shockwaves propagate at much slower speeds and has the highest pressure superficially at the skin's surface. So, two RCTs, both at lower risk of bias, provided pain data for this comparison during the short term, but it measured pain in different ways. In all instances, the statistically greater proportion of patients who received radial shockwave therapy achieved pain success at three months followup.

Two RCTs, one better quality and one poor quality provided intermediate term data for pain and reported pain success and mean change from VAS pain scores compared with baseline, both of which favored radial shockwave therapy, both statistically and clinically. Pain in this case was not otherwise specified, and when considering the trial with the lower risk of bias, the results remain similar. We had no functional outcomes reported for radial shockwave versus sham in plantar fasciitis.

The only active control identified for radial shockwave in this population was ultrasound. Two small RCTs provided data on pain with conflicting results, no functional

outcomes were reported. One poor quality trial found no difference between groups over the short and long term in the proportion of patients with success, defined as a score of zero or one on a ten-point VAS scale. When first walking in the morning and during ambulation. The other trial at lower risk of bias reported a statistically and clinically greater improvement in pain not otherwise specified from baseline with radial shockwave over both the short and intermediate term. Both differences exceeded the MCID of 1.5.

So, that concludes the evidence for plantar fasciitis. Moving onto our second indication for lateral epicondyle tendinopathy, the second of our two FDA approved indications. Again, the majority of the evidence compared focused shockwave with sham. So, three different pain measures were reported across these studies, pain with resistance, pain not otherwise specified, and pain at night. We will begin with short-term results for pain with resistance during wrist extension.

So, focused shockwave therapy resulted in significantly more patients achieving success, defined as a greater than or equal to 50% improvement over baseline and pain with resistance across both trials, both at lower risk of bias. And additional trial provided data for the analysis looking at mean change from baseline. It's the plot at the bottom of the slide. When all three trials were pooled, the difference for this outcome was not statistically different between the treatment groups; however, the third trial was of poor quality, and reported results inconsistent with the other two trials, and when we looked at the two higher quality study trials, the difference did favor focused shockwave statistically; however, the mean difference was not clinically important.

So, still talking about focused shockwave versus sham, now talking about pain not otherwise specified over the short term. There was no difference between treatment groups in the pooled estimate. Again, due to the large amount of heterogeneity, we evaluated separately the higher quality study with the lower risk of bias. Those statistically significant, again, the mean difference did not meet the clinically important threshold.

Results were inconsistent across the two trials that reported the mean change from baseline and pain at night over the short term, two to three months of followup. While the pooled estimate did not show any statistically difference between the treatment groups, again, when we evaluated separately, the higher quality study focused shockwave showed statistically better pain improvement, but again, was not considered to be clinically meaningful.

As for plantar fasciitis, the majority of evidence for lateral epicondyle tendinopathy was over the short term for pain. Only two trials reported the mean change from baseline and pain with resistance at 12 months of followup, and the results were inconsistent.

Again, while the pooled estimate did not show a statistical difference, the higher quality study with the lower risk of bias did show that focused shockwave therapy provided better pain relief. However, the mean difference, again, was not clinically important.

So, switching now to function, looking at short term results, two trials reported the mean change from baseline in the upper extremity function scale at three months of followup, which was significantly improved in patients receiving focused shockwave versus sham according to the pooled estimate. We could not find a minimally clinically important difference for this outcome for this specific indication.

A total of four trials reported the mean change in grip strength over the short term, two of which additionally reported data over the long term, and there was no difference between groups at other time point. In the short term, there was quite a bit of heterogeneity in the results. So, again, we looked at the lower quality trials, as well as performing some sensitivity analyses, and the estimates remained similar.

So, a total of three trials provided evidence for the comparison of focused shockwave versus an active control. So, again, we've switched from focused versus sham now to focused versus an active control. Two small trials, both at higher risk of bias compared to focused shockwave therapy with corticosteroid injections. The results from one trial reported less improvement in pain not otherwise specified

over the short term with focused shockwave compared with steroids. The second study reported no between group differences in the short term, but significantly more improvement with focused shockwave and pain with resistance and function according to the upper extremity functional scale over the intermediate and long term. In the third trial, there was no difference in improvement in pain with resistance over the short and long term comparing focused shockwave with percutaneous tenotomy and no functional outcomes were reported by this last study.

So, switching now, again, to radial shockwave versus sham for lateral epicondyle tendinopathy. Two very small RCTs, both at high risk of bias compared radial shockwave therapy with sham. In the short term, three months followup, there was no difference between groups in pain and function in one trial. In the intermediate term, the second trial reported a higher proportion of patients achieving pain success in the radial shockwave group compared with sham, and success was defined as greater than or equal to three points improvement from baseline, and I realized that the title of that last table is incorrect. It should say intermediate success.

OK. So, moving on now to shoulder tendinopathies. For this indication, I am going to show you data points mostly around rotator cuff tendinopathy, since that's where the bulk of the evidence is. I'll describe the other conditions in the summary tables that appear at the end of the section on efficacy.

So, this slide is looking at pain not otherwise specified, the mean change from baseline, for focus shockwave versus sham. Two trials reported this outcome. In the pooled analyses statistically and clinically greater pain improvement was seen with focused shockwave versus sham at all three time points, three, six, and 12 months. Of note, both of these studies were in patients with calcific tendinopathy. So, this slide is talking about a couple other pain measures that were reported by two small studies, both at moderately low risk of bias, and no difference was seen between groups for any outcome or at any timepoint measured. Of note, both studies were in patients with noncalcific tendinopathy.

So, talking now about function, specifically function success for focused shockwave versus sham. A total of four RCTs, all at lower risk of bias provided data for function success. Only two reported data that could be pooled and found no statistical difference between focused shockwave therapy and sham in the proportion of patients that achieved function success over three months. These trials used a cutoff of greater than or equal to 30 points improvement on the constant shoulder score. These patients had noncalcific tendinopathy. A third trial, also in patients with noncalcific tendinopathy also reported no difference between groups in the achievement of function success according to the [inaudible] in the short term, and that's the bottom row of the table at the bottom of the slide there. The fourth trial defined function success as greater than or equal to a 30% improvement in constant shoulder score and reported a statistically greater proportion of patients in the focused shockwave group achieving success at all time points. Of note, patients in this trial had calcific tendinopathy.

So, we're still about function and the mean change from baseline in the constant shoulder score. A total of five studies, three in patients with calcific tendinopathy and two in patients with noncalcific tendinopathy recorded the mean change from baseline and constant shoulder score. In the pooled analyses at all time points, there was a statistically significant difference between groups and improvement in function, which favored shockwave therapy. We were not able to identify a clinically important threshold for this outcome, however. Because these analyses resulted in a large amount of heterogeneity, which is starting to sound familiar, I'm sure, we analyzed separately the results from the higher quality trials, and results were similar. The estimates were smaller but still statistically favored focused shockwave therapy.

So, looking now at shockwave versus active controls, one small RCT at lower risk of bias compared focused shockwave therapy with ultrasound-guided needling and corticosteroid injection. The only difference between groups in pain not otherwise specified and in function, according to the American Shoulder and Elbow Surgeon Score and a simple shoulder test was seen at long-term followup with much less improvement on all measures

following treatment with focused shockwave compared with a steroid injection. We did identify a second small study that compared focused shockwave with transcutaneous electrical nerve stimulation; however, all data was considered insufficient.

Gregory Brown: I have a question there. Was that one, I didn't hear, is that with or without calcific?

Erika Brodt: This one, let me go back. I think it's variable. Let me go back to that one. We're talking about the function?

Gregory Brown: Yeah. Your previous slide.

Erika Brodt: Yeah. So, three, three of the studies had calcific tendinopathy and two did not.

Gregory Brown: OK.

Erika Brodt: So, there are five, yeah. There were five total.

Gregory Brown: I've never seen needling with ultrasound-guided needling without calcific tendon.

Erika Brodt: Oh, I'm sorry. I thought you were talking about this slide. You're talking about . . .

Gregory Brown: No. No. No. The previous one.

Erika Brodt: . . . this one. To be honest, I am not sure if it's calcific or not. Cassie, could you look up Kim for me.

Chris Standaert: I've seen patients get needle for noncalcific tendinopathies.

Gregory Brown: Oh, really? OK.

Chris Standaert: In the ultrasound peer review world. Yeah.

Gregory Brown: I've just never referred for them. So, that's why I'm being confused.

Chris Standaert: I'm not saying I have either. That's not what I said.

Gregory Brown: I know. I read between the lines.

Erika Brodt: Kim is calcific? OK. Let's see, where were we here? OK. So, for radial shockwave therapy for rotator cuff tendinopathy, two comparator groups were identified reported by one study each, which were both at higher risk of bias. For the comparison was sham, no significant difference seen between groups. In pain not otherwise specified and in function, according to the constant score and the simple shoulder test at three and six month's follow-up. Compared with ultrasound-guided percutaneous lavage, or UGPL at the bottom of the table, radial shockwave therapy resulted in significantly less improvement in pain at three, six, and 12 months of followup.

So, turning now to our evidence for Achilles tendinopathy, you're going to notice that the evidence bases start to get smaller from here. We have a total of five trials that provided evidence for this indication. So, for Achilles tendinopathy, we only have short term data. None of the included studies reported outcomes over the longer term. Also for this condition, I want to note that we stratified results for these outcomes based on whether the pathology was insertional or noninsertional. So, whether the pathology was on the tendon directly at its insertion into the heel bone that would be insertional, or whether it was located a bit above that, usually two to six cm, I think, and that's considered noninsertional or a midbody Achilles tendinopathy.

So, for focused shockwave versus sham in this population, we identified two trials. After three months of followup compared with those who received sham, patients who received focused shockwave therapy reported statistically greater improvement in VAS pain scores from baseline with running or playing sports. The mean difference in change scores is considered to be clinically significant. Similarly, across these same two trials, compared with those who received sham, patients in the focused shockwave group reported a statistically significant improvement in pain scores at three months while walking. Again, the mean difference was clinically significant or important. We found no studies that compared focused shockwave with an active control in this population.

So switching now to radial shockwave therapy, there were no studies that provided data for the comparison with

sham, and the only active control we identified was eccentric loading, and results were inconsistent across the two trials that reported this outcome, and the pooled estimate did not show a statistical difference between the groups regarding mean change from baseline in pain during the day; however, the analysis resulted in a large amount of heterogeneity. Both trials were at lower risk of bias, and the heterogeneity could be due to the type of tendinopathy treated, as you can see noninsertional, insertional, or going in opposite directions. Patients in this study by Rompe 2007 had a shorter duration of symptoms and were older. Otherwise, both trials were similar in most other aspects.

So, this is patellar tendinopathy now that we're turning to. The evidence is limited with only two small RCTs identified, which met our criteria. Both were at high risk of bias, and both reported improved pain and function with focused shockwave therapy. One compared focused shockwave therapy with sham over the short term, and the other with conservative care over the long term. We had no evidence for radial shockwave therapy for this population.

Similarly, for osteoarthritis of the knee, the evidence base is limited. Two small RCTs met our inclusion criteria. One trial at higher risk of bias, talking about the first row in the table here, compared focused shockwave therapy plus isokinetic muscular strengthening or IMS with both IMS alone and in combination with post-ultrasound and reported significantly more improvement in pain not otherwise specified over the short or intermediate term following treatment with focused shockwave compared with both control groups. The difference was only considered to be clinically important for the comparison of focus shockwave versus IMS alone. The second study at lower risk of bias compared radial shockwave therapy with sham and also reported significantly better results over the short term for pain with walking and for function according to two different outcome measures.

So, that concludes kind of the detailed evidence slides. The following slides are intended to provide a summary and visual overview of the evidence for each indication based on strength of evidence, and specifically for strength of evidence for which we have some confidence that the evidence reflects the true effect. Therefore, data graded

insufficient is not presented in the color-coded slides but will be mentioned. Again, to remind you, there may be some indications that were not detailed previously that will be mentioned here.

So, before I begin to orient you to the slides quickly, what we've done is grouped them by short, intermediate, and long-term, and then we have the outcomes in purple. That is any pain outcome. Blue is any function outcome. Then, we have the strength of evidence low, moderate, and high, and we've color-coded each outcome. Green means that the results favor the intervention. Dark green is with large effect. Light green is with small effect. Red means there was no statistical difference between the groups. Blue means that it favors the control.

So, beginning with plantar fasciitis and the comparison of focused shockwave versus sham, there is high quality evidence from up to eight RCTs that focused shockwave therapy results in pain improvement over the short term when considering pain when first walking in the morning and composite pain measures. However, effect sizes were small and not all pain measures showed a significant effect, as you can see by the red. Function was reported less frequently than pain over the short term with no differences seen between groups, and there is much less evidence, all low quality, over the intermediate and long-term, that make it hard to draw conclusions.

Chris Standaert: Can you just define short, intermediate, and long term so I know as you go through these?

Erika Brodt: Sure, yes. Short is greater than or equal to three months. Intermediate is greater than three to less than 12, and long term is 12 or longer, 12 months or longer.

For focused shockwave versus active control for plantar fasciitis, we have moderate strength of evidence that focused shockwave therapy is less effective, both statistically and clinically, at reducing morning pain over the short term, but not the long term compared with corticosteroid injections, and we only had low strength of evidence from one small RCT that focused shockwave and endoscopic plantar fascia release result in similar pain and function improvement over the short and long term.

For radial shockwave therapy versus sham, so switching from focused to radial, there is moderate quality evidence that radial shockwave therapy results in greater pain improvement, though statistically and clinically compared with sham over the short term using multiple methods of describing pain across three trials. The results are similar over the intermediate and long term, although the evidence is less certain in the long term, as we have only low quality data from one small trial at 12 months. I would like to add a small caveat here, or maybe a big caveat here. So, where you see the asterixes by the squares that are in the darker green, these do include the trial that Dr. Franklin brought to the committee's attention, Ibrahim. We re-reviewed the results of that trial, and going through the grade process and grading it, it was considered moderately low risk of bias based on what they reported; however, it does make us skeptical, the results. It is hard to believe, given the natural history, of one, of plantar fasciitis that it does just get better over time for one, and also that all the other studies, like Dr. Franklin said, reported quite a bit more improvement in the sham group than this study did. It makes us skeptical. We can't downgrade based on skepticism, and following our objective processes, felt we should upgrade for it; however, we did want to bring that to your attention, because I think it is an important consideration. That large effect should probably be taken with a bit of grain of salt.

So, regarding radial shockwave therapy versus ultrasound, one small trial had low quality evidence suggesting that radial shockwave therapy resulted in greater improvement, both statistically and clinically in pain over both the short and intermediate term compared with ultrasound. However, the effect sizes were small. This comparison, we did identify a second poor quality study that reported no difference between groups and pain success at any timepoint, but all evidence was insufficient.

Turning now to lateral epicondyle tendinopathy, the summary for focused shockwave versus sham. Over the short term, there is conflicting evidence of efficacy, depending on how pain and function are measured. Over the long term, the evidence suggests no difference between the groups.

For focused shockwave therapy versus active control, all the evidence we found was graded as insufficient. We found two small RCTs comparing focused shockwave with corticosteroid injection and with percutaneous tenotomy.

Similarly, for radial shockwave versus sham, all evidence was considered insufficient from two small RCTs that reported short-term data only.

So, for rotator cuff tendinopathy, focused shockwave versus sham, in the short term, we have low quality evidence, and the results are inconsistent across the trials. On the other hand, we have moderate strength of evidence for both the intermediate and long term. Of particular note is the moderate evidence for long term pain improvement, which favors focused shockwave therapy, the effect for which is large. I would like to also note that all significant effects were from studies that enrolled patients with calcific tendinopathy, and the five studies that reported the constant shoulder score at short term, three of the five were in calcific tendinopathy.

For focused shockwave versus active control in this instance ultrasound guided needling plus corticosteroid injection. There is low quality evidence from one small trial that focused shockwave therapy is no more effective than ultrasound guided needling plus steroid injection in providing pain and function improvement over the short and intermediate term, and less effective in the long term. We found also one other poor quality study that compared focused shockwave transcutaneous electrical nerve stimulation; however, all evidence was insufficient.

The evidence base for radial shockwave therapy for rotator cuff tendinopathy was all insufficient. Again, we found two trials comparing sham and ultrasound guided percutaneous lavage.

For subacromial or unspecified shoulder pain, we had moderate strength of evidence from one small RCT that radial shockwave therapy is no better than supervised exercise in reducing pain and less effective than exercise in improving function over the short and intermediate term. Over the long term, there is low quality evidence of no difference between groups.

For adhesive capsulitis of the shoulder, also called frozen shoulder, the evidence base for focused shockwave therapy was all insufficient. We found two small studies that compared focus shockwave with sham and with oral steroids.

For radial shockwave therapy versus sham, still for adhesive capsulitis of the shoulder, there is both moderate and high strength of evidence from one small lower risk of bias trial that both pain and function are improved over the short and intermediate term with radial shockwave compared with sham. The effect size was large for function.

For primary long bicipital tenosynovitis, one small lower risk of bias trial was included, and we have both low and moderate strength of evidence that favors the intervention regarding pain and function. The low quality evidence was in the short term. The moderate quality evidence was in the long term, and at long term followup, the effects were large.

For Achilles tendinopathy, focused shockwave versus sham, we only had low-quality evidence that focused shockwave therapy results in improvement in some measures of pain, such as with running or sports, while walking and rest, and function according to the AOFAS score over the short term, but not in others, as you can see. Effects sizes were small, and there was no evidence over the longer term.

Summary for radial shockwave therapy, again, we have three comparisons, none versus sham, and again, all data was reported over the short term. So, we have low evidence from two trials, but there was no difference between radial shockwave therapy and eccentric exercise in pain and function. Low strength of evidence that radial shockwave with the addition of eccentric exercise results in improved pain and function versus eccentric exercise alone. Low strength of evidence that radial shockwave therapy provides better functional improvement but not pain improvement compared with no treatment. Again, all effect sizes were small.

So, this slide contains a summary for both patellar tendinopathy and knee osteoarthritis, given the small evidence base. So, for patellar tendinopathy is at the top of

the slide and the trial comparing focused shockwave with sham for this condition was insufficient. So, here, we're presenting data for focused shockwave versus conservative care. We have low strength of evidence from one small trial that favors the intervention with large effect for pain while walking on stairs and function according to the VISA-P. For osteoarthritis of the knee for both the comparison of focused shockwave therapy plus IMS versus IMS alone and versus pulsed ultrasound plus IMS. So, I'm talking about the table on the left, focused shockwave is going to be on the left, radial is on the right at the bottom for osteoarthritis of the knee. We have low strength of evidence from one small trial that favors focused shockwave therapy for pain not otherwise specified over the short and intermediate term. Similarly, for the comparison of radial shockwave versus sham, we only have low strength of evidence from one small trial that favors the intervention with pain while walking and for function according to two different measures. Again, the effect sizes were small.

So, that concludes the evidence on efficacy. I'm going to turn now to key question two, or harms and complications. For this presentation, I'm focusing in greater detail on the serious or potentially serious adverse events, but I do list the most common nonserious adverse events that occurred. So, the serious adverse events were determined both by the literature and by consensus from our clinical experts and included the following: Tendon or fascia rupture, aseptic necrosis, humeral head necrosis, neurovascular complications, neurological disorders, infection, adverse reaction or allergy to anesthetic, systemic complications, and death.

So, regarding serious or potentially serious adverse events, a total of 65 RCTS reported data related to safety. Serious or potentially serious adverse events were rare overall but did occur. A total of 17 events occurred in almost 3200 patients who received shockwave therapy, and five events were reported in over 2200 patients following control treatment. The frequency of serious adverse events following shockwave therapy and control was 0.5% compared with 0.2%, and the difference was not statistically significant. Looking at the table, you can see that all but one event occurred with the use of focused shockwave therapy. So, the 17 serious adverse events

reported across the studies are listed below the table. The first one is acute bursitis subacromialis, and that occurred in six patients in one RCT of shoulder tendinopathy. We classified this as a serious adverse event, because the author stated that it was possibly associated with shockwave induced penetration of the calcium deposits into the adjacent subacromial bursa. However, the authors do state that all patients went on to show significant clinical improvement.

Michael Chang: Did they use local anesthetic to infuse to the treatment area? Do you know?

Erika Brodt: I do not know the answer to that. We can find out, though. Cassie, can you look up, it was an RCT in shoulder tendinopathy that reported acute bursitis subacromialis? I can't remember which one it was off the top of my head. Whether they used anesthetic? Is that what, yes? OK.

Michael Chang: Because some clinicians, without understanding the mechanism will try to reduce the pain through the treatment by infusing anesthetics to the treatment area, which is a no-no, because the fluid there is going to induce more cavitation. More cavitation means more local tissue injury. So, you always have to block the nerve, proximal to the treatment area, not infuse anesthetic to the treatment region.

Erika Brodt: OK.

Michael Chang: That's a big no-no. So, you need to find out.

Erika Brodt: OK. Thank you. We'll find that out. The second serious complication listed is allergy or reaction to anesthetic, and this was reported across two RCTs looking at elbow tendinopathy. There were five events in both treatment groups, focused shockwave and sham, over the course of the trial. The frequency was similar in both groups and of note, these were the only complications reported to occur in the control groups, and these were likely just local reactions. No authors mentioned systemic complications or anaphylactic shock or anything like that. There were two patients who sustained midsubstance plantar fascia tear during the course of the trial. This was one trial in plantar fasciitis and it was focused shockwave therapy at high

energy. One of the patients, there were some details regarding one of the patients. It was a female, and she sustained the tear after vigorous activity four weeks after shockwave treatment. However, the author stated that this patient had undergone multiple cortisone injections with the most recent being five weeks before shockwave therapy. No details were provided regarding the other patient.

Michael Chang: Just another comment, because cortisone injections, which are so vastly used in the clinical community, the tissue has to be under constant tension or force. It is not a good idea to inject cortisone, especially multiple injections of cortisone. Actually, that makes the shockwave treatment much less effective actually.

Erika Brodt: Mm-hmm.

Michael Chang: And then we always have to wait three or six months after the last cortisone injections to do the shockwave treatment. The shockwave is trying to induce local inflammation, control the inflammation. If you have a cortisone injection there, that will defeat the purposes.

Erika Brodt: Correct.

Michael Chang: And then multiple injections can weaken the tissue and make the future treatment very, very difficult.

Erika Brodt: Mm-hmm. Well, it's part of the reason I brought to the committee's attention that caveat surrounding that patient. Also, some of the trials did require that patients had not had a cortisone shot within, I think, like three or six months prior, not all, however. So, this could be one area to consider, because obviously this trial didn't have that criteria.

So, moving on, there were also two incidents of tendon rupture in one trial of Achilles tendinopathy. There were two patients, both female, who experienced the rupture within two weeks of their first treatment. Again, focused shockwave therapy was used at a moderate energy level, 0.2. The authors state that each patient elected to have nonoperative treatment for their injury and that both made unremarkable recoveries. Additionally, we found one case

report that documented another incident of tendon rupture in a female patient two months after shockwave therapy. The energy level was unclear. This patient went on to receive tendon reconstruction.

Michael Chang: Again, sorry, did they infuse the local anesthetic to the local treatment area, or does it . . . for the focused shockwave therapy, did they infuse or they do the block or general anesthesia.

Erika Brodt: Cassie, can you use the microphone, please?

Cassie: To respond to your previous question about the acute bursitis, the study did use local anesthetic for the procedure, and what is the study here?

Erika Brodt: The second study is Costa 2005, two tendon ruptures, Achilles tendinopathy. So, while she looks that up, I'll move on to our last event, death, which is quite serious. There were two cases across two RCTs, one in elbow and one in the shoulder. In the RCT looking at elbow tendinopathy, the patient had preexisting coronary artery disease and died of cardiac failure; however, the authors state the death was not causally linked to the shockwave therapy. In the second trial in shoulder tendinopathy, the patient was only noted as lost to followup at 12 months, and the authors did not provide a description or a cause for the patient's death. So, it is unclear if the death was related in any way to the treatment, and there were no deaths in the control group.

So, moving on to nonserious adverse events, they occurred quite frequently and were primarily expected following shockwave therapy; however, they were also reported inconsistently across the trials. The most common were pain or discomfort during treatment, which some of these ranges are a little bit misleading and, you know, zero to 100 and 5 to 100, but pain or discomfort during treatment is quite common, I think as has been alluded to, this procedure does cause some pain inherent to what it does. There was also transient reddening of the skin, which was fairly common. There were local changes, such as petechiae, bleeding, hematoma, or bruising that were fairly common. There was local swelling and mild or transient neurological symptoms, such as numbness or tingling, and these were more common with high energy.

So, moving on to differential efficacy. We did not find any studies evaluating differential safety. Data regarding this was limited. One trial, which compared focused shockwave therapy versus sham in patients with plantar fasciitis looked at whether sex, age, or body weight modified the effect of treatment and found that it did not. The strength of evidence for that was low. In two trials evaluating focused shockwave versus sham for rotator cuff tendinopathy, energy intensity was found to modify the effect of treatment in direct comparisons in these trials, such that focused shockwave therapy was better than sham when used with high but not low intensity shockwaves, and all other data was insufficient. Three trials looked at whether symptom duration, sex, or calcium formation modified treatment effect, but again, insufficient data.

Lastly, cost-effectiveness, again, we found no formal economic evaluations, but I did provide a little bit of information here regarding cost to give you some context. I also had difficulty finding any more hard data regarding CPT codes or what insurance companies pay, but like Dr. Franklin, I found that the cost of shockwave therapy can range from \$900 to \$3000, and it does depend on the number of sessions, who does it, what other kinds of treatments are involved along with the therapy, where it's done.

Chris Standaert: So, question on cost, I mean, this isn't consistently billed, and all the T-codes or tracking codes, there is no cost. So, this is just sort of what the market will bear.

Erika Brodt: Right. This is not . . .

Chris Standaert: This is a cash business of what the market will bear.

Erika Brodt: Right. Correct.

Chris Standaert: So, tracking costs is quite difficult.

Erika Brodt: Correct. Exactly, and I searched quite a bit and came up with the same range that Dr. Franklin did actually, and it's hard to nail down exactly what the components are and give you a good breakdown of the cost, but as you can see, it's not cheap. High energy, while I was looking, seemed to cost a little more than low energy, but you might only require one treatment they were saying was maybe a

benefit of that, but, again, it's really hard to tell. Any questions?

Chris Standaert: I doubt there will be any of those.

Gregory Brown: Actually, I don't have any questions. I have a lot of comments.

Chris Standaert: Well, that's another slide. We can't go there yet. Alright. So, this is our chance to formally, at least, ask questions about the evidence report, but our vendors will be with us through our discussion. So, we have a bit of time to talk about our questions. We don't want to blend too far into the . . . what we will discuss as a group, but certainly questions on the presentation data and other things are quite pertinent at the moment. Dr. Walsh? You guys want to just go to our questions? Yeah, let's just do our questions, then we'll take a break.

Kevin Walsh: I'm interested in why the analysis of the RCTs was limited to what I would call relative improvement, as opposed to absolute improvement. I know that a lot of the studies present their data in terms of relative improvement, because it's a way of, I would say, stacking the deck in the favor of the treatment. If we go back to Dr. Franklin's slide, number 10, when he broke out the additional scores for plantar fasciitis, and it showed quite succinctly that there really was no benefit when you looked at a more absolute level, they're using a VAS score. So, a VAS improvement from therapy to control might look statistically significant, but as he pointed out, if the VAS score is still greater than 4, it's probably not functionally significant for the patient. So, we've asked in several retreats that information be presented in absolute not relative terms, and I'm going to ask again and we'll keep asking for this information to be presented to us in absolute, not relative, terms, or if that's beyond the capability of the vendors to do, to give us the studies and let us do it if we want to spend our time doing it, because to look at relative, statistically significant relative improvement is like looking at the sun through a wall to me. It doesn't mean anything. I can't . . . I know that I am forced to make a decision based on this, but I feel like the vendor has the responsibility to help us understand the studies. When the studies present their findings in what are I would

say subjectively favorable ways, it doesn't help us really get to the meat of, is this really a benefit to the patient or not.

Chris Standaert: Erika, do you have a response or do you have any comment from this group? That wasn't really a question, but it was a statement, but certainly there are some questions in there.

Erika Brodt: Well, again, I mean, we are at the mercy of the literature, and I will take into consideration that request to look at absolute rather than relative differences in the future.

Kevin Walsh: And I would also ask . . . a lot of these decisions are based on one RCT. So, I would say, I don't need all 15 RCTs that were included in the analysis of the study. If one RCT is really what swings it, give us the one RCT. Give us a link so that we can look at the numbers ourselves.

Chris Standaert: Yeah, Greg.

Gregory Brown: I think the other issue there is the classic industry funded RCT as a weak comparator, be that a placebo, which most of these were, or be that a dose of a medication that's so low it's not effective or so high that it causes side effects. So, to me, that's what this literature is showing and welcome to my world as an orthopedic musculoskeletal literature in evidence.

Chris Standaert: I have a question for you on blinding in these studies, this seems very difficult to blind, right? I mean, this is . . . you feel this. This hurts. It's a high energy shock into your body somewhere, and you're not supposed to put local anesthetic where you do it, and that's what some of the studies did. Putting a metal plate over the heel and saying, or whatever the plate was, it seems . . .

Erika Brodt: A plastic plate, yeah.

Chris Standaert: So, what I didn't . . . I looked at a few of those studies, and I didn't see things about how effectively blinded people were, and I'm bothered by these rates of complications of zero to 100%. That doesn't help me, frankly, at all.

Erika Brodt: I know.

Chris Standaert: Right? So, to say that is essentially meaningless. You know, some idea of if, you know, pain is near ubiquitous, the study is saying it doesn't hurt are probably flawed, right?

Erika Brodt: Right.

Chris Standaert: If not biased or if not overtly distorted or made up, right? So, that's troublesome that they get thrown in the mix and that we can't sort this out, and do you believe the zero or do you believe the 100?

Erika Brodt: Mm-hmm.

Chris Standaert: And I have trouble with this whole concept, again, of how effectively this is all done in these studies without people reporting results, efficacy of blinding and does it work and the complication rate. It's all . . . it just raises a lot of concerns about the body of literature that we've been presented.

Erika Brodt: Those are great points, and there were a lot of flaws in these studies. I mean, small sample sizes for one, blinding was an issue in some of them, although some studies did try to do a good job of blinding the person doing the treatment, giving them some kind of systematic way of speaking to the patient and talking to the patient, however. Lots of investigators were not blinded, couldn't be if they were using sham versus an active control. I agree there are inherent limitations in these comparisons. The studies, some of them did the best they could, I think. Others, it was more unclear, but you're right. When you're giving someone a shockwave and they can feel it, and in the sham group they're not, that's a problem for sure. As far as comparing, obviously, shockwave to a conservative treatment or corticosteroid injection, blinding is just not possible. So, again, sadly some of these studies were well done, and some of them were poorly done, which is why we tried to stratify in the forest plots based on whether the study was better quality or lower quality and try to frame whether the better quality studies agreed with the overall conclusion or not.

Joann Elmore: I have seven comments. First, I would ask going forward that our evidence vendors help us to understand conflicts of interest in the publications. I had to dig through and the

first slide lists five RCTs of moderate to high ‘quality’ according to your scale, but almost all of them had funding, and that is important. Secondly, I agree with our request to get data in absolute terms, as opposed to relative terms. They are often used by the authors, because they sound better, but we care about outcomes and data and evidence, and we need to dig deeper. In the tables when they give the wrong numbers, it should be able . . . you guys should be able to help us with that. I agree, that would be much appreciated. Then, this third point is that many of the papers listed 20 different scales that they had assessed on these patients, and it seems like we were picking and choosing, kind of, the scales in your many different tables, but I worry about multiple comparisons and did they use the Bonferroni correction, etc. So, I did worry about cherry picking on some of these, either the authors may have done it, or we weren’t informed of it. Four, I did appreciate your trying to throw in the information on the minimally clinically significant difference, because I need to know that for some of these scales. Some of you have expertise in this area. I am a general internist and an epidemiologist. So, I needed that help, but things like a VAS score that improves in the treatment group from 7.7 to 3.4 versus in the ‘placebo’ group 7.7 to 4.1, you know, that’s statistically significant, but we need to get the clinical significance. So, it helps me when the vendors or experts talk about both quality reviews, not just using your concrete score but digs a little deeper about the evidence. So, that’s four. Number five is, the quality of the blinding. Some of these ‘placebos’ the therapist was aware of what the treatment was. They used block randomization, blocks of 25 and they only had 50 people. I mean, I question the rating scale when one actually looks at some of the details of the studies. That’s five. Number six, this gets back to one of my earlier questions about harms. We’re evaluating a technology, first we must do no harm, as clinicians, and I was also disappointed, as Chris was, the range of potential pain and harms is zero to 100%. I don’t know if any of the studies used standardized pain assessment to find out in intervention and placebo, did this hurt, because I would care about that. I see this subjective sentence at the end, only two people said it hurt in the treatment, but I didn’t see in the methods that it was gathered in the standardized way. So, I’m left, as a committee member, not knowing how painful is this procedure. I’m hearing nerve blocks and

things, and that, indeed concerns me and is something that the committee needs to pay attention to. So, that's five, or that was number six. Number seven, in the end of our discussion we go over the guidelines, and in looking . . . and I appreciate the detailed review that everyone does on this. They picked out Colorado State guideline, because they had mentioned it, and my question is, well my question is the converse is the lack of approving and mentioning it, does that mean that people have actually reviewed this and are just not mentioning it, because they don't want to include it? So, I'm wondering about the converse of all these guidelines, because we're showing two or three very small groups that may have a guideline, but all the other states that don't approve it, does that . . . how many of them have actually reviewed the literature. So, those are my seven quick comments.

Michael Chang: So, a quick answer, the pain. So, the focused shockwave treatment is very, very painful, and you have to use nerve block, and a lot of people, when they start it, it is actually . . . people use general anesthesia plus the nerve block.

Joann Elmore: Good to know.

Michael Chang: Yeah. Then, at UW, we treat athletes, we use conscious sedation. So, in the middle of the treatment, actually the patient wakes up, it is very painful, yeah, but for the radial pressure wave, radial pressure wave, I don't call it a radial shockwave device, by the way. So, radial pressure wave device, you can treat it in a clinic without block actually. Also, the treatment, if you treat a patient, start from low and kind of ramp up the energy and the frequency, then usually the patient tolerates it very well, including the focused shockwave actually. So, there's a technique you do that you could make the patient more tolerable.

Joann Elmore: Tolerable, but that means that it's notable by the patient.

Michael Chang: It is notable.

Joann Elmore: So, a placebo is hard?

Michael Chang: Yes.

Joann Elmore: Thank you, so much. That's very helpful.

Michael Chang: You're very welcome, yeah.

Chris Standaert: That sort of brings up one other word I heard more times than I'm comfortable with was heterogeneity, frankly. So, a lot of heterogeneity in study, study design, and application of the modality and measurement of outcome and defining of primary outcome, and reporting of outcomes and reporting of complications. I mean, it's like trying to put my thumb on . . . we've had this before. What is it? What is the standard treatment? So, and then, what is the way to do it. So, is there . . . do you block people. Do you put them out? Do you sedate them? What do you do with it? How do you administer it? Is there some certifying body to tell you that you're competent to do this? It isn't just like you put a wand in somebody and zap them. There are different depths and different things in there and probably people who, like Dr. Chang, really understand the physiology of what they're doing, but I don't know that's mandatory or standard or accepted or any of that. All that really kind of bothers me. I'm having trouble putting my finger on what exactly is this. How many treatments are we talking about? What is the intent? What is the mechanism? What is the . . . and then again, this heterogeneity of study design, outcome, blinding. It's like, are they studying the same thing, right? It makes me wonder all that a bit. So, that sort of bothered me as we went through that.

Erika Brodt: Yeah. Well, this was, this was difficult literature to go through, for sure. That's why originally we tried to stratify . . . or we were going to stratify on high, low, medium, whether they used anesthetic or not, and because of the variability it left us with a single study here and there for various things. So, we grouped them and tried to acknowledge where there was heterogeneity and account for where that . . . why that might be, either based on the quality of the studies or based on some of the study designs or the patient population, but this is definitely an inherent limitation of the literature. Again, the sample sizes of these studies were very, very small. I'm talking 20 people, 30 people, 50 people, and when I presented the background, as Dr. Franklin said and I have said, there's just no . . . there is no standardization currently, because no one agrees, I mean, they don't know the mechanism of action. So, I think that impacts if that's the case how do we standardize? Is low better than high? So, I think there's a lot of inherent

limitation in the literature out there currently regarding this treatment, and we did our best to try to present it in a homogenous way, but it was difficult. Again, multiple pain outcomes. We focused on primary outcomes, all of which we get from our clinical experts. We don't just pick them. We talk with our experts, and they help us decide which to focus on.

Chris Standaert: The authors should be defining that, right? A paper should have a primary outcome.

Erika Brodt: And they do, and if they define it as a primary, often we will report it as such, yes.

Chris Standaert: But some of which makes me worry, you know, the . . . your grading scale. We have the moderate, low, and high.

Erika Brodt: Mm-hmm.

Chris Standaert: With all that, I mean, high in the grade systems means you have very high confidence that future data will not change the outcome. I have trouble understanding how you could come close to deciding that on this, from what I saw. So, I just question that, you know?

Erika Brodt: Mm-hmm.

Chris Standaert: You rated these as fairly high compared to some of what we see, but then it's mixed with this underlying . . . lots of small heterogeneous studies.

Erika Brodt: Mm-hmm.

Chris Standaert: Which, I just . . . the consistency part and the bias part and the industry funding part, and it all sort of bubbles underneath it that made me . . . that troubled me also.

Erika Brodt: Mm-hmm.

Joann Elmore: Were your ratings of these papers done by two of your staff independently?

Erika Brodt: Correct.

Joann Elmore: OK.

- Erika Brodt: And then we resolved any disagreements by consensus. There were only a couple of instances where there was high quality evidence. I believe one was for plantar fasciitis in the short term for some pain outcomes. We did have high and moderate for, I believe, like adhesive capsulitis and I can't remember.
- Chris Standaert: Again, you had so few studies on adhesive capsulitis, and they're so troublesome. One of them wasn't even in PubMed when I went looking. I mean, it's . . . to say that's high is troublesome.
- Erika Brodt: Yeah, and that, you know, that could be an inherent limitation of grade and how we apply it in some respects, you know? And we have actually talked about this within our own institution, but following the processes that we implement in an objective fashion, as much as possible, that is what we arrived it with, yes, obviously the caveats, one small study, can't really say much. I wouldn't probably expect you to based on one small study. I did want to address the minimally clinically important difference. This is another area that is difficult with the literature identifying what is clinically meaningful, because that really, I know, is what's important. We have tried to focus on a percentage of patients, a proportion of patients who achieve some kind of success that's based on guidance by Cochran, the Cochran handbook. Those are also called responders. So, that tends to be what we look for first, because that's usually based on some kind of evidence to suggest that that's a good indication of patients who are showing good clinical response to the treatment, but we did report the mean differences, as well, and they can be misleading, because when you look at a minimally clinically difference of 1.5, if patients have a . . . if there's a difference between groups of 1.4, does that mean no patients do well? It's not clinically important? The same way of 1.6. Does that mean all patients do clinically better? No. I mean, it doesn't account for variability. So, we try to report both measures to give you guys both pieces of the puzzle in a sense, but that is difficult currently, figuring out what is clinically meaningful.
- Michael Chang: So, we can appreciate the RCT is very difficult and very costly to run an RCT. Remember, almost 40 years ago, the lithotripsy machine was brought to the market and started

to be used in the clinical setting, because that RCT was very easy, because you either break the stone or you don't break the stone in the OR. So, when we first get the OssaTron, which is the high energy device, at the UW, we practice using the device to shock the stone, because they have a protocol provided by the vendor. In 200 shots, you have to break the whole stone, 200 shots. So, we practice in the lab. If our technique is not used correctly, you either use it 1000, couple 1000 shots, or you never disintegrate the stone. If you didn't put the gel on, conduction gel, you never break any stone there.

Carson Odegard: Who did you practice on?

Michael Chang: Well it is a simulated stone. We do it in vitro. So, I think that all the clinicians need to learn from the basic shock of the stone to learn how to use the device, and the clinician needs to understand the mechanism. Once you understand the mechanism, you will design the RCT. You will not fail the RCT actually.

Chris Standaert: But there isn't a certifying body or a standard thing. Or there isn't a medical organization that defines practice parameters for this?

Michael Chang: No. Actually for almost 40 years, people in the lithotripsy communities, basic science people, engineering, physicists, had studied this technology a lot, but that knowledge is very hard to . . . until the clinical setting. That is the problem. A clinician has to understand, that is our limitation, because we don't understand the mechanism. We do not understand the mechanism. Once you understand the mechanism, you do not need an RCT. The rest of it is engineering based on the patient, patient's anatomy, where is the problem, and then you decide your treatment protocol.

Gregory Brown: I'm sorry. I can't disagree more. I mean, randomized control trials are level one evidence for therapeutics. Basic science, which is what you're describing, is level five evidence. I'm a Ph.D. engineer. I understand where you're coming from, but that is not how evidence is defined.

Michael Chang: In the regular settings, you have to approve a device, the building, and so on, you need a large population to test the technology.

Chris Standaert: Part of it is, people are complicated, and they're not math equations, and pain is very complicated. So, that's where it becomes tricky to say that if people all followed rational physiology, pain would be much easier to take care of.

Michael Chang: I understand, but . . .

Chris Standaert: Dr. Odegard had a comment.

Carson Odegard: Yeah, I'd like to get back to the safety and harms, because I would have liked to have seen this parsed out in . . . we talked about pain. Pain was one thing, but tissue changes are another. When you go from zero to 100%, and we talked about this, as well, I just can't imagine anything being 1% to 27%, 1% of local swelling. I mean, the whole idea of the procedure is to promote swelling, bleeding, petechiae, hematomas, the whole thing. I would imagine that everybody would have that, and if they didn't, then it didn't work. So, it would be . . . when you say zero to 100%, is that because you're using a radial technique versus focused technique, because the focused technique would cause all of that, I would imagine.

Chris Standaert: One would think. Right. Unless there are more questions right now, we can take a quick break and come back at 10:40. Do you have a comment?

Erika Brodt: Well, I did just want to address the funding issue. I anticipated that question, actually. I didn't include it in any of the slides, but I did look up the funding for each of the studies, and 17 were industry funded, that's out of the 59; 11 had grants from various government or educational institutions, and unfortunately 31 did not describe where their funding came from, some of which did say that the authors had no conflicts of interest. They made a brief statement to that effect, but I just wanted to provide that for your information.

Chris Standaert: Thank you.

Gregory Brown: Actually, could I just add one clarifying thing. You mentioned using this technology for knee arthritis.

Erika Brodt: Knee osteoarthritis.

Gregory Brown: Right. We're not talking patellar tendonitis, we're talking knee arthritis?

Erika Brodt: Correct.

Gregory Brown: OK.

Chris Standaert: OK. We're going to take a break until 10:50 by that clock. Then, we'll go through our process. That's 12 minutes. It's 10:50.

Alright. If people could take their seats, we'll get started again.

OK. This is the committee's time to talk amongst ourselves about what we think and eventually we get to the point where we make a vote here. We still can ask questions of the evidence folks. Dr. Chang is here, and part of our discussion. He can help us with that, too. There is a bit to wrap our heads around here in terms of heterogeneity and what we think of all this.

Gregory Brown: I'd like to make three comments.

Chris Standaert: You can make whatever you like.

Gregory Brown: One is, the AOFAS outcome measures have never been validated. So, actually . . .

Chris Standaert: The American Academy of Foot and Ankle?

Gregory Brown: American Orthopedic Foot and Ankle Society.

Chris Standaert: OK.

Gregory Brown: Their measures have never been validated. So, actually, the American Academy of Orthopedic Surgeons have reported patient reported outcomes for foot and ankle, it is not listed as a recommended outcome measure. So, just an FYI. I mean, I don't think it makes a big difference, but second of

all is, calcific tendonitis versus other tendinopathy in the shoulder are two totally different animals. So, we have to . . . I think we have to think of them separately. I mean, they may come out the same answer, but I think we need to think of them separately. The third one is, I co-chaired our clinical practice guideline on osteoarthritis of the knee treatments, nonoperative treatments, and this wasn't even, we didn't even look at it, there was so little evidence. So, I'm actually baffled that there is evidence on it. So, anyway . . .

Chris Standaert: Those are the questions you start to ask when you start your search.

Gregory Brown: I'd never even heard of it for that. That's why I clarified, are we sure we're not talking about patellar tendonitis here, because that's what everything else is a tendonitis or an opathy. So, anyway, those are my comments.

Chris Standaert: Understood, yes. I thought the same thing about the calcific tendinopathy versus, like, saying rotator cuff tendinopathy is a very distinct phrase. I think of calcific tendinopathy, which is its own predicament. Whatever illness you may ascribe to it, actually, but yeah.

Gregory Brown: I mean, I think the other thing is, is just a discussion of what I call the physiology of aging. So, the acromial spur is just calcification of the acromio-, coracoacromial ligament, you know? The calcaneal spur in plantar fasciitis is just calcification of that tendon at its insertion site. It's . . . I don't think . . . I think it's just purely aging. I don't think it has anything to do with some pathology, per se.

Chris Standaert: We certainly didn't get data that would suggest that from what we saw. So, some, so correction. Dr. Chang, hold on.

Carson Odegard: Just in one of the articles I was looking at, they talked about ruling out Baxter's neuritis in the heel before doing this treatment, because the treatment could actually injure the . . . or it's a swollen what lateral plantar nerve. Have you run into that at all?

Michael Chang: So, that is a good question. People have done studies using shockwave to, a very high energy focused shockwave directly to the nerve, actually neurovascular bundle is

actually at the femur triangle. So, it includes the femur nerve, femoral artery, and then femoral vein using very high energy, the highest energy you have to shock those areas. These are animal studies, and they found out that the nerve has very minimal injury, very minimal injury. However, you can . . . clinically, you can evoke the action potential of the nerve by using high energy shockwave applied directly to the nerve. There is no injury from histological studies. The most injured tissue is actually artery usually. Artery has a lot of injury, because the mechanism . . . because of the cavitation injury to the vasa vasorum, the small vessels of the arterial wall, and because the high pressure is inside the arteries and actually sometimes cause pseudoaneurysm over the artery.

Chris Standaert: If you want to finish the question, that's fine. I just want to start with some idea of where we are.

Carson Odegard: I was just asking if you'd run across a situation where you have to rule out that kind of neuritis versus the pain from the tendonitis, itself.

Michael Chang: Yes. Usually, we would do, in my clinic, we would do an electrodiagnostic study if we have those suspicions. We would do an electrodiagnostics to rule out the nerve conditions before we treat the plantar fasciitis.

Chris Standaert: So, to start talking about where we are and where we go from here, we have to think about this on a couple levels, I think. We have somewhat heterogeneous treatments that we were given, different ways of delivering this particular treatment, and we certainly have heterogeneous conditions, which are being treated, knee osteoarthritis versus plantar fasciitis versus calcific tendonitis. These are not the same tendinopathies. These aren't the same thing. We can parse them all out if we think they're worth parsing them all out. We can take a more gestalt view if we think there are common themes that run through the literature for us, or common impressions or concerns people have, but we have to start thinking about how we define and work through this a bit, I think, to help ourselves along. If we pick off the individual trees, we might miss the forest here a bit, so.

Gregory Brown: I'm often a splitter, but I'll be a lumper on this one. My earlier comment was is that virtually the only time they found any success with this treatment was comparison with placebo or sham, and I don't think that's a fair comparison, you know? We have other active treatments for all of these conditions. So, comparing them to sham or placebo is of no value to me. So, I would propose that we do not approve this technology for any of the conditions that were reported on.

Chris Standaert: So, as a lump sum, it did seem that whenever there are active comparators put in, which were not terribly radical. Some are exercise and stretching and other things, which are fairly standard.

Gregory Brown: Corticosteroids.

Chris Standaert: Or corticosteroids. The differences faded.

Kevin Walsh: Or they performed worse

Chris Standaert: Or performed worse, right, when you started using more conventional treatments.

Tony Yen: I favor your comment in many ways, and what is kind of curious to me is that, the only, I think, positive parts of these studies, or at least with the literature that we have available, was actually with osteoarthritis, which was . . . and I was trying to make sense of that, you know, just from a physiologic sort of standpoint, but regardless, that's the only part of the literature that I saw that actually favored the intervention with extracorporeal shockwave therapy. I would suggest an approach of looking at the literature maybe, and I guess I'm a bit of a splitter, so looking at the literature as comparing the intervention of extracorporeal shockwave therapy against some sort of standard intervention rather than looking at just sham. I think looking at sham just verifies whether or not this technology doesn't make a difference or something like that compared to basically doing nothing, but I think we do have other treatments that are available now.

Gregory Brown: I mean, again, so in addition to co-chairing the guideline, since that time we've done a separate meta-analysis on hyaluronic acid that's been published. We've now got a

network meta-analysis of nonoperative treatments on knee osteoarthritis, and I've never even seen it mentioned as a treatment in all the background of those. So, I mean, I'm not denying it's out there. It's just having treated knee arthritis my entire career, I've never even heard that this was a treatment option.

Chris Standaert: Well, I mean, in some ways if there is, you know, high quality that existed, you know, there we'd look at it, but I'm not sure that's the case here, right? So, a study that exists somewhere in the ether, again, with limited pathophysiology and small sample sizes and everything else gets troublesome.

Gregory Brown: We did have a similar event when we developed the, you know, we wanted to look at, you know, exactly what's the question that you asked. So, we asked about basically diet supplements to treat knee arthritis, you know, wanting to look at chondroitin sulfate and glucosamine and things like that, and we found two studies on ginger extract that were published in English out of Iran. There was no counter studies. So, but ultimately we said as a committee that this is just such an uncommon practice, we're not gonna comment on it. So . . .

Chris Standaert: Knowing physiology and all sorts of other reasons get in there.

John Bramhall: I thought there might be a diamond here somewhere, but I couldn't find it, and the problem with our approach . . . so we've asked, we invited the vendor to produce a reasonably exhaustive review of the extant literature, and, I mean, without mincing words, an awful lot of that extant literature is not very stimulating intellectually. So, the problem you have with lumping is that my tendency is to say exactly what Greg and Kevin might be saying. It's to say it's unproven, there's no clear signal here that there's a benefit that we would want to pay for it and all the rest of it, but on reflection, that's sort of tainted by the fact that a good proportion of the literature is then filling in my lumping area is just really it shouldn't be there. So, subjectively, I'm looking for the key study, the key bits of evidence that would show that for one specific isolated pathology with a more closely defined modality of treatment, that it did

crystalize out to be something that would be worthwhile to offer to our state population.

Chris Standaert: Did you see that?

John Bramhall: I didn't find it. The concern I have internally is that no, I'm swishing around, this is all very unsettled. The evidence is poor. The studies . . . we don't even know whether some of these people know how to hold the probe. We don't know anything about the energies involved. We don't know anything about really when we divide it out to this pneumatic system versus a [inaudible]. These are very different, and yet we're putting them together intellectually. Can't help it. So, it's very problematic, and what needs to be done clearly is some coordinating force needs to determine a set of studies that are clearly articulated and are clearly run properly to try and nail some of these things down, and that's the function of the NIH or, you know, that's their function, right?

Chris Standaert: Yeah.

John Bramhall: They haven't been done.

Chris Standaert: Right. I think to, you know, we only get what we get, right? So, the idea that there's a lot of noise in the background . . . well a lot of it . . . it's almost all noise is what it comes out to. Then, the question we always come down to is this issue of what? We have coverage under no . . . coverage universally, no coverage, or with conditions, and conditions means we're drawing circles. We're finding the diamonds. We're finding spaces where we think there's data to support some efficacy, safety, cost considerations, and I don't . . . and whether it's that it gets washed out or whether it's not really in there because of all the uncertainty and heterogeneity we discussed before is another question that people have to sort of run through in their head. What do you think, Chris?

Chris Hearne: You know, as far as lumping and splitting, I guess I approach it as looking at the conditions for which it's most well studied, and that appears to be the best evidence out of everything, which is sort of the plantar fasciitis and lateral epicondylitis, and then everything else. So, just looking at those two conditions, which seem to have the most robust

evidence, they work only in comparison to sham and only for short term pain outcomes, not so much function, and we already have reasonable therapies for these usually self-limited things. So, ideally, if you were looking to see that this technology is efficacious, you would want something that is effective in people who fail those conservative therapies, people who fail PT, people who fail steroid injections, activity modification, but even this relatively high quality evidence doesn't give us that. It only shows us that it has short term pain outcomes, and it does not tell us, this is going to work. This is going to be a good option for people who failed that. We have no evidence that suggests that. So, I guess for me, even in those conditions for which all the concerns about the quality of the evidence notwithstanding, it doesn't look that good to me. Then, another thought is just, you know, it's not our, I guess it's not our job to police people's clinical practice, but my impression, just from what Dr. Chang is telling us, there are a lot of ways in which these studies were done where safety practices were not observed and my intuition is that if even in studies these things are not observed, you know, for example, anesthetic and waiting an appropriate amount of time between corticosteroid injections and things like that, even in studies these safety practices were not observed, my sense is that in clinical practice, they're going to be observed even less. So, that's . . . we have to think about how it actually gets used in the community, as well, I think.

Chris Standaert: And part of our conundrum is defining what we're talking about, right? So, what is it that we're . . . if we cover it, what is it that we're covering, but then that issue, the purview of conditions under which it is safe and appropriate are ours to define, as well, should we so choose, right? So, when you think about a technology, you know, we've done this a number of times where we have drawn out exclusion criteria or circumstances in which it should be done or whether there is, you know, a certifying body that sort of certifies an organization do it or a person to do it. We have sort of relied on those at various points. It's a lot harder when that doesn't exist, right? Because then you're sort of, what are the standard protocols? What is that and what is the standard safety approach, and how do you make sure that if it's done, it's done safely so that people have the requisite training to be doing it. They know how to turn the machine on. They know where they're going, and they know what the contraindications are, so they're not doing

it . . . they don't do a steroid injection Friday and this on Tuesday, and they don't put a ton of fluid in there and cavity, you know, all the things that Dr. Chang was talking about, but how do we . . . how do you wrap your heads around that, because that is part of the purview of maintaining a safe and effective medical practice for the state. So, I think those are reasonable things that will be running through your head, you know? What do you think, Joann? Are you a lump, splitter, see a diamond? I have to ask.

Joann Elmore: I guess I would almost ask for a straw vote to see whether there are any conditions that other committee members feel should be called out. Otherwise, I split everything. I look at all the details, but I see nothing there. So, I would just ask if there's any other discussion that's needed about any specific disease entities, because I don't see any, and I'm ready to move forward.

Chris Standaert: It seems like we have a fair amount of uniformity here in discussion. So, I think we can move on, and I guess that actually will come up, as we go through this if somebody really thinks there are circumstances.

Chris Hearne: I just want to ask one question for the group. Is there a reason to linger over the tendinopathy versus calcific tendinopathy distinction? Do you think there's a reason to get into the weeds about that?

Gregory Brown: Again, as a shoulder surgeon treating shoulder tendinopathy, I would say that the gold standard of treatment for calcific tendonitis, and I think it is a tendonitis, not a tendinopathy, it's a deposit of calcium crystals. So, I think it is different is ultrasound-guided aspiration of the calcific deposit or barbotage is the term that's often used, but where it's aspirated under ultrasound guidance so that you're actually removing. It's a paste. It's not like a renal stone that you're breaking up. This is a paste that you're sucking out. So, the pathophysiology doesn't make sense to me in this case.

Chris Standaert: I think the point is that the . . . the point here is that there are different diseases, right? So, a tendinopathy from a calcific process, like calcific tendonitis or whatever term you want to give it are different pathophysiological processes,

but even that being said, if you still don't think there's any great data to support it one way or the other, recognizing that clinicians are different is fine, but you can still accept that in the setting of this, the data didn't really help you pull out one versus the other. Yeah, Carson?

Carson Odegard: Yeah, I was kind of surprised I ran across the recent AETNA policy paper that they wrote on this, and out of all the 25 things that they reviewed, the one thing that they covered was calcific tendonitis, which really surprised me. Where did they get that? From what we're seeing in the literature, unless you've seen it or the vendors have seen some robust literature on that, I thought that was kind of surprising.

Chris Standaert: Yeah. I saw that, too.

Michael Chang: So, for enthesopathy, all calcified enthesopathy, dystrophic calcification, we have done some studies with bioengineering at the UW and tried to use high energy. So, high energy focused shockwave device in vitro, some in vitro study when I stewarded the faculty at UW, and clinically, I did only a few cases where I spent a lot of time studying and actually did it. So, for those cases, what we find is the shockwave will deposit the energy at the interface. That's where the acoustic waves always behave like that, at the interface. So, the insertion site is, the bone and soft tissue interface, that has a lot of energy deposit there. Then, shockwave, the physical effect of shockwave has two effects, one is sheer force, and the other one is cavitation. So, to disintegrate the calcium, you need both of them to be effective. So, the renal stone, why we can do lithotripsy to break up renal stones so easily with a couple thousand shocks is because renal stones are in urine, sitting in the renal pelvis in most cases. So, the cavitation needs fluid there. So, for the calcification of the tendons, they don't . . . you do not have a lot of fluid there. You only have a blood vessel, and they release a very minimal amount of bleeding there, not enough to break up the calcium. So, the sheer force, itself, is not enough to do the job. What it helps is actually probably still back to the local inflammation. The inflammation, controlled inflammation induced the area to bring in the healing and the treatment also bring in some pain relief, short term pain relief, but the long term, so we're looking for healing or resolution of the calcium. The calcium is still there, but the patient had better function,

better pain relief, and there are some studies that show in the long run, they show the calcium reduced, but it is not a remarkable reduction. Breaking them up is probably from the inflammation that helps the healing and helps the macrophage or those other cells to take care of the calcium, yeah.

Chris Standaert: We're going to move to our tool. This is on page five of our decision document. So, the point of this tool is two-fold. One, we need to document that we went through all these different considerations, that we thought about safety, cost, and efficacy based on the data that we had. So, we just need to sort of document how we talked about that and went through it, and that's a useful thing. Then, if there are concerns, they start becoming apparent in here to people about what they are concerned about or impressed by good, bad, or otherwise.

So, we'll start with safety. So, adverse events that have been prepopulated for us are things like anesthesia reaction, meaning the . . . that's actually fairly significant if you start thinking these people need conscious sedation or general anesthesia. So, that's not a minor concern, exactly. Local anesthesia is less of a concern, but the sheer fact that you need to be thinking about conscious sedation or general anesthesia because it hurts so much is a problem. So, that would seem to be a significant concern just in the fact of doing it.

Joann Elmore: I would add to this list, I mean, this is safety. I consider that harms of the technology and the technology hurts, and I think just pain from the technology, to my mind's eye, needs to be included here.

Chris Standaert: Pain is a fairly important outcome, also.

Kevin Walsh: Except it's the only one that they reported.

Chris Standaert: Right.

Joann Elmore: Well, they don't report on it, which is, yeah.

Chris Standaert: Yeah. They don't all report on it.

Joann Elmore: Oh, for the outcomes. They don't . . .

- Chris Standaert: Highly variable.
- Joann Elmore: . . . report on the outcome of how painful was the procedure.
- Chris Standaert: So, things like fascial rupture, tendon rupture, are fairly important. You tear the plantar fasciitis, you're kind of in trouble. Death, obviously death is a tricky one in these studies. Is it really causally related to the intervention or not, but there are some fairly strong biological effects. So, it seems like a low concern that that's an important outcome but of low concern that it's going to be causally related to this procedure, but fascial tear and tendon rupture look like they occur, depending on technique in some ways, and that would both be problematic. So, it seems, in terms of, like, safety, I mean, this is more than we typically have for some of these things, right? We have direct tissue harm from the procedure. We have procedurally related complications to be worried about, and we have pain associated with the procedure, itself with bleeding and ecchymoses and all sort of other things.
- Gregory Brown: I agree with the pain, the tissue injury is, I mean, the whole point of the procedure is to deposit energy in the tissue. So, to call that a . . .
- Chris Standaert: You're inducing harm essentially by . . .
- Gregory Brown: But I mean, you know . . .
- Joann Elmore: The harm leads to an improvement.
- Gregory Brown: Correct.
- Chris Standaert: In surgery, you induce harm too.
- Gregory Brown: Well, right, yeah. Exactly. Making an incision on anybody is the harm, but it was intentional.
- Chris Standaert: Right.
- Gregory Brown: So, I guess that part to me is . . .
- Chris Standaert: Less consequential.

- Gregory Brown: . . . less consequential.
- Chris Standaert: But these you have actually tearing the fascia or tearing the tendons, which is more consequential than just the short term effects of local tissue injury, because that's actually intentional is what you're saying.
- Gregory Brown: But I mean, again, one of the . . . at least for lateral epicondylitis, one of the treatments is percutaneous release of the tendon. So, again, intentionally tearing that fascia or insertional attachment. So, to say that that's a harm when it's the goal of the treatment just is confusing to me. I mean, the fact that the pain is . . .
- Chris Standaert: Right. I mean in this case tearing the fascia, the plantar fascia is not the goal of the treatment, right?
- Gregory Brown: But there is surgical plantar fascial release as a treatment for plantar fasciitis. So . . .
- Chris Standaert: Yeah, we're not doing that.
Kevin Walsh: This isn't . . . this isn't . . .
- Chris Standaert: That's not where we're going.
- Kevin Walsh: This is not an intended consequence.
- Chris Standaert: Exactly. That's why it's a harm, right.
- Gregory Brown: But that's where I'm say . . . I guess that's where I'm pushing back, because, again, if one of the treatments for plantar fasciitis and one of the treatments for tennis elbow is surgical release of the fascia, then calling . . . we don't know the mechanism of how it works.
- Chris Standaert: But that's only fair to say if you have a very essentially identical clinical indication. If you're going to say the same patient population, which you would operate and release a tendon is the patient population for this, then maybe that effect is less relevant, but if you're saying, well we're going to do this rather than exercise, rather than . . . this is very different. We're not going to say to somebody with Achilles tendinopathy, well you can, you know, exercise or we'll cut your tendon. They're pretty equivalent, right? We don't do that. So, that's where it's not a . . . it's not an intended

effect of the procedure, and the procedure, in some ways, is intended to avoid getting to the point where that's a consideration, but if it leads to it, that's a problem.

Gregory Brown: What I'm saying is, it's intended in the elbow and plantar fascia. It's not intended in the Achilles tendon and the rotator cuff. So, it's just, anyway.

Chris Standaert: Alright.

Gregory Brown: So, efficacy. So, what are the more important outcomes we would have liked to have seen? So, not sort of what we did see, but what you guys wanted to see regarding this. What would you have liked to have seen?

Carson Odegard: Long term function.

Chris Standaert: Long term function would be our most important outcome?

Gregory Brown: These are all done for pain. I mean, there's loss of function because of the pain.

Chris Standaert: But we're not, so I didn't ask what they . . . I asked, so the committee, what would they have liked to have seen, right? Would you like to see that people would improve, right? And so does short term pain relief translate into function becomes a relevant question in terms of efficacy, I would think, yeah? So, long term function is what people would have liked to have seen. Do they see it? No. So, no data one way or the other really? How do we deal with the pain thing, right? So, global pain composite improvement, morning pain, night pain, pain activity, or is that why it really becomes about function? Does it matter if you feel better when you wake up in the morning if it hurts as much the rest of the day and you can't do any more, and you're still taking pain medications? Are there more global things more important to us?

Kevin Walsh: They've prevented us from really assessing that, because they report relative improvement in a VAS score, not what the absolute difference is. So, we can't . . . there is no context in which to apply this supposed improvement to decide if it's really an improvement, even in pain.

Chris Standaert: Even in pain. That's the data side of it, from the important side, though, these issues of . . . it gets to Joann's question earlier of, like, you're looking at five or seven different outcomes, and you say, well this particular period of pain is better. Is that more relevant than like a long term functional outcome or long term I don't hurt? It doesn't seem to be, but that's what they report.

Joann Elmore: I think as a committee, we don't want to downplay, for the record, that we do care about patient's pain. We do care about medical technology that can potential help our patients, but the issue with the pain as assessed in the studies is that we have concerns about the study design. We have concerns about this supposed placebo. We have concerns about multiple comparisons. So, it's not that we, as a committee member, don't feel that pain is not important as an outcome.

John Bramhall: My guess would be, and confirmation, that most patients presenting for this type of therapy would be presenting because of pain rather than decreased function that was independent of pain. That's just my speculation. Is that rational? I mean, I think pain is what you go for?

Chris Standaert: It's sort of both.

John Bramhall: My knee hurts.

Chris Standaert: No, but my knee hurts so I can't walk. My knee hurts and I can't run.

John Bramhall: But the concern for the patient is pain.

Chris Standaert: No, no, no. I don't agree with that. So, you can see my plantar fascia hurts when I run, and I can't run. Well, if you don't run, does it hurt? No. Well, then you're fine. You have no pain. That's not a valid answer. The problem is, the pain inhibits the function. So, if you're not measuring the function at the end, you can make pain better without improving anybody's quality of life, whatsoever, if you only treat the pain. I think my own experience, as a clinician, is people really want function. They want to be able to do it. So, saying . . . so that's one of my problems with this. So, I don't have pain. My pain is better when I wake up in the morning, but I can't run, but I can't walk three miles, but I

can't get on an elliptical, but I can't go outside and play soccer with my kids. That becomes a very relevant outcome, and we don't have any of that. So, just saying . . . I agree that pain is important. I don't want to downplay it, but the translation of . . . people come in saying I hurt, but when you get at it, the issue is what the pain stops them from doing becomes the more paramount issue for most people I find, rather than just . . . because most people don't hurt, like plantar fasciitis doesn't hurt all the time if you're doing nothing. If you're just sitting there, it doesn't typically hurt. It's when you do things. So, that's where just making it not hurt doesn't quite get you too far. I think it begins to complicate it. That's my perspective.

Joann Elmore: Let's not split hairs. Function and pain, they're all important to patients.

Gregory Brown: They're separate domains.

Chris Standaert: Yes. And grip strength was another one of our outcomes, which that looked like that was nonsignificant. It's important, but . . . you have a, yes.

Erika Brodt: I just want to comment quickly on the absolute versus relative comment. In the forest plots, we do provide the absolute scores, the means and the standard deviation. We don't give the baseline, but we do provide those scores in the forest plots for you, as well as a pooled estimate.

Chris Standaert: OK.

Kevin Walsh: Is that labeled?

Erika Brodt: Yes. It's labeled.

Joann Elmore: The font was so small. I couldn't read your slides, I'm sorry.

Erika Brodt: That's OK.

Josh Morse: And I take the blame for that. I apologize, and we'll fix that between now and the next time we print these.

Michael Chang: Can I make a comment between pain and function.

Chris Standaert: Mm-hmm.

Michael Chang: OK. So, when people have shockwave treatment, we always advise them the treatment is only for 30 minutes or so, but it takes one month for healing to happen. So, the tissue has to heal, and then you take two months, two extra months for strengthening those tissues, because those tissues, once they heal, they're still weak. So, you have to strengthen them. To strengthen to the level of function that you want to use them for. So, initially after the treatment, people actually have pain relief actually, because you stimulate enough, there is a stimulation that depletes some primary transmitters in the [inaudible] ganglion. You deplete them, and they actually have pain relief, but a lot of people do not understand that pain relief is short term. You want healing. The long term effect is the healing. That takes a month, one month for the tendons to heal. Then, you have two extra months to strengthen them to do whatever the function that you want them to achieve to do. Thank you.

Gregory Brown: So, if I were to interpret that correctly, then basically you're saying any of what we're defining is short term relief is inconsequential, because we're still in the healing process.

Chris Standaert: Yeah. And you're not doing anything because you told them not to do anything because they're, yeah. Cost. There was nothing, I mean, zippo. Cost is important to us. So, I have to say it's an important outcome. The direct cost and the cost-effectiveness and indirect costs and other things would all be lovely to know. We know less than we know of than just about anything, because we don't have any information whatsoever, other than what they ascertained from . . . I don't even know where they got . . . Google I guess. I don't know where they got the data from. Shopping, Amazon.

Special populations. So, we always have issues of age, gender, other cultural sort of factors. We ran into trouble with small sample sizes here. So, again, these are important, and it would be nice to know if we could find these out, but I don't know that they were parsed out. Anybody have any different thought on that? So, again, important but nothing. Alright. You can't pick up your pink cards yet. You can only pick up your yellow cards.

Chris Standaert: So, this is where you take your yellow cards. So, we don't have the more. We don't have the right cards. I don't have a more. I only have three.

Female: Well, we have more of those.

Chris Standaert: That's OK. I'm good.

Joann Elmore: I don't think we're going to need it.

Chris Standaert: That's OK. Everybody should have them. If everybody has them.

Gregory Brown: I don't have a more either.

Chris Standaert: Yeah. Everybody should have a more so it's an option.
Joann Elmore: Just make sure we have unproven.

Female: Nobody has a more?

Chris Standaert: Does anybody want a more?

Joann Elmore: Hold up a pink one if you think you want a more.

Chris Standaert: Fair enough. So, if you want to go more, just hold up any one of your pink cards. That'll be more. Oh, I don't have a some either. No. I don't have a some. I don't have either one.

Kevin Walsh: Here's a some. This is extra.

Joann Elmore: Oh, you have two somes?

Chris Standaert: Safety. Is there sufficient evidence this technology is safe for the indications considered, and you can vote unproven, less, equivalent, or some, or all.

Gregory Brown: OK. Say that one more time.

Chris Standaert: I don't have a less either. So, safety. Is there sufficient evidence this technology is safe for the indications considered?

Josh Morse: Four unproven, one, two, three, four less.

Chris Standaert: Efficacy. This is where we got into our language here. We didn't just want to say what does it do. We want to say does it have a meaningful impact on people and their lives and their care. So, is there sufficient evidence this technology has a meaningful impact on patients and patient care?

Josh Morse: Six unproven, two less.

Chris Standaert: For cost, cost outcomes, cost-effectiveness, sufficient evidence this technology is cost-effective for the indications considered.

Josh Morse: Eight unproven.

Chris Standaert: Alright. So, based on the evidence vote, we can move on. I don't sense a need for a straw vote myself. So, I think we're going to move on to our vote, and this will be based on the evidence about the technology safety, efficacy, and cost-effectiveness. This is where you vote, and you have three choices. You have not cover, cover with conditions, or cover unconditionally, and if by chance there's a preponderance of people who want cover with conditions, we can certainly discuss what they may be. I don't sense the need for that. If somebody else thinks differently, please speak up. Alright. So, based on the evidence about the technology's safety, efficacy, and cost-effectiveness, it is not covered, covered unconditionally, or covered under certain conditions.

Josh Morse: Eight not covered.

Chris Standaert: So, next up, Medicare decisions. We don't have a Medicare decision, right? So, are we consistent with expert guidelines and similar things? They're a little all over the place, you know? Some people like it. Some people don't like it, it depends some on the condition. A lot of other providers don't do it. I think Colorado, we see Colorado all the time. I think Colorado actually has a much more robust process for making statements on this thing than other states is why you see it. I don't know that Maine and Alabama are different, but they don't seem to show up. So, some of these, again, they're varied. We are somewhat different in that we didn't approve it for anything. So, we're slightly different than these, but again, our evidence process may be different, as well, and I think the committee

seems to feel fairly strongly that there was nothing to convince them that this should be a covered benefit. No. So, what happens now is, our decision gets published and put online, and people can respond, and we can get public comments that we can talk about next time, but otherwise, we are done with this topic. Yeah?

Josh Morse: Yes. Thank you.

Chris Standaert: Is there anything else?

Josh Morse: Thank you, very much.

Chris Standaert: Alright. We're a little early, but we can get out of here early, 'cuz now we're just into ourselves and what we do as a committee. That came out wrong, sorry. So, this is just all about us. So, this brings to a close the actual meeting on extracorporeal shockwave therapy. So, Dr. Chang, you're welcome to stick around here, as we yack about other things, or you're welcome to go.

Michael Chang: Oh, OK.

Chris Standaert: But we appreciate your expertise and your clarity. I wish your clarity were more understood by other people who may be using and studying this.

Michael Chang: Thank you, very much.

Chris Standaert: Thank you for your help. Alright. Josh, so we have an issue with bylaws. So, Josh, do you want to introduce this to people?

Josh Morse: So . . .

Gregory Brown: I'm sorry. So, this is still an open meeting, we're just done with the?

Josh Morse: Yes. We're on to . . .

Chris Standaert: This is still an open meeting.

Josh Morse: . . . yes.

- Chris Standaert: Because we're going to talk about bylaws, and one of the requirements of amending our bylaws is that it be done in an open forum.
- Gregory Brown: No. I just wanted to clarify.
- Chris Standaert: Yeah. So, it's still an open meeting, but we're done talking about our selected topics. So, people on the phone can hang . . . if anybody who wants to talk about shockwave, we're done.
- Josh Morse: Pass those that way. So, I'm passing around your current bylaws. These bylaws have not been updated in a number of years. The program rules were updated about six months ago, and there are some meaningful changes in the rules that would lead to changes in the bylaws. So, now is an opportune time to consider the whole set of bylaws, and I would, I have a separate document, which is my initial edits at some of this, but obviously, you don't have to accept it, and I can work with the chair between now and May. We do need to go through a . . . allow public comment on these before they're finalized. So, I think, you know, if we can modify these to the degree that you want between now and May, you can finalize them then or it could be July or it could be in the fall.
- Chris Standaert: So, with the bylaws, again, it has to be a public process, and we have to put our . . . any amendments or changes we have up for public review for a certain amount of time. So, if we look at it today, and we can, amongst ourselves, agree on language we think we would like in our bylaws, and we write our own bylaws. We're the body that does that, then we can put it online and open for public comment and come back in May and if we are still happy with our changes, and if the public comment hasn't altered our thinking substantially, we can then approve what we had. If there's some major edit we have to make based on public comment, then we'll have to do that one more time. Minor or a word here, then probably not, but I don't know the exact tightness of that, but again, if we largely like what we say today, then we can vote on it in May and be done with that process.
- Gregory Brown: I guess I'm confused. What are the . . . you said there are some substantial changes.

- Josh Morse: So, there's some cleanup. I'll call it that. So, I can walk you through some of the changes I've put in there already.
- Gregory Brown: OK. So, this is the unedited copy, and this is the edited copy.
- Josh Morse: Yeah. You'll see a few track changes in the edited copy, and it says draft in the watermark there.
- Gregory Brown: OK.
- Josh Morse: So, some of the cleanup involves language related to the director is no longer called the director at the Healthcare Authority but is instead called . . . or he's no longer called the administrator, as it was originally. He's called the director. So, a minor word cleanup. We have added to the rules a definition of the internet based communication tool. So, I would propose adding that definition to the list of definitions you have in your bylaws under appendix A. Director is also added to the definitions. I think it's worth considering whether you want to put the definitions up front before the reader goes into the bylaws or if you want to keep them in the appendix. I have edited out the introduction a bit to one sentence for clarity. I have edited the purpose to match what's in the law, in the rules.
- Chris Standaert: And you wiped out this paragraph on the primary decision tools that help the Technology Assessment. I'm just curious.
- Josh Morse: I'm not sure it really fits under the purpose. That's kind of under process. So, it could be located somewhere else under how the committee does its work versus being under its purpose.
- Chris Standaert: OK.
- Josh Morse: Yeah. So, some of the edits are for clarity, like that. And then there's another major change in here for the Authority to actually make bylaws is now a rule that didn't exist before. So, we've . . . I have inserted that under, I believe it's under committee authority.
- Chris Standaert: And I say the first two on here, our purpose . . . we don't seem to have a large role in that. I mean, these guys ask us once in a while about technology that should be covered

and once in a while will this be problematic or addressable, and I don't recall anybody ever directly petitioning our committee to select a health technology for review. Is that something the public can do?

Josh Morse: Yes.

Chris Standaert: Just nobody's ever done it, but somebody can send a letter to us, not to the director, not to you, to the committee, to the chair or whoever saying, we would like you to consider this, because we've never had that happen, that I know of. Carson? No.

Josh Morse: Procedure . . . let me find that.

Chris Standaert: I guess do we want that power?

Josh Morse: Well, there's nothing in here that you don't actually have. That's part of the cleanup is to make sure that nothing is . . .

Chris Standaert: Right.

Josh Morse: . . . stated beyond . . .

Chris Standaert: No. We just don't do that. Of course, I guess do we want to do that? Should somebody say, I want you to look at this, do we want to be the body that says yes or no? Or do we just want to be . . .

Gregory Brown: You can argue it's a check and balance.

Josh Morse: You have that authority, though, is what I'm saying.

Gregory Brown: Yeah. So, if the director doesn't wasn't something reviewed and the public does . . .

Chris Standaert: We can.

Gregory Brown: . . . then we . . . if we feel it's important, we could say we think it's appropriate to review, I mean.

Chris Standaert: Well, listen, in politics no one's willing to give up power that somebody gave to them. So, we'll try spend their whole

- careers doing the opposite, trying to accrue more and more.
- Carson Odegard: Is there a reason that you omitted the definitions of recency and relevance.
- Josh Morse: Those were removed from the rules.
- Carson Odegard: From the rules?
- Josh Morse: Yeah. So, the rules . . . the rule itself no longer includes some of those words.
- Carson Odegard: Oh, OK.
- Josh Morse: So, it's meant in the bylaws to match what's actually in the administrative code, right?
- Chris Standaert: So, on the second part, the authority, is what gives us the authority to amend our own bylaws.
- Gregory Brown: I'm sorry. Can we go back up to purpose quickly? The second, well I guess it's the second sentence there. HTCC uses an open process and relies on evidence based medicine techniques about safety, efficacy, and cost-effectiveness. I'm not sure what scientific means, I guess, is.
- Chris Standaert: Scientific . . . evidence based reads a little funny, I have to say.
- Gregory Brown: Yeah. So, I would say, you know, relies on evidence based medicine techniques to assess safety, efficacy, and cost-effectiveness.
- Chris Standaert: The way it's written, it sounds like evidence based isn't scientific. That's what it sounds like, you know? Well, we could use real science or this fuzzy evidence stuff. Yeah. That's not quite what we're trying to do here. Relies on evidence based medicine approach to assessing information about, something like that? Evidence based medicine techniques? That's our key is that we are evidence driven, right? That's our . . .
- Gregory Brown: I would . . . that's why I say, I'd say rely . . . relies on evidence based medicine techniques to assess the safety, efficacy,

and cost-effectiveness, because that's what . . . we're providing an assessment of the evidence.

Chris Standaert: Yes. And if we lose the focus on evidence based, we get very fuzzy, since it's not really scientific, so.

John Bramhall: Is there any interest in putting publically available in front of the word scientific, in light of the correspondence from the lady to our last meeting. So, the beef is, you know, you guys didn't look at a bunch of information that we presented to you, but it wasn't published, and it wasn't publically available.

Gregory Brown: But that's part of the evidence, that's part of the grading, you know, every search has got be, you know, published in English, ages, you know, peer review journal.

John Bramhall: Right, but do we want to make that explicit here?

Gregory Brown: I think that's part of the process to me for evidence based medicine.

Chris Standaert: I think I understand. I agree with your point, but I think I understand that to be evidence based medicine, as well. That's the benefit of taking out the word scientific, because that leaves it more fuzzy. We could say evidence based medicine process, then yeah. This is discovery of evidence.

Gregory Brown: Well, but the . . .

Chris Standaert: So, that's where you start.

Gregory Brown: . . . but the point is, to me, the key thing in there is peer reviewed, and that's part of the evidence based medicine process. If you just start saying publically available, there's a lot of stuff out there that's publically available that's not peer reviewed and would make our vendors' job impossible.

Chris Standaert: But the word scientific has to go away. It's too fuzzy.

Gregory Brown: Sorry. I regressed.

Kevin Walsh: Can I make a suggestion about the appendix? When the terms that are explained in the appendix are listed for the

first time in the document, it would be helpful if there was a parenthesis, and it said A1, A2, so you'd be referring the reader to where the definition is. It's not . . . this is not a user friendly format at all, and we could make it more user friendly.

Josh Morse: Right. Some bylaws that I've looked at put the definitions up front. That's kind of how our rules are written, too.

Kevin Walsh: You see them up front, but then you have to remember that, as you're reading through the document. This is referring you right to where it is if you want the definition.

Josh Morse: OK. So, on the first appearance just put, like, appendix A1 symbol? OK.

Kevin Walsh: Or you could hyperlink it. We could use 21st century technology and hyperlink it.

Josh Morse: So, hyperlink. OK.

Kevin Walsh: Excuse me, but did you, Josh, make the changes that we had to be considering in this document in your draft?

Josh Morse: Some of the changes. I did not get as far as I had hoped to get. I did have . . . I did run this by a state attorney first pass already, and what I will do with any comments I receive today and any work that I do outside of this meeting with the chair and the vice chair on this in preparation for the next meeting, is take this to our rule writing group, and they will prepare a document so you can see what's changing, and that would be a more official draft for . . . I would call this a work product to try and work from my rough edits, so far, on the things that I know need to change or that I suggest changing.

Kevin Walsh: I'm missing substantive changes. I don't see any substantive changes. I mean, you've consolidated some of the statements and . . .

Josh Morse: Substantive changes would be the fact that the rules now contain the authority to make the bylaws and include some procedures for making the bylaws, which includes the public comment process. Another substantive change is a section on the rotating clinical expert nonvoting committee

member. We might want some, if you want more structure around that, it's feasible within the existing law and rules. That would be helpful to know. Then, the other . . . the rest of it, I think, is largely cleanup.

Kevin Walsh: I would ask . . . we've been concerned in the past about when the announcement came to us that the clinical expert was going to be sitting at the table and was going to be a participating member of the discussion, we had some concerns about that person not being familiar with the culture of this group and potentially bullying or taking over the discussion, because they are a subject matter expert in their own opinion compared to us, and I'm wondering if we need to put in any kind of rules of engagement language into 3.5 to clarify our expectations.

Josh Morse: I would say understanding, and I can show you or share with you the location of the committee members . . . I think I would put it in section 2.3. I'll boil it down to that. So, under committee participation and responsibilities, if you feel you want to add more clarity around how you're going to govern yourselves and expectations around that, because this would apply to all committee members equally. I think you'd want to put it in a section, review what you have now and see if . . .

Chris Standaert: So, does the, so do they . . . so Dr. Chang and Dr. Oskouian and whatnot, do they get this thing to look at?

Josh Morse: Do they . . .

Chris Standaert: Do they have to sign something saying they're going to do this? [inaudible] be well prepared, recognize public interest is a top priority, recognize, you know, all this stuff. Do they get this? Christina, are we using that . . .

Christine Masters: They are not signing that at this time.

Josh Morse: OK. That's something we can do.

Chris Standaert: Well, they should. I mean . . .

Kevin Walsh: So, I, I . . . let's kind of do this sequentially if we could. So, thank you for pointing out to me that it probably is more applicable to talk about the behavior of the whole group,

because they are becoming, for that meeting, a member of the group.

- Josh Morse: They're, yes, a committee member for that.
- Kevin Walsh: So, I think that the language . . . I read 2.3 as being adequate. I don't think we need additional language for 2.3, but Chris's point is exactly the issue and that is, we want them to sign that they have read and understood the rules of engagement ahead of time. So, that . . . and that might moderate behavior.
- Chris Standaert: So, I thought when we talked about getting a committee, that they were going to have to sign what we signed. Like, these people who come on our committee and sit there for one day, we all have to sign a document saying we're going to behave this way at some level when you sign up for this committee, and . . .
- Josh Morse: You, do. Yes.
- Chris Standaert: . . . I think the issue of . . . so, this one statement of you have to act in the public interest. So, I think these people come here thinking . . . I think Dr. Chang just sort of came here as a curious kind of guy who does this somewhat and, you know? So, that's interesting. We'll go do that. I think some of our other people have shown up to advocate their position either to their own benefit or the benefit of their greater ecosphere for whom they work, their institution, their colleagues, their field, but their job is not that. Their job is to act in the public interest, which is what our job is, and that needs to be in something they read and sign that says your job is this. You're not here to, you know?
- Gregory Brown: I think that's too narrow of an interpretation. To me, I interpret acting . . . if I'm advocating for something that I think will help patients, I'm acting in the public's best interest.
- Kevin Walsh: Then, I would ask that we put in another qualifier or another bullet point that says that we really are limited to the evidence that we are presented. So, our awareness of other things or our experience of doing 10,000 of these procedures does not really bear on the decision. The decision that we have to make really is limited to the evidence that we're presented, whether it's inclusive,

whether it's good, whether it's up to date or not. That's all, in one way, irrelevant.

Chris Standaert: Well, no. I mean, our, the laws . . . if you read these they say, we take public comment for a reason. The expert's here. He or she is level five evidence, right? Can a person say I've done 10,000 of these? They work. They can say that. That's level five expert opinion, and do I . . .

Kevin Walsh: I don't mind if they . . . I don't mind it being said once.

Chris Standaert: Right.

Kevin Walsh: But when it's used as a club, then I mind.

Chris Standaert: Right, but that's my comment, like, I don't . . .

Gregory Brown: You can't legislate behavior to some extent, you know?

Chris Standaert: . . . so, but I don't think people . . . so this issue of, like, public interest or not public interest, coming in saying I represent a national organization, and I'm going to sit at this table, they are not acting in the public interest. They are acting in the interest of the organization, which has its own stance, which is really a response to its membership that pays for that organization. If that's what they're trying to represent, they shouldn't be sitting here.

Kevin Walsh: I agree with you, but I also agree with Greg that they would think . . . they would say that they were acting in the public's best interest, because they have this subject matter expertise that exceeds ours.

Chris Standaert: I guess I just want them to see this and read this and sign this and say this is what I'm going to do.

Josh Morse: I do, too. Me, too.

Chris Standaert: And I think that the disclosure of interest, the conflict of interest thing, it should be strict for them.

Gregory Brown: So . . .

- Chris Standaert: But they are members of the committee, so we can make them sign what we have to sign. I thought they were going to. I think they should.
- Josh Morse: I agree, and that is something that we probably could add to section 3.5, you know, the expectation for . . .
- Gregory Brown: Well, no. I think we're in the right spot. I guess where I see it is, is examine all available evidence before making a judgment. To me, the issue is, is examine all available evidence and make a judgment based on the evidence.
- Joann Elmore: Based on the evidence. That's what I was bothered by, yes.
- Gregory Brown: So, it's not . . . you can give us your opinion. You can give us your society's opinion. You can give whatever, but this is an evidence based medicine discussion.
- Joann Elmore: OK. So, under 2.3 about the fifth bullet down, it says examine all available evidence before making a judgment. That makes it potentially sound like you can examine it, but then you could make your judgment based upon conjecture.
- Chris Standaert: So, no. I think what that's saying is, you shouldn't come in with a preconceived notion and disregard the evidence. So, this is saying, this is, like . . .
- Joann Elmore: But nowhere does it say that the judgment, that we as committee members. This has nothing to do with the clinical person, but the judgment we make is supposed to be based upon evidence.
- Chris Standaert: Well, it says that in multiple places in the document. This says for individual behavior within a group. These are, like, group rules. These are, like, rules of your committee, your group rules, right? You can't come in here with I've already deemed X and I don't want to listen to any of you . . .
- Joann Elmore: OK.
- Chris Standaert: . . . because I think this is right. I think that's what this is saying. I mean, if you want to put a line in saying, you know, the committee members should be prepared to weight the

evidence in the manner subscribed in the document or whatever you put it to make a decision.

Gregory Brown: I can tell you that much of the confusion or discussion about HTCC decisions when I'm on the Washington State Orthopedic Association is reminding them that this is an evidence based process, and so putting it in one more place is only going to help.

Carson Odegard: I think the discussion that we have with the clinical expert when they come here is important, too, and we've always done that in the past when they sit over on that table, but now that they're here, it might be nice just to bring that up when they're sitting here, because I think it's been pretty effective.

Gregory Brown: Do they have to do the open meetings training, too?

Christine Masters: They do not.

Gregory Brown: OK.

Josh Morse: I think they should have to do what we have to do.

Joann Elmore: They should.

Josh Morse: Initiate that either, yes. So, part of this has to do with the timing of this. So, one thing I'm realizing is until about three or four meetings ago, I was doing a more detailed presentation of the process, and I'm thinking it might be helpful if you want that I bring back some of those process slides, because this person is coming in pretty cold. I do try to converse with them before, to explain more robustly what the process is, but we could also have a meeting expectations slide, which is something that the Health Care Authority has begun to do more in the past couple years to basically remind us what our. . . the culture we're striving for, what our expectations are in this meeting and many of these things could be things that you want on that slide.

Chris Standaert: I agree. I think you should put it up at the meeting, but I think before they even get here, they should have that.

Josh Morse: Yes. No. I agree.

- Chris Standaert: Does it have . . . these are the expectations.
- Kevin Walsh: I don't think Josh is staying instead.
- Josh Morse: No. I'm saying in addition to, yeah.
- Chris Standaert: Right. They should have both, and I think the description of the rotating expert, we need to expand this somehow, because they should be expected to . . .
- Kevin Walsh: Let's make sure that . . . I want to catch your point that you had said before, which is that we need to clarify in the language of the expert that they have to do a financial disclosure.
- Christine Masters: They do that.
- Kevin Walsh: But it's not reviewed with us at the meeting.
- Josh Morse: It's included.
- Chris Standaert: It's in there.
- Josh Morse: It's in your binder. It's published.
- Gregory Brown: Well, it's just . . . it's the issue of finding an expert that's nonconflicted is part of the issue.
- Kevin Walsh: I don't know . . . well, I'm just saying I want to be clear about who's at the table. I understand that it's hard to find one who is not, but at least . . .
- Gregory Brown: Chris usually . . .
- Josh Morse: And what . . .
- Gregory Brown: . . . Chris usually asks, you know, do you perform this procedure or, you know, and . . .
- Kevin Walsh: Well, that doesn't mean you have, right, but just because you performed the procedure does not mean you have financial . . .
- Gregory Brown: Oh, no, no, no.

- Kevin Walsh: . . . financial disclosure.
- Gregory Brown: But you ask, do you perform . . .
- Chris Standaert: Yeah, today I didn't ask him . . .
- Gregory Brown: . . . this procedure or do you have other financial . . . conflicts of interest.
- Chris Standaert: . . . I read his conflict of interest form, and he doesn't have any. He did research [inaudible]. I think the . . . some of the point of getting people to fill these things out is so that if they don't actually abide by what they said they were going to do, then these issues of, you disregarded the expert, right? Well, the expert didn't exactly follow the rules of engagement, as defined, right, and didn't disclose conflicts of interest, and didn't disclose the Medicare billing that showed up in the Seattle Times, for example. Just as an aside, but things like that. So, this public . . . this information becomes publically available isn't disclosed, right? So, I'm not trying to impede on a particular individual, but in the process that if you say you're going to do something, if the rules of engagement are clear before you do it, and this is what's expected, and these are what you're going to say to people, that's what you do, and if you don't do it, then your participation in that project becomes in question, right? People can't come back at us and say, well you disregard XYZ, but then we say, and I'm not saying somebody did or didn't do this, but if they are asked to sign this stuff and fill out these things saying this is what they accept as an approach, then if they don't follow that, we don't necessarily have to engage with them or what they said the same way, you know, because they essentially violated what they said they would do or they were incorrect in their disclosure, or they . . . and if we have it on record that they signed saying this is it, then we have it. It's right there, you know? By the way, that wasn't disclosed, and that's important to the committee. Therefore, that's a problem for us, but we need them doing that. We need them putting their name on it.
- Joann Elmore: Well, it looks like Josh is adding 3.5 conflict of interest, and that should be relevant for all committee members. So, we should be covered there. So, I'm not certain what else you want added, Chris, or what you're suggesting.

Chris Standaert: So, I want the conflict of interest, and I want them to understand the . . .

Joann Elmore: To read this.

Chris Standaert: . . . purpose . . . and sign, well this, a document like this. I want them to understand the purpose of the committee, the rules of engagement that we have, and this issue that gets brought up about having to use evidence to make a decision in the public interest, based on safety, efficacy, and cost. So, that's really what overrides us. That's our process, and I think they should be aware and saying I recognize this is what I'm here to do and here to help accomplish this task.

John Bramhall: So, I'm getting the feeling that you want them to use the evidence that we are exposed to more than their own . . . so last . . . two months ago we get a guy who earns half his living putting implants in, right? I mean, it's clear he's got . . . I'm not speaking in any way pejoratively. It's clear that that expert has a conflict of interest. It's how they earn their money. So, to be . . . we don't need to be naive about that. The role of the person sitting in the chair, for me, is to interpret minutia and difficult technical issues. I thought today this was very useful to have somebody comment on the role of local anesthetic injection, for example, and I hadn't got that from . . . I hadn't picked up on that. I mean, I do it all the time and hadn't picked on it from the literature. So, that kind of comment is very useful, and whether or not the person making that comment has a vested interest from an NIH grant or from a commercial clinic that they operate, or, I mean, in a way it's sort of irrelevant if what they say . . . to me, at that time, if what they say is information that stems from that conflict of interest. In other words, if the fact that they do things and they earn money from it and all the rest of it, if the fact that they do it gives them an ability to give me an insight into some of the technical issues, I'd be quite prepared to accept that they are biased, but the information that they give me is just like all the studies that we look at. We have to determine whether these are biased in some way. Are they funded by Glaxo? We make that all the time. So, I'm not . . .

Chris Standaert: Yeah, but . . .

- John Bramhall: . . . all I'm saying is that I'm not quite sure that we have to have someone who is extremely pure.
- Chris Standaert: No. No.
- John Bramhall: And I'm not sure . . .
- Gregory Brown: The whole point is they're non-voting.
- John Bramhall: Huh?
- Chris Standaert: No. And I think from my . . .
- John Bramhall: But they influence the vote.
- Chris Standaert: Right.
- John Bramhall: The fact that they don't vote, but they can influence the vote.
- Gregory Brown: Well, right.
- Chris Standaert: I don't think . . . my point isn't that we need people pure. I don't think that's quite the issue, and I think . . . I agree that experts by definition have a vested interest in what they do. I think if they have to acknowledge that this is how the committee runs, we can say to them, I understand, but as you saw, and as you read, our committee functions on the basis of the evidence presented to us, and this is what we have, and you can sort of end that, and they know this coming in. So, maybe it would be more effective in getting them to accept that's how we work.
- Gregory Brown: Well, right.
- Chris Standaert: That's all.
- Gregory Brown: I mean, I have no issue with having them sign this. I'm fine with that. I guess I haven't seen a problem. What I've seen is you very politely say, we've heard you, you know, and we need to move on and redirect the conversation that way. Again, putting something in the bylaws, you can't legislate behavior. You can have them sign it and you can remind them that these were our rules.
- Chris Standaert: That's the reason we sign it.

- Gregory Brown: Right.
- Josh Morse: So, I wonder if it'd be helpful to go through these bullet points in 2.3 and just see if they all apply to the non-voting member.
- Gregory Brown: They don't because they're not going to attend all meetings.
- Josh Morse: So, I wonder if we should separate these and says voting members are expected to meet all of the following. Non-voting members are expected to . . .
- Chris Standaert: I guess we can just transport it over under this, under that section on the person. You just take the ones and say that they're expected to ping. You move a list. You just put it on a separate list under their category. Be well prepared for the meeting. Probably legislative process and issues affecting the committee, probably not so relevant for them. So, this one. They don't really make a judgment. What did you say? How did you want to change that statement, Joann?
- Gregory Brown: Examine all available evidence and . . .
- Joann Elmore: Make a judgment based on the evidence.
- Gregory Brown: . . . based on the evidence.
- Joann Elmore: I don't feel strongly, you're right, in other parts of the document. We state that we try to make decisions based upon evidence, but if the only thing you're showing to the clinical experts are these bullets, they need to know that that's how we make our judgment. We often have to remind audiences.
- Chris Standaert: I guess for them, I would say . . . change it to recognizes that the committee must examine all available evidence before making a judgment and make that judgment based upon the evidence, so they recognize what our charge is. Something like that?
- Josh Morse: OK.

- Chris Standaert: So, it has to be language that's amenable to them so they don't . . . because they don't really get to make the judgment, right? They don't get to vote, but they should recognize that's what we have to do.
- Tony Yen: What I would try to do here is make a judgment dependent on the evidence that is made available by the vendor. I think that's what we're supposed to be doing, at least.
- Chris Standaert: Largely, but I mean, again, that's why there's public comment. You can listen to the public. You can listen to patients who present, and they can influence your decision making, as can the expert.
- Tony Yen: Right, but are we also asking the expert to try to make the decisions based on the . . .
- Chris Standaert: No. That's why I'd say, I just want them to know this is what we have to do. They don't make a judgment. We don't want them voting or thinking that they can vote. So, what their final determination is isn't really relevant necessarily.
- Tony Yen: Right.
- Chris Standaert: But the other ones, communicate well. The other ones are all just normal, decent human behavior in a group, which are fine. I think those are just expectations of just being on the committee, and they should have the same ones. So, this says to seek input from enrollees of clients of a state purchased healthcare program. Is that patients?
- Josh Morse: Which section are you in?
- Chris Standaert: 3.5. To seek input from enrollees of clients of state purchased healthcare programs.
- Josh Morse: Advisory groups, um . . .
- Chris Standaert: What's an enrollee of a client of a state purchased healthcare program.
- Josh Morse: Somebody's who is in Medicaid or UMP.
- Chris Standaert: So, a patient?
- Joann Elmore: Patient, yeah.

- Chris Standaert: OK.
- Joann Elmore: Or an insured.
- Chris Standaert: This says enrollees of state purchased healthcare programs or clients of state purchased healthcare programs.
- Josh Morse: Well, I have a feeling this comes straight from the RCW, which I will look up right now, 7014090.
- Chris Standaert: OK.
- Josh Morse: This is the right citation. So, yes. This comes straight from the law that creates the program that cites your ability to . . . you may establish ad hoc temporary advisory groups. The citation should probably be in there for clarity.
- Gregory Brown: There's a typo in 3.2. At the end of that paragraph, I would say Washington State Medical Association and Washington State Osteopathic Medical Association should be caps for the.
- Josh Morse: Do you have enough to go on for now? We feel that we have enough to go on between now and May to flush this out further.
- Chris Standaert: So, to release it to public for review do you mean, or to . . . are we going to come back in May and run it by one more time and then release it?
- Josh Morse: I can work with you on this further with another draft that we could then put out for comment, and anybody on the committee could comment, as well, and that version could be brought back to the committee in May for consideration.
- Kevin Walsh: For comment, can you also send it to us directly?
- Josh Morse: Yes.
- Chris Standaert: Yes. We can do that.
- Joann Elmore: There's nothing in here on the vendors evidence. Let's see. Evidence review. In other words, what are the bylaws governing who the vendors can be, their quality?

- Josh Morse: So, that's all . . .
- Joann Elmore: Where is that? Is that in another document?
- Josh Morse: . . . so, the law gives us the . . . is pretty directive about the requirements for the vendors. They have to be contracted. They have to be an evidence based practice center or like an evidence based practice center. When we contract with them, we go through this evaluation process following State contract law to make sure that those requirements in the law are met.
- Chris Standaert: So, do they ever have to fill out disclosure? So, what if our vendor is working for industry working for a medical society working for, you know, I mean, they have multiple clients, not just us. So, they try to stack their work on top of itself, I bet, because it's economically efficient.
- Joann Elmore: That's a great question.
- Chris Standaert: They do have disclosure rules in contract about employees and their work.
- Joann Elmore: So, they're filling out these kind of forms just like our clinical expert is?
- Gregory Brown: Are they directly asked if they have other clients that have requested similar reviews? In other words, when we see this, do we know that they've done six of these already or do we know that this is a new one for them?
- Chris Standaert: Or, do we know who hired them to do them, right? So, it's who is the . . . who is paying their bills, right? Is that . . . do we know that and is that something they have to disclose?
- Josh Morse: We can know that.
- Chris Standaert: Have they worked on this or a similar topic for any other organization, so we know who they work for? It gets very muddled when you do that, because then . . . but maybe it is very muddled, and we should know that.
- Josh Morse: Can you use a microphone? Chris has a comment.

Christine Masters: I just wanted to say in the RFP process that we just finished, all of the vendors have to give us three years' worth of clients that they stack up, and they have to also give us a huge list of works that they have already accomplished in that last three years. So, I mean, we get a . . . and they have to give us their conflict of interest disclosure that all of their people have to sign, as well as their consultants. I mean, it's a very comprehensive . . .

Chris Standaert: Do you link their clients to the products . . . to the work products?

Joann Elmore: Technology.

Christine Masters: A lot of the time when they put down what they've written, they will link them, but not always.

Chris Standaert: That would be useful to know.

Joann Elmore: That would be helpful, a simple question of both the clinical experts and these vendors, is any part of your prior income related to this technology. I say that because of the clinical experts, because I've noticed they all check no under question 3B, source of income. Does any income relate to, you know, any business that has or may come before the committee, and of course, you know? He did five procedures. So, and many of our other clinical experts should be checking yes to that box, but because of the way it is worded, it is not transparent, and because this is a public open forum, I would like that to be clear to the audience and the public.

Gregory Brown: I think when you hear if you have a conflict, that doesn't come to mind. So, I think it needs to be an explicit question.

Joann Elmore: It's an additional line.

Gregory Brown: Does your clinical practice, you know . . .

Joann Elmore: Do you use this technology and does your . . .

Gregory Brown: . . . in your clinical practice.

Joann Elmore: . . . income [inaudible].

- Gregory Brown: They wouldn't be an expert if they didn't is almost the answer, so.
- Joann Elmore: But I think that that is something that we understand, but other people may not, and it would be helpful to have that documented.
- Gregory Brown: Actually maybe a better way to say it is they're here because they're the expert. So, they have to be using it. So, it's . . . how many times do you use this technology per year on average, you know, five to ten or?
- Chris Standaert: If it's more than 10 or 20 or more than 1% of your income derived from the use of this technology in clinical practice or something. So, people know if somebody does it all day long.
- Joann Elmore: I wouldn't make it a percent of their income. I would make it a dollar amount.
- Gregory Brown: I mean, I don't know. I get RVUs for an operation. I don't know exactly how much I made for which operation, you know? I mean, there's four different ways to treat hip fractures. No, I used this only twice not four times, you know?
- Chris Standaert: Right.
- Gregory Brown: That's what, I'm just giving a sense of how frequently do you use the technology, because some technologies are more expensive than others and everything. You know, like, if you're doing disc replacements, you know, you may get \$20,000 for a disc replacement.
- Joann Elmore: I want a simple binary question. Does . . . something about their income benefit from this technology. I think we all know it, but I want to be transparent, and I'd like it documented.
- Emily Trent: I'm Emily Trent. I'm a new associate medical director at the Health Care Authority and I have no voice today, but he also is on the industrial advisory board of a shockwave device manufacturing company. Another thing that would seem likely to be a conflict of interest.

- Josh Morse: I'll be honest and say that we are working to revise and modernize the conflict of interest form. We are looking at multiple other sources, including the form currently used by AHRQ and the methodology and the form used by the U.S. Preventative Services Task Force. They are a bit . . . they appear to be more robust than what we currently have. It may be easier to fill out. So, we are trying to . . . I am trying to get that brought forward a little bit and made at least administratively easier for people.
- Gregory Brown: I mean, but be careful here. I do subacromial injections. I treat rotator cuff arthropathy. I treat elbow epicondylitis. I treat plantar fasciitis. So, if we're really going to get into that detail, a lot of us are going to have conflicts on some of these things. I haven't done any fecal transplants yet.
- Chris Standaert: Epidural injections for me came up, and cochlear implants for Seth.
- Gregory Brown: So, I mean it's . . .
- Josh Morse: That brings up another very important part that maybe . . . and I failed to really consider before I came, but the language around recusal in here is probably something that should be examined. That . . . because there is going to be a parsing here between a voting member and a nonvoting member. Clearly, a voting member does not have to recuse, because they're not voting, but . . .
- Chris Standaert: Yeah, nonvoting.
- Josh Morse: That's what I mean, if I didn't say it. That's what I thought I said but.
- Chris Standaert: So, this issue of you do it clinically versus you own the device, you work for the company . . . these are different things. Saying Dr. Manor who came in and talked to us about knee replacement shouldn't be there because he does knee replacements doesn't make any sense. If he were there and said he's there to talk about knee replacement, but he happens to be a consultant for seven different device manufacturers who make knees, we should know that. That's a relevant thing, and I think the committee the same thing. I think . . . I don't think any of us can be . . . I mean, if we work for industry, we probably

can't be on the committee. Don't we have to sign off on all that stuff? Yeah. So, I think our external monetary conflicts outside of the clinical practice of medicine are already sort of vetted, because we can't be on this committee if we have them, I don't think.

Gregory Brown: Have them, but you're just not conflicted with what we're doing, yeah.

Chris Standaert: But if we had somebody on the committee who worked for a device, say Seth had worked for the people who made cochlear implants, he should have recused himself. He doesn't, but he should have, had that been the case.

Gregory Brown: Right.

Chris Standaert: It doesn't mean because he works for that company he can't talk about knee replacement or bone stimulators or whatever.

Gregory Brown: We deal with this. I'm trying to deal with knee and hip arthritis guidelines trying to find surgeons that don't have relationships with manufacturers. It's exceedingly hard to do. I gave an instructional course lecture and one of the speakers said, yes. I unfortunately have no conflicts of interest to disclose. So, that's why I say, to me just a simple thing of how many times do you do this. Again, that's not bad. That's just part of assessing the expertise, if you will.

Chris Standaert: Misunderstand, miscategorize, I don't want to use a more pejorative term.

Josh Morse: Do you have examples? Are you conscious of . . .

Chris Standaert: Mm-hmm. Yeah. We had one expert who had not disclosed . . .

Josh Morse: No. No. No. I don't mean individuals, I mean forms.

Chris Standaert: Oh, forms.

Josh Morse: Are you conscious of really high quality conflict of interest forms or forms that you would recommend that we look at?

Joann Elmore: [inaudible] Task Force.

- Josh Morse: USPTF. OK.
- Chris Standaert: I think for [inaudible], I think frankly you want people on the committee who practice medicine, and that's the whole point. That's why we're here.
- Josh Morse: I think the question just comes up on the material conflict, which is a vague term.
- Chris Standaert: Right.
- Josh Morse: And I think it's important, though, to keep in mind that it's important to be conscious of this requirement and check in when necessary.
- Chris Standaert: OK.
- Gregory Brown: I have a question and that is, could the American Academy of Orthopedic Surgeons be a vendor for musculoskeletal, I mean, we've got an evidence based committee, but we have a staff that do all the literature reviews and pull all that. We got a Ph.D. that's a director for our program.
- Chris Standaert: I think there may be a state law about this, but from my own standpoint, societies are not all created equally, right? The extent of funding and where the money comes from and who pays for the society is highly variable, and you would need some way to vet that, and I think truly society guidelines carry weight but limitations, because they are, by definition, written by people who do it, right? Then they sort of go both ways. I actually have a lot of respect for what AAOS does, but . . .
- Gregory Brown: I'm more asking, one of the issues is you put our RFPs and nobody responds.
- Josh Morse: No, we get a good response.
- Gregory Brown: You did this time?
- Josh Morse: Yeah.
- Gregory Brown: OK, because I, I mean, I was hearing . . . last time I heard that there was two, that you didn't have a lot of choice, I thought or that one of them . . .

- Josh Morse: No, I felt very good about . . .
- Gregory Brown: . . . was getting out of the business and such.
- Josh Morse: . . . so we haven't put out an RFP, since 2011. So, we just released an RFP, I guess it was officially released in 2017. I think we had a fair response to the RFP, and I have not seen the results of the evaluation process yet, but I . . .
- Gregory Brown: Is that closed?
- Josh Morse: Yes.
- Gregory Brown: OK.
- Josh Morse: This part of it is. I mean, we could always, if we needed to, we could reopen it, but from what I understand, we're in a good position right now, but again, I don't know the results, but I think they were high quality.
- Gregory Brown: Well, again, I'm part of the process. So, I'm very biased in that sense, but I think we do a very good job of not allowing conflicted people on the committees. We do a best evidence review, not just everything review. We came down on not recommending HA. We've come down on not recommending a number of things.
- Chris Standaert: As a committee, we have looked at guidelines and frankly, I don't look at every one the same, you know, and every society the same. Every society is not created equally, but I don't know that there is an independent arbiter of that.
- Josh Morse: Well you do have . . . I will say that each one of those guidelines that's in the evidence report is evaluated, and its quality is assessed for you by the contracted vendor.
- Joann Elmore: But the lack of listing a guideline, there may be some guidelines at state levels that reviewed the similar topic, but they just didn't say it's not covered. They just didn't mention it, and we don't know that.
- Chris Standaert: The AAOS didn't mention it for knee osteoarthritis.
- Joann Elmore: And I'm just thinking the public's perspective, like, oh, Colorado approved this. Why didn't you? Like, there could

be other 30 states that reviewed this topic and didn't include it and just didn't mention it. So, it seems . . .

Chris Standaert: Because it wasn't worthwhile.

Joann Elmore: . . . a bit, yes. It seems a bit . . . it puts us in a spot.

Chris Standaert: Right. If you had other guidelines on tendinopathy saying who didn't mention it, [inaudible] tendinopathy not talking about it. That's a statement, right?

Joann Elmore: But see, that is work on the vendor's part that might be helpful to us. Does that make sense?

Josh Morse: I . . .

Joann Elmore: In other words Colorado State reviewed the evidence, and they included it. How many other people reviewed the evidence and didn't even include it.

Chris Standaert: So, what you want are guidelines and the condition, not the technology, right?

Josh Morse: . . . uh, yeah. I don't know how they'd be able to answer that question.

Joann Elmore: I don't know either.

Josh Morse: I do know that you have a legal requirement to consider national . . .

Chris Standaert: Society guidelines.

Josh Morse: . . . level, I believe national and state level society guidelines and to make a judgment on the quality of the evidence from your perspective.

Chris Standaert: Are we good?

Josh Morse: We're good. We have what we need to move this forward between now and May.

Kevin Walsh: Can I make a request? What do we have to do to get the vendors to do the math to change the relative

improvements into absolute numbers or give us the key RCTs and let us do the math?

Chris Standaert: I have found some of these reports, like this one, frustrating, because they get too far in the weeds. They break it up into so many things and they lose the numbers.

Joann Elmore: And they don't describe the weeds.

Chris Standaert: And they don't describe the weeds. It just gets lost and it's frustrating. I go through the reports and we talked about hyperlink before. I would love a hyperlink that I could, in the table saying this study, I have to go, which study are they talking about? You have to read the fine print. I have to go to the index, find the study, go search for it to find it.

Joann Elmore: We are doing a lot of work.

Chris Standaert: If there are hyperlinks. If they would just start . . .

Joann Elmore: Because these reports . . .

Chris Standaert: . . . doing this and give us the data differently.

Joann Elmore: . . . do not help us.

Chris Standaert: Put in a hyperlink so we can [crosstalk].

Kevin Walsh: Or could we, I mean, the other option, I guess, if they can't, if you don't have the ability to require that of them, would be to have a step in the process where you give us the draft and let us identify what the key RCTs are and then you get the studies and you send them to us. I mean, but I agree with you. I mean, we are doing a lot of . . . all of us are doing a lot of work. It's a lot of repetitive wasted work, and we're paying somebody to do this stuff. I don't know why we can't require them to do what we want. I just . . . I mean, the vendor, she came up and said, oh here. It's all in the scatter plots. I said that's relative. That's not absolute. You have to go . . . you would have to go back into the studies and convert these into absolutes.

Joann Elmore: What was even her degree? [inaudible]

Josh Morse: I've heard your concerns about this particular report, and I've taken some very detailed notes about the presentation. I will converse about this report with them and make sure that they were meeting the requirements that we asked for previously, because I . . . that is an expectation that you have, and you should . . . it's expected that you get what you've asked for around the absolute versus relative.

Joann Elmore: So, there's two very concrete simple things we've asked for. Number one, we want easier access to the actual articles, and I know . . . and you pointed out to us that that's kind of hard. You can't have a Dropbox, because of publishing things, I don't know, but that's one thing we really need. I mean, I'm an academic, so I have access. I have a secretary. I can get them, but it's a lot of work. Number two is, when there are only a handful of important articles, I don't want them to show as 32 tables. I want them to walk us through the four RCTs and the methods and discuss them like an epidemiologist and a scientist and an evidence based person. Those things are lacking.

Josh Morse: OK.

Chris Standaert: That last one, I don't know, we've been asking for that last one for . . . ever since I've been on the committee. It seems very hard to get that.

Josh Morse: We had a pretty robust conversation about this in September. Given our current methods, we are striving for completeness, and the other thing that they're not doing is making any judgments along the way about what's the most important, what's the least important, and honing their . . . I can tell you, there are other places that do more apriority definition of what the target is going to be. Like, if you look at the Oregon Health Evidence Review Commission work, they have staff who say, we're going to look at up to five outcomes and no more, and they define those in advance, and then they put that out publicly and they deal with the . . . they take public comment on that, but they're limiting at the outset what will go in.

Joann Elmore: You make a good point. We're covering ourselves with detail. So, you can check that, that the evidence vendor has done that, but we need more. They're getting lost in the weeds, and they're not describing the weeds to us.

- Chris Standaert: We're missing something on the qualitative level of evidence. We're missing something on an RCT from the New England Journal that is 1000 patients and well vetted. I'm having trouble distinguishing that from a piece of crap from a journal from God knows where that was peer reviewed in three days, and I don't know why they don't do that. I don't know why they don't . . .
- Joann Elmore: In other words, they have their rating . . .
- Chris Standaert: . . . their ability to do that is . . .
- Joann Elmore: . . . well, they have their rating scale, and she even . . .
- Chris Standaert: . . . it is not there.
- Joann Elmore: . . . stepped back and said, well we had to rate it moderate because that's our scale, but they should have gone beyond to say, you know, we also thought it was suspicious that nobody in the placebo sham arm got better, but you know, you should accept a placebo and, you know? They should have said here are the five things. They did block randomization at 25. Like, no. You don't do that. They should have mentioned the five things. That would help us.
- Chris Standaert: Right. then she blamed it on grade is what she did.
- Joann Elmore: So, we are getting stuck in the format, and we're doing the transparency. We're doing the checkbox yes, we have reviewed all the 'evidence.' We're being awash in evidence, but it's making our job harder. In fact, if the evidence hadn't been such crap, I almost was going to abstain and say the report was not adequate for me today to evaluate it.
- Josh Morse: I will say you can do that if you do not have the information that you need.
- Joann Elmore: I felt comfortable, kind of, after reading all the articles that I had to ask for.
- John Bramhall: The remit is to do what, do an exhaustive review of the extant literature?

- Chris Standaert: Well, the idea is to take the things that are fundamentally driving the evidence on the topics and really dig in and present the raw data of what actually happened here. So . . .
- Gregory Brown: So, virtually every forest plot, you will see one study that's driving it.
- Chris Standaert: Right, and the reality is for most the things we talk about, there aren't 70 important articles. If there are 70 important high quality articles, we're not talking about it. There are five, there are two, and there are 12.
- Gregory Brown: That's what I mean. HA you're wrong.
- Chris Standaert: So, that . . . getting that . . .
- Kevin Walsh: Is that what, John?
- Chris Standaert: . . . in there, you know?
- John Bramhall: Well, so we're saying to the . . . are we saying to the vendor give us all the information that you can find and grade it according to a standardized grading, and then we'll do the cut, and when we have our discussion, we won't bother about all these stupid reports that came out . . . that are just poor quality or they're irrelevant. We'll concentrate on the New England paper that came out three weeks ago.
- Joann Elmore: The problem is that they're giving us everything. They're doing what we're asking of them. They're giving us everything, including the kitchen sink.
- John Bramhall: That's what I'm asking.
- Joann Elmore: And they're giving the numeric information without giving us a high level qualitative here's this . . . there may be five studies, but four out of the five had a conflict of interest. Study one had these problems. Study two had these four problems. Study four had these strengths. I mean, they're not giving us that.
- John Bramhall: Yeah, but that's what I'm asking, because it's unfair to beat up on them if what we're asking them to give is an exhaustive bibliography.

Joann Elmore: That's a good point.

John Bramhall: And then when we get around the table . . . so, most of us read their output and make our own decisions. I completely agree with you. I mentioned it the very first time I came here that it's outrageous that there should be any barrier to the access to the journal articles that are being cited, outrageous. I know this is sort of a national issue, but of course you need the five papers that are the key papers that are going to drive the decision, of course. How can you do it without that? Then what happens is, we get around the table and we have someone from over here wave a paper from Norway and say you can't look at that. This is impossible to put this into the mix, and if you do I'll create a fuss or someone from over here says, yeah. I know this guy. He didn't know how to hold the equipments, it's, you know, it's rubbish, you know? So, we then have to make a human integration, and it's really difficult, because you've gone through the 74 papers of which three were significant, right, and it's noise, and then one of the significant papers is shot down by somebody in real time, and you have to integrate that now and say well now, I was relying on that Norway paper. The Oslo paper was the thing I was going to make my decision on, but he tells me . . . and that's not peer reviewed, and it's not . . .

Kevin Walsh: The statement's not peer reviewed.

John Bramhall: We don't know the basis of the decision that's made to say, guys, ignore this paper because. Part of the problem is that we're wanting it to be pure, and it's not. It's a human activity, right? I mean, it's a human activity, and even, not to go on, but it's a human activity that I will . . . I will look at a paper from, OK, just, you know, from PNAS or New England and think that that's a better paper than one from the online open access Indian Journal of whatever, right?

Chris Standaert: Mm-hmm.

John Bramhall: And that's a human decision, because objectively the two studies that are presented may be fantastic, you know?

Chris Standaert: Right.

John Bramhall: So, my plea is probably that we shouldn't try and be too pure. I mean . . .

- Chris Standaert: No. I don't think it's . . . I agree with what you said, but I don't think it's a too pure thing. I mean, studies, like, you know, we had that one that was an advertisement is what it said at the bottom of the article. That troubled me a lot.
- Joann Elmore: And we have to pick up on that. What did the vendor do?
- John Bramhall: No. No, but some journals, am I right, some journals do that and they say . . .
- Chris Standaert: But that, in my head, that makes it a much more questionable level of evidence, right?
- John Bramhall: No, but I, I thought that there was a legalistic issue that if then, you have to brand it as an advertisement.
- Chris Standaert: Yeah, because I mean, somebody's paying for the publication of their own article is what that means, I think.
- Joann Elmore: But these are qualitative issues that right now we're getting quantitative data that uses a standardized grading scale and what we would like to do is ask them to go beyond that to help us and to sort of point out advertising, point out the things that we are doing to help us with that.
- Gregory Brown: All the grading scales allow you to downgrade if you've got concerns of bias or conflict or other things. So, it's . . . the scales aren't as rigid as they're implying.
- John Bramhall: Right, but the real downgrading is not . . . I'm not going to downgrade a paper because it's bias necessarily. I'm going to downgrade it because it's a bad paper, or that the experiments are poorly designed. In a way, if something's funded by [inaudible] fine. I don't have a problem with that. That's whose going to pay for it, right? The problem is, if the paper itself is internally inconsistent, I can pick that out. What I'm unlikely . . . unless I am sitting there, unlikely to know the track record of the labs involved, you know? I'm not . . . whether there's a bunch of retractions in the literature from this same group. I mean, stuff like that, I'm probably not going to know, unless I am a subject matter expert on all the things that we look at, which I am not. So, what I have to do as a member of our group here is to look at the information that they present, and I found this today, not to reiterate, extremely cluttered. It's, like, show me

everything that you could find when you Google it under this term and then exclude the ones that weren't papers. Exclude the ones that didn't have images. These were the 473 left, and out of them, one, that's what I guess I want, but I don't know that they, not you, they do that. I think we do that. This is the one paper that's going to drive our decision. We do that, don't we?

Chris Standaert: We do, but I think you can . . . if you read a review, there are reviews that are just book reports. I read this book it said that people take and they tally up . . . this one had seven RCTs to support it. This one has two. That's really annoying, because seven crap RCTs is zero in my own head, right? So, it's not a seven to two thing. It's, like, what's better. You can do a review where you say, look. This is what's out there. This is what people say. However, there are these common underlying themes of industry sponsorship, poor randomization. She said it. These are really small studies. There are inconsistent techniques being applied. If you say that as an overview, you're saying, look. I know this is what the studies say, but when you really at them, these are common themes you see in there. If you say that, you're giving us a much different view of the landscape, and the score tallies of, well we have seven RCTs so it's high. No, it's not. If you have seven terrible RCTs that's low or indeterminate or insufficient, right? And they don't do . . . and I think that's what's missing. That's what annoys me that they're missing . . .

Joann Elmore: And as our evidence . . .

Chris Standaert: . . . this component of it.

Joann Elmore: . . . reports are transparent, and they're open to the . . .

Chris Standaert: Yeah.

Joann Elmore: . . . public, it might help to educate the public if these caveats and comments were stated, because the public may see a bunch of pretty multicolored figures that have a lot of dark green, but if underneath that you said comments and then you listed a couple of the comments about caution should be used, small numbers, you know. Three of these four were industry supported, you know? There was concern about the placebo not necessarily being a placebo

because it was given by the same investigator that gave the technique. There's . . .

Chris Standaert: Right. There are themes.

Joann Elmore: . . . that would help.

Chris Standaert: And I think, you know, from my own . . . one of the things I said at our retreat last year, the idea I introduced, this idea of, like, how do we make this decision? Is there a way to really start understanding how we're all doing this and how as a committee we do this? And can you document it or repeat it or build it or structure it in a way so that you understand what's driving the decision. Then, once you start getting it, if you can do that is, what's important in making this decision? If somebody wants to go study technology, they can start understanding, no. These are the things that society thinks are irrelevant and important from the investigators of things that they want to do to people. This idea of you can't just make it a tally, right? So, if you look at this and you look at them and say why did we say it didn't work? Well, it's kind of weird, 'cuz they had a lot of slides saying it did do stuff, and we said it didn't work, but their slides didn't capture what Joann is saying. So, I think in terms of our own ability to go backwards a bit and say, why did we decide that? What is driving our decision? How are we weighting evidence and quality of evidence versus safety and cost? How are we doing this? I think there's . . . this is . . . I think it is a move in the Health Technology Assessment world to start getting at this so it becomes . . . so our group does function a bit . . . can we start seeing how we're functioning compared to NICE or compared to Oregon or compared to wherever, and are the relevant ideas and concepts for what constitutes appropriate care being defined better so that we can start really driving how people are doing research and studying this. I think if we're not really digging into these studies in some way, and nobody is doing that, we're not getting that. We're losing it.

Joann Elmore: And it's not as easily transparent if five years from now someone questions our decision and they look at that evidence vendor and all the green little boxes, it would take us some digging to sort of go through again our thought process. I'm wondering, can we see . . .

- Kevin Walsh: So, I'm going to . . .
- Joann Elmore: . . . what's given to the evidence vendors?
- Kevin Walsh: . . . I'm going to put on rose-colored glasses.
- Joann Elmore: What their instructions are?
- Kevin Walsh: I've done this for five years. I think that over the course of that time, I've started to see a lot more emphasis in our discussions placed on function. MCID is new. I didn't see it five years ago in these reports. I'm seeing it now. So, I think that what you were saying, Chris, I agree with you, but I see it incrementally happening, and it's incrementally happening even within this group that we are . . . I mean, today we all saw all . . . I mean, 90% of the information that was presented was about pain, and we kept saying, yeah, but, tell us about function. So, I feel like we are, even though it might feel glacial, well glacial before 1990, it's happening. I feel like it's . . . I mean, we're moving in the right direction. It's not nearly as fast as I want it to move.
- Chris Standaert: No. I think we're trying to pull them with us. I think we're trying to go there. I think we need them to come with us. I think we need them to . . .
- Joann Elmore: So, what written instructions are given to the vendors? What bullet one-page, you know, instructions are given to them in regards to what our needs are? I'm not certain I've seen that. I know, I see the four questions, but, what instructions are given to the vendors about what we really need? I'm sure you've got documents.
- Josh Morse: Oh, there's . . . there's lots of documents, yes. There's a robust process for defining the key questions in the scope. Those documents can be quite detailed. There's an analytic framework published. It goes through a process. So, there's an agreed upon framework. Behind that, there's a work plan that includes a little bit more detail than the key questions and scope. It talks about, in some cases, a little greater detail about the level of evidence to go to, and this is a very interesting conversation, because we've talked about this a few times. I think, what I recall from today's presentation, for example, is all RCTs, and I imagine there are many other studies below that that you didn't see today. So, there are discussions about that. The MCID and

the functional outcome questions we have embedded that into the expectations. So, we're seeing to understand what the MCID is, what the evidence is behind it, if necessary, whether it's validated or not. So, those are all things that have been incorporated, I think, into these work plans over time.

Gregory Brown: And there was a problem we ran into before where you specify RCTs, so any registry data gets thrown out, because it's not an RCT.

Josh Morse: We include the caveats, yes.

Gregory Brown: Yeah. No, no, no. I know. So . . .

Joann Elmore: It depends upon the technology. There are some . . .

Gregory Brown: The vendors. I mean, I . . .

Joann Elmore: . . . technologies that it is OK to look at . . .

Gregory Brown: . . . got in an argument with a vendor over that. They're saying, well it's level whatever because it's not an RCT. So, based on their definition and interpretation of the grading, they will never look at registry data.

Carson Odegard: It's buried in the appendices that we can see, I mean, I think there's . . . it's in the area that we never look at.

Joann Elmore: Oh, I looked at it.

Carson Odegard: Do you look at that?

Joann Elmore: I mean, I looked for things that I didn't find.

Carson Odegard: The grading aspect of it, though?

Joann Elmore: Yeah. They all use . . . they use their own standardized grading.

Carson Odegard: Right.

Joann Elmore: I guess . . . I'm hearing two concrete suggestions from the group. One is that we want access to the primary articles, all of them, and number two is that instead of giving us the numeric concrete stuff, which they're throwing at us, I want

a little bit of a qualitative discussion about the actual articles that goes beyond their grading, because there are things that are missed in their concrete grading scale, and that's what we're paying them for, and they know how to evaluate these things. They're aware of it. They're not putting it in the reports, and that's important, because we are voting on these things that we all are aware of and that come out in our discussion that are not in the evidence report. They're throwing numbers at us. They're not throwing a true, good quality review. They're probably hesitant to do that, because a lot of it is subjective. You have to be careful with the wording, and it's more work.

Kevin Walsh: I have to confess that I find it very difficult and listen to their chatter and noise for 45 minutes and keep . . . it's almost like my receptors get oversaturated. I'm lost in meaningless numbers. I have to almost, like, write down what I think is important before they start talking, or I'll be . . . I'm lost, because I'm battered with meaningless information. How many types of pain are we going to be hearing about today? Pain with salt. Pain with ketchup? Pain in the morning? I mean, that was . . . all that said to me was really, you don't have anything of benefit, so you're trying to find statistically significant stuff to batter us with, because that somehow is significant, and we all said, no. It's not significant. Thank God that we said that.

Joann Elmore: Well, but too, the devil's advocate for them, I mean, their job is to make certain we don't miss evidence. Their job is to report everything. The thing is, they're doing that, and it makes our job even harder, because we want them to do one more thing, which is, we want them to help sort of describe the quality beyond just the grading.

Josh Morse: I have been thinking about this, because I think as Health Technology Assessment processes have evolved, and these grading systems have become kind of accepted and systematic, there's a response that we recognize there are places where the grading system breaks down, where they don't downgrade for concerns that you in your mind are downgrading for in 11 different ways, right? So, is there a common way? Is there a systematic way? Would we expect the qualitative assessment to be the same across the vendors, and how would we describe that? These are the things I wonder about, and the same with how deep to go

versus not go. So, I think we're . . . we try to cast a wide net to get . . . to meet the requirements and get the evidence that you . . . you don't want to miss any details, and then how do we restrain that in the presentation in a qualitative way that satisfies you individually and as a group, and that's the challenge. It goes through the public, right? So, there's a 30-day . . . and again, I'll . . . we talked a bit about . . . there are other processes out there, like, U.S. Preventative Services Task Force whereas, and I have never witnessed it, but as I understand alternative ways of doing work like that is to bring a draft to you and have a conversation with the people who are creating the draft and, at that point, you would make significant potential inputs on where you want it to go.

Gregory Brown: These seem to be the six studies we really want you to focus on.

Josh Morse: If it met the policy question, you probably could do that, and that's kind of what we tried to do in the scoping part. Again, to meet the policy need, we're drawing lines that might be a little bit more broad than six studies.

Gregory Brown: You can't do it until [inaudible].

Chris Standaert: I think we need to . . . in some ways, this is yet another topic for the retreat in September.

Kevin Walsh: I was, yeah. Josh hit on something I thought we should consider and that is, could we have a discussion at the retreat about are there factors that we could all agree on that would downgrade the quality of a study and we could start submitting that. The other thing I'd like to know is, how are other states doing this process? How are, you know, how are they getting information upon which to make a decision? Is it similar to ours?

Gregory Brown: How many states even do this?

Josh Morse: To my knowledge, there are very few other programs. This process is somewhat different from those that I'm aware of. I've described what I know about the Oregon process, which is there's a much greater involvement from the administrative side where they're making decisions in advance.

- Kevin Walsh: In the state of Oregon.
- Josh Morse: State of Oregon, yes.
- Chris Standaert: Oregon has, but Oregon isn't a true Health Technology Assessment like this. I mean, when this program has been compared to other programs around the world, we are . . . we have way more components than almost every other program in existence in the world, in terms of how we do this, in terms of public outreach and comments and everything else, right? Transparency and . . .
- Josh Morse: Independence, right? This is important [inaudible].
- Chris Standaert: . . . we have many, many steps of what should be in a system like this and are much more mature at it than every other state, certainly, but again, there aren't many in the world that do it to the level that we're doing this.
- Kevin Walsh: I'm not talking about the whole process. I'm just talking about the evidence that people, I mean . . .
- Chris Standaert: Right.
- Kevin Walsh: . . . I have to say that I think, just like over time I've seen us become more adept at looking at function and are more focused on it, I have to say that when OHSU quit doing the reports, I saw a huge diminution in the quality of the reports that we go. I hope that we saved a lot of money in this state, because we lost a lot.
- Joann Elmore: I almost want you to invite the vendors for a phone call with our next retreat so that we can go back and forth with them and going forward, I wish that we could have hyperlinks in their big electronic report to sort of click there and pull up the actual article, and click there and for every article that they review, I want to have one page. Here's the strengths of this article. Here's the limitations. Here's the unclear, like, I mean, very simple. One page for each article. I want more than just the numbers.
- Chris Standaert: Alright. We'll let Josh off the hook then. So, lunch is over there.

- Gregory Brown: They have to have an abstraction form that they do on all these.
- Josh Morse: So, are we adjourned?
- Chris Standaert: Do we have updates or reviews in progress? Did you want to do that?
- Josh Morse: I gave those updates early in the morning.
- Chris Standaert: I do have an announcement I have to tell everybody. I am leaving the state in September.
- Joann Elmore: Oh, no.
- Chris Standaert: Yes. So, I am leaving UW and going to Pittsburgh, as of September 3rd I'll be starting there. Yeah.
- Joann Elmore: You can't do that.
- Chris Standaert: So, I will be here for the next meeting and for July, but I won't be there by the retreat.
- Kevin Walsh: You'll be at the next meeting but not at the retreat?
- Chris Standaert: Not at the retreat, yeah. So, you all, this is, of all the things I had to think about leaving to leave here, this was the hardest one to leave.
- Kevin Walsh: Harder than the Seahawks?
- Chris Standaert: Well, I guess I'll watch them. No, this has been the most, probably, other than . . . I like my patients. This is one of the clearly more fulfilling endeavors of my career, in terms of the intellectual engagement and the meaningfulness. It's not really matched by anything else I've done. So, I have to thank you all, because you're the ones who did it, right. It's a group thing.
- Joann Elmore: Boy, we're going to be devastated. You so skillfully manage the discussion and the personalities and when we act up. You do such a great job.
- Chris Standaert: I appreciate that, but this will be eight plus years I've been here, right? So, I never asked Josh how much time I had

left. I don't know if I wanted him to tell me, but I assume next year would have been my . . . this would have started my ninth year. So, I'm not too far from being done as it was, yeah, but it was a complicated decision. I'd be happy to talk to anybody who wants to talk with me at any point about why or what happened, but it was a complicated decision, and a lot of it is driven by UPMC is a whole different structure where they have their own insurer and they have a great mix of outcome data and financial data, and they want to change their spine care policy, which is really what I want to do, change how we deliver care for spine issues. That's why they hired me. That's a lot of my job.

Joann Elmore:

Cool, yeah.

Josh Morse:

We are adjourned at this point.