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**Health Technology Clinical Committee Public Meeting**  
November 20, 2015

**Craig Blackmore:** Well good morning, everyone. I want to call the meeting to order. This is the Washington State Health Technology Clinical Committee, and I'm Craig Blackmore, the chair, and we have a quorum of committee members. So, we are now in session. Let's start off with any program updates, Josh.

**Josh Morse:** OK. Thanks, Craig. Welcome. I would first like to welcome our new and returning committee members to their first decision meeting today, Dr. Brown and Dr. Kaplan. Thanks for being here. So, on today's agenda are two decision topics, lumbar fusion for patients with degenerative disc disease uncomplicated by comorbid spinal conditions, and this is a re-review. And the afternoon topic is tympanostomy tubes in children.

So, a quick background on the topic. The lumbar fusion topic, this was selected for re-review by the director of the Health Care Authority in 2014. It was originally selected and reviewed in 2007 by this committee. And your meeting materials contain the original policy information, and we have copies of the original report, as well as the new report available to you this morning.

The afternoon topic, this was a new topic, is a new topic for the clinical committee, and it was selected also in 2014 by the director of the Health Care Authority.

Scheduled for the rest of this year, looking ahead in January, are two topics, Novocure and Cardiac stents, a re-review, followed in March by spinal injections, another re-review, and a new topic, extracorporeal membrane oxygenation. And then in May, we have scheduled bronchial thermoplasty for asthma, and platelet rich plasma for healing for musculoskeletal conditions.

So, for our stakeholders and anyone else interested, these are the ways to participate with the program. We have information sheets about how the program works, and you can learn more about the functioning of the program and the committee following the website there. And we have information on our website. If anyone wishes to comment today, there are forms available on the table outside to sign up, and there's a comments section here shortly, in about 30 minutes. Thank you.

Craig Blackmore: So, the first item for business today is actually review and approval of the minutes from the prior meeting, which was in July. We did not have any new business at that meeting. That meeting was focused on approval of decisions previously made. So, the, uh, minutes have been distributed to the committee members and publicly available. So, I would entertain either a motion to approve or if there were any concerns or comments about those minutes.

Chris Standaert: Motion to approve.

Seth Schwartz: Second.

Craig Blackmore: Alright. Vote in favor of approval of the minutes, I'll just have you raise your hands.

Josh Morse: That is eight approve.

Craig Blackmore: And we have abstentions from people who were not participating in that meeting.

So, the first new business for today is the re-review of the lumbar fusion topic and we'll start off that discussion with the presentation by the Washington State agencies, Dr. Franklin.

Gary Franklin: Christina, the slides are going to be pulled up here.

Christine Masters: It should be, if you touch the screen.

Gary Franklin: What?

Christine Masters: If you touch the screen, then it should come up. No. It's not working.

Gary Franklin: OK. I can see that. Thank you. This is an extremely important topic. I'm not going to beat around the bush today about how important this is to the state agencies and especially to L&I. Lumbar fusion for patients with chronic lower back pain and degenerative disk disease is a covered benefit under these conditions from the 2007 decision, and the thing that was done in that decision was that because lumbar fusion was found to be equivalent to intensive rehab, multidisciplinary rehab in three randomized trials, the committee decided that if a patient had degenerative disc disease and met the criteria for, you know, they could have a pain program. And if they failed that pain program, they still had their chronic low back pain, they could get a lumbar fusion. That was pretty much it. There wasn't really a huge amount of attention paid to the safety profile or to the cost at that time.

The medical directors then and now gave high scores to concerns over safety, efficacy, and cost-effectiveness.

Degenerative disc disease, of course, arises from a natural degeneration of the intervertebral disks and adjacent structures. The theory, which in my view is unproven, is that degenerative disc disease is associated with low back pain in

many individuals, but some patients with chronic low back pain get better with no treatment or with treatment, such as intensive rehab, graded exercise, chiropractic, cognitive behavioral therapy, etc.

Lumbar fusion may have a clear role for treating traumatic injuries. Patients with significant and measurable instability, congenital defects, or central canal stenosis with neurological impairment. A significant proportion of the fusion procedures are done, however, in patients with chronic low back pain and uncomplicated degenerative disc disease. The surgical premise for fusion is that this degeneration causes pain that can be reduced or eliminated by immobilizing the disk. Oddly enough, the introduction of the artificial disc would sort of imply that the opposite is true, that if you increase movement, you might reduce pain. Substantial evidence shows that lumbar fusion is no better than intensive, structured, multidisciplinary treatment for chronic low back pain, but with much worse safety profile and greater cost. The re-operation rate is high, and surgical complication rate is high. Multilevel fusions and circumferential approaches are often performed without strong evidence of corresponding improvement in pain and physical functioning.

I'm sure that others may speak to this as well, but since about the late 1980's, in addition to trying to fuse the spines, the bones together, a lot of hardware is placed. Back in the late 1980's, it was primarily pedicle screw fixation devices, and then starting at about September of 1996, the first threaded fusion cage was introduced. And now, well over 90% of our patients receive either one or both of these devices for lumbar fusion.

One of the markers of appropriateness of treatments is how much regional variation there is in these treatments, and it turns out that from the Dartmouth Atlas and the work Jim Weinstein did, back surgery, and especially lumbar fusion, has the highest coefficient variation, as much as 20:1 compared to other elective procedures in this country. Just, for example, there is a lot less lumbar fusion done in the Northeast than there is in other parts of the country.

Current state agency policy, obviously, because of the last decision is, uh, that we preauthorize and allow lumbar fusion.

This is a utilization and cost data of lumbar fusion, just from three years. You can see that L&I pays for more lumbar fusions than the other agencies. The overall costs per year is between 30 and 35 million dollars. I believe that the lumbar fusion for a while at least was the highest inpatient cost for the State Public Employees Benefits Board, and you can see the overall costs there. They average out to about \$50,000 per fusion.

The folks that are getting most of the fusions are middle-aged, working-aged people. L&I, for many years, had a, a more restrictive guideline that required measureable instability or neurological impairment, or neurological signs related to, say, stenosis, but starting with the last decision, we added the fact that someone could get a pain clinic program, and if they flunked that, they could get a fusion.

So, that's what happened, um, we paid for a lot more pain programs, since that decision, but the number of lumbar fusions did not really change, and in fact, the data is not on the slide here, but we have been able to look at some actual rates of lumbar fusion, the number of fusions per, say, thousand low back cases, and that rate actually went up, because L&I's number of incoming claims has gone down over the past seven or eight years.

I think the evidence report is quite clear about the fact that there is no benefit of fusion compared to intensive rehabilitation, and I, I don't really want to go into much more detail, because that will be presented by ICER.

One thing I wanted to go through a little bit is how much worse the outcomes are from lumbar fusion in worker's compensation. We've, every time we do a, do a, look at a new topic, the vendors always look at special populations, and, you know, that part of the review almost never comes up with any special populations that do particularly worse from the things we usually look at, but lumbar fusion, it turns out, there are many studies that have shown that the outcomes of lumbar fusion are way worse in worker's comp than in non worker's comp. And our state's Spine SCOAP program has found the same thing.

We've conducted three studies using population based data from our state worker's compensation program. These are three published studies. The first one was published in, I believe, 1994, and it was from all of the fusions that were done in the state and worker's comp between 1986 and 1987. We found that 68% of workers were still totally disabled two years after the lumbar fusion and that 23% had additional surgery within two years.

The next study was actually a much larger study. It was designed the same way, but it was done between 1994, cases that were done between 1994 and 2000. Again, this was every single fusion. This was not, we didn't cherry pick the cases. Every fusion and injured workers, and again, 64% were completely and totally disabled at two years, 22% were re-operated on. We have also looked at the pension rates in our patients who had a fusion at least ten years ago, and approximately 41% of our workers are totally disabled on either our pension or SSDI from ten or more years ago who had a fusion.

The safety issues of lumbar fusion are significant. This report goes into this, and I'm not going to go over that any more.

We did do a third study that looked at mortality after lumbar fusion surgery in our injured workers and found that mortality was increased. It wasn't particularly increased in the perioperative period, but it seemed to be related to opioid-related deaths in the, in the months and years following. So, you know, pain is not really improving in a lot of these patients.

Something that's not really called attention to in the report very much, but something that all of us that practice and see neurology in the outpatient setting, see failed back surgery syndrome. It's actually, you know, FBSS. It's, this is a, you know, a syndrome that you see of people that have had lumbar

fusion mostly and lots of scarring in their spine and, you know, such terrible pain and neuropathic pain especially, arachnoiditis. This is extremely disabling, often leading to other invasive procedures.

The costs, as I mentioned earlier, are about \$50,000 per paid case in our state, but you have to add to that the high cost for repeat surgery and failed back surgery syndrome.

The ICER integrated evidence rating, they will go over this, but this is a low value procedure.

Starting a few years ago, some private payers, especially starting in the Blue Cross/Blue Shield of North Carolina, decided not to cover lumbar fusion for degenerative disc disease, and now other payers have done the same thing.

This is the Blue Cross/Blue Shield North Carolina policy. I'm not going to go over it in detail.

And then I did want to point out that the Washington Statutory Bree collaborative, which is a public/private collaborative of most of the healthcare players in Washington State, came up with a lumbar fusion warrantee. This was led by Bob Mecklenburg at Virginia Mason and some other leaders in surgery, and some of their conclusions were that this model does not endorse the use of lumbar fusion to treat back pain associated with degenerative disc disease in the absence of structural instability, and even in the presence of spinal instability, a structured, conservative nonsurgical approach is preferred for patients without neurological symptoms or signs. They also concluded that the failure of other therapies is not a clear indication for lumbar fusion.

So, with all of this in hand, it seemed quite clear to the agency medical directors, that lumbar spinal fusion for chronic low back pain and uncomplicated degenerative disc disease should be a noncovered procedure. Thank you. Any questions?

Chris Standaert: Gary, do you know how many, what, of all the fusions done and paid for by state agencies, do you know how many are for degenerative disc disease alone, as opposed to spondylolisthesis or other various structural problems? Can you, have you broken that down?

Gary Franklin: I think in the L&I's data, we didn't break it out. Did you, did you have data on that?

Female: There should be an update in the evidence, within ICER.

Gary Franklin: I think in L&I in our two studies, spondylolisthesis was, I think, around 20 or 30% of the cases, but the rest is pretty much chronic low back pain with all manner of additional things added into the diagnoses because of MRI findings and x-ray findings, but most of these patients having fusion in our system have chronic low back pain.

- Chris Standaert: OK. And as a correlate, do you know how many of those people going to the chronic pain programs, the SIM programs, how many people had their course altered by doing that? How many people went in with back pain and did well versus how many went in and wound up going to surgery? Do you have any idea of the success rate of those?
- Gary Franklin: Well, we, we don't. We didn't...
- Chris Standaert: OK.
- Gary Franklin: ...we, we weren't able to do a, you know, we tried to look at that a couple of times, and it was just very hard to look at. Overall, though, you saw that, you know, we, we paid for a lot more pain programs. The fusion, number of fusions didn't go down, but the fusion rate went up. So, you know, it didn't look to us like it really, you know, had much of an impact, but we didn't look at outcomes. Yeah?
- Michelle Simon: I'm curious about the pain program that these patients were referred to. Were they comprehensive? Did they include, what, what did they include?
- Gary Franklin: yeah. So, we only pay for CARF accredited intensive multidisciplinary pain programs that have at least three inputs, including physician, psychologist, and therapy. These are, these have, over many years, been done by contract. Now, we have a fee schedule. It's usually five days a week, six to seven hours a day for four weeks. And then starting with this decision, we actually added more incentives for follow back into the community so that there would be at least better handoffs. Once people left the pain clinic, we went to, L&I went to a huge amount of trouble, it took us over a year, to implement the policy, because we wanted to do it right and, you know, we don't have outcomes from that, but we didn't see any decrease in the number of fusions. In fact, the rate went up. These are very highly-structured programs and they're around \$15,000.
- Michelle Simon: OK.
- Gary Franklin: Yeah.
- Joann Elmore: When you say you don't have outcomes, you don't know if the people who had the fusions are the people who went through the pain program, or you don't know how many of the people who went through the pain program had fusions?
- Gary Franklin: Our impression is most of the people who went through the pain program still had a fusion, but we don't have outcomes. We didn't, we didn't talk to people. We didn't get, you know, measure their outcomes. The, you know, the best way to do that would have been to do a prospective study of baseline and follow up on pain and function and other kinds of measures. We didn't do that. We don't have good data on that.

- Seth Schwartz: And just to be clear, these pain programs, are these different than the intensive rehab that were used, that, that we're talking about as the alternative to surgery? Are these just pain programs?
- Gary Franklin: No. I think that, the pain programs that we do in this state are similar to the pain programs that were done in the three randomized trials.
- Craig Blackmore: Thank you. So, next on the agenda are the scheduled and open public comments. So, we've had some people contact us in advance that they wish to address the committee. There is also the opportunity for anybody who is here if they wish to say something to the committee, there's a signup sheet out in the hall. If you want to address us, you need to sign up. I think Christine is going to bring that in. We can start off with the scheduled presentations, of which there are?
- Josh Morse: There are two. I have the first as a group of four individuals. They each have three minutes.
- Craig Blackmore: OK. So, we have one Dr. Yam who signed up. If anybody else wants to address the committee that's here, please let us know, and we'll start with, forgive my pronunciation, Drs. Chapman, Oskouian, Nussbaum, and Dr. Fewel. We allow three minutes for each presenter. So, collectively, you have 12 minutes, as there are four of you, and the slides are on the board. We will let you know when there is a minute left.
- Jens Chapman: Dear Mr. Chairman, dear members of the committee, my name is Jens Chapman from the Swedish Neuroscience Institute, a member of the Providence Health Services. Speaking as an orthopedic surgeon, it is a distinct honor to speak on behalf of many neurosurgical societies, in fact, all major neurosurgical societies, with input of orthopedic spine surgery leaders in the field. Dr. Matt Fewel sends his apologies. He had a major family emergency, and we wish him all the best for this. Thank you for taking his absence into your consideration.
- To the point, thank you for the opportunity to speak. The combined group of surgical spine experts from around North America was surprised at the re-review and identified that basically in our best professional opinion, this is a repackaging of previous data that has been presented across the street in the Marriott at SeaTac several years ago with many of the present members in attendance. We did not identify significant new data that would identify or support a change in the policy drafted back then with your collective wisdom.
- In terms of the subject of uncomplicated lumbar disk disease, our field continues to try to identify variables, which more or less help us understand what is going on in these complex patients and just a list of these variables is depicted here. We find that these are uniformly not present or adequately addressed in these studies available that are the basis of the ICER report, as we reviewed it.
- We did identify that nonoperative care remains a field, which has received limited scrutiny. All of us, as surgeons, espouse and cherish the value of

appropriate nonoperative care in these patients and fully support it. We also identified that there are significant limitations that remain in the field as identified by our agency director, Dr. Franklin, just right now. We identified, also, very much to our surprise, and this now in the peer reviewed literature, that this area of cognitive behavioral therapy is actually not one therapy but is actually a family of vague therapies. We quote the Cochrane collaborative, which identifies that cognitive behavioral therapy has an effect... a positive effect of patients, but the major question remains to be answered, and that is what type of CBT, of the over 20 different therapy concepts, helps for what patient. This is currently simply not known. So, the question that we, as surgeons, responsibly ask you members of the committee to consider is, what kind of nonoperative care actually could be considered and should be considered for degenerative disc disease patients and how effective is it truly?

We did find some exception to the very kind of cherry-picking way of looking at the methodology of the selection of patient data that is available. We found that there is a substantial and robust body of peer-reviewed published literature data that identifies the positive effects of fusions in selected patients and a number of prospective trials. That includes the fusion cohorts in the artificial disc replacement group, the SPORT Trials, cost-effectiveness data, even certain prospective randomized clinical trials, one of which was performed here in the State of Washington, itself, by my former partner, Dr. Sohail Mirza, that fusion remains the, with all its stated limitations, the most powerful intervention we have in selected appropriately-performed patients. Special society guidelines, especially from my colleagues in neurosurgery, have done a yeoman's job with experts in the field including nonoperative colleagues, identifying socially responsible, evidence-based guidelines for the appropriate treatment of patients with degenerative disc disease. There is also a very robust data registry movement, which our state, I daresay, with a sense of pride is a leader nationally and internationally in having... through spine scope. We do want to ask that the reference to spine scope made by agency director, Dr. Franklin, be kindly disregarded, because we have strong procedural and methodological concerns about this use and interpretation of data, but there is a surgeon-led, hospital-derived database, which is very strong, and you have the opportunity of asking questions about its applications and interpretations in terms of patient safety and outcomes to several members here in the audience.

The current literature identifies that significant improvements can be made in appropriately-selected patients with appropriate modern day surgical therapies, which have significantly evolved, since the early 2000's. If you decide that fusions are not appropriate, this is really a problem for patients because an alternative therapy really does not exist.

So, when is a lumbar fusion indicated in the degenerative disc disease population? We, as societies, have really tried to do a very responsible job narrowing this field down and helping our patients and our society, as a whole, with prudent decision-making guidelines, which are not fiscally motivated on our part.

The proposal to you is... the challenges of current policy are based off inadequate data with flawed analysis. For instance, just one vignette, the much touted European studies came from a different society, different legal structures, different compensation plans, and even included patients who did not have fusions but modified rubberbands placed into them with the intent of not fusing these patients.

Bundling patients into low back pain under generic grouping restricts patient access and may have very significant adverse outcomes on these patients with significant disease burden. Chronic low back pain is, without a doubt, an unsolved major health and resource burden to the effected patients and society. There is not a single, simple answer for this treatment problem. Operative versus nonoperative care we find fundamentally flawed. Legislating away surgical care will not solve the problem. Recent prospective randomized trials, such as the one by Fritz, et al, in JAMA 2015, identifies nonoperative care with PT programs and some other structured programs to be ineffective.

What are possible solutions? Well, denying access to surgical care without an appeals process is not supported by the scientific literature. An integrated, multipronged approach with a combination of nonoperative and surgical care for those who have failed appropriate nonoperative care, offers a likelihood for success. We have the luxury of having realtime, U.S. derived data, high quality, hospital derived, without surgeon filters that now offers unprecedented insights if it so pleases the committee.

In appropriately selected patients, we have lumbar fusions that are safe and effective surgical treatments with complication rates that, in our best professional assessment, are way lower than those that the committee has just been presented with by Dr. Franklin. I rest my case. Thank you ladies and gentlemen. I introduce Dr. Rod Oskouian.

Rod Oskouian:

So, I just have a couple comments. One, you know, the, the, being a neurosurgeon, this societies and the AANS and the congress, you know, we know low back pain is a major problem, and just in the last year, this society has come up with very strict guidelines. In fact, I think Dr. Chapman pointed out earlier, you know, I think the real issue for us is, you know, how do you, in the nonoperative group... what are some structured ways that, you know, patients who need to get treatment, you know, what are, what are those programs? So, for example, if a patient who's got chronic low back pain, there really isn't good alternatives for them in a community, whether it's L&I, Medicare, private insurance. So, I think most of the surgeons, if you look, you know, in the last ten, fifteen years, most guys aren't doing low back fusions for low back pain. That just doesn't happen. Usually, and I think to Dr. Standaert's point, I think when you start to look at the patients actually getting fusions, they have either a spondy, and it's a redo. They have foraminal stenosis. So, I don't think, you know, today, we don't... we don't do low back fusions just for low back pain. In fact, most patients who have low back pain, you know, we don't want to have unhappy patients. We know those patients don't do well if they don't have isolated structural problems. So, I think the notion that, you know, all these

fusions are being done just for... because someone's failed conservative management is not true.

Charles Nussbaum: Charles Nussbaum from Virginia Mason. I don't have a whole lot to add to Dr. Chapman's excellent comments, but as... I'm from Virginia Mason, and working at a place that has been trying really passionately to add more structure around patients with low back problems, in general, not just degenerative disc. What constitutes organized nonsurgical care, especially if you're not in the L&I population with access to some of these things is very difficult. Nonsurgical care is very fragmented right now, very poorly reimbursed by payers, often is really focused on people getting multiple, inappropriate injections without any emphasis on reconditioning. There are some patients that do benefit from fusion for degenerative disc. It's a very small minority. All surgeons would agree with that. Then also, all surgeons would agree that nonsurgical care is the first step, but we need help, really, in developing a better nonsurgical filter if you will, so that we are focusing our efforts on the patients who really need surgery, and I think that the data for both nonsurgical, you know, as well as surgical outcomes to a certain extent right now, is very, very messy, but our specialties are starting to do a very good job at tracking these outcomes and trying to refine this with the SCOAP efforts and N2QOD efforts, but even at our organization where we're really trying hard to focus on the nonsurgical aspects of these patients, to put it really simply, getting reimbursed for that and tracking those outcomes is very, very difficult. I would also say that the safety of these procedures has improved substantially compared to 14, 15 years ago, as presented in a prior presentation. So, thank you.

Craig Blackmore: Thank you.

Charles Nussbaum: If it so pleases the committee, I would like to introduce Dr. Marjorie Wong. She is a neurosurgical colleague from the State of Washington. She has just arrived. She came from the eastern part of the state and had a travel delay. Dr. Wong, would you like to make some comments about operative versus nonoperative care?

Craig Blackmore: So, let's just, procedurally, Dr. Wong, you're welcome to sign up and we'll give you an opportunity. You may go now, that's fine. Either way.

Marjorie Wong: I don't think I have any specific comments. I'm sorry for my (inaudible).

Craig Blackmore: OK. Well, thank you. Next, we have Dr. Trent Tredway. Is he... he's here.

Trent Tredway: Thank you for inviting me today. Or, I think I invited myself, but I'm Trent Tredway. I'm a neurosurgeon here in the State of Washington in private practice, formerly of University of Washington. I was the associate professor and trained a lot of residents and fellows. We've heard some excellent presentations generated by both national and local spine surgeons and given by Dr. Chapman and colleagues who did an excellent job. I wholeheartedly support their presentation. We have also heard from Dr. Franklin and the Washington State Labor and Industry regarding his findings and conclusions from the cohort

of injured workers in the state. I would like to discuss some of the problems and point out some of the issues with the slides.

First, we need to remember that the patients with associated conditions, as he listed, are not supposed to be included in this decision. However, this is not the case, as these conditions have not been included... or have been included in the criteria when attempting to try to get a spinal surgery approved.

Second, as he also states... he also stated that patients must meet conditions and structured intensive multidisciplinary program, as established by the agency. And as you have pointed out, this isn't having... this never really gets set up to evidence-based medicine. It hasn't been really evaluated and some of the literature that we would like to see from that group would be very helpful. It needs to be held to the same standard as the surgery group that they always tell.

Third, it is not appropriate for Dr. Franklin to assert that there is a higher complication rate and cost when comparing surgery to nonoperative treatment. The cheapest and easiest is to absolutely do nothing in these patients, but that's not ethical. So, that really shouldn't be looked at. One of the questions that I also have for Dr. Franklin, as well as the Health Technology Assessment group, is that the rate of return to workers, excuse me, the rate of return to work on these injured workers from the agency's conservative treatment of low back pain, I would like to know what, you know, what the cost is and actually what the rate of return of work. It's also very important to notice that these patients that receive lumbar fusions are delayed over three years from the diagnosis to treatment. There is also a pilot program in L&I that's supposed to fast track these patients, but I haven't seen any published reports on that either. Dr. Franklin's research often is anecdotal and retrospective at best, and it has not really been held to the same scrutiny by the Health Technology Assessment, as demanding of the spine surgeons.

Fourth, the data that presented with the spine SCOAP should be looked at a little closer, especially in its relationship, once again, to the delayed treatment of these patients with low back pain. There is inherent biased that the difference when comparing Washington State workers that are injured compared to the non workers and to some of the patients that are self-insured, we'd really like to see what the difference is in that, but I think it may be due to this delay of almost three years. I have, personally, witnessed a number of patients that have been depressed, injured workers trying to wade their way through the L&I system, and that should really be looked at, as the inefficiency of getting these patients to actually proper treatment.

I would also like to discuss some of the problems of the highly-touted BREE collaborative lumbar fusion, which is part of the Health Technology Assessment to a certain degree. I was absolutely astonished in the way this procedure and process was performed. The comments and information that we provided from the state societies and the stakeholder surgeons fell on deaf ears. It was ramrodded through the committee, and although there were a number of individuals on that committee that agreed with my assertions that the

committee did not engage properly with the state societies, it was heavily favored in the payer, and they also included some of the things that we kind of shake our heads at of a physiatrist, which I have many friends and consider them very good physicians, but they're the ones determining the surgery. That's almost similar to having an Emergency Room doc determine who goes to bypass or who gets an angioplasty, and it's just not real acceptable in my opinion.

So, finally, I am concerned that the power and decisions the Health Technology Assessment committee makes are unconstitutional and discriminatory. The decisions made here actually affect Washington State injured workers, as well as their economically challenged patients, also known as Apple Care patients, formerly known as DSHS or Medicaid patients. I do not see any route of appeal process, and as you are aware, Isaac Ruiz won a decision against the Health Technology Assessment regarding the constitutionality of the decision to deny patients treatment with dorsal column stimulation for chronic back pain. I want to state that many surgeons around the state are happy to help with you guys, but you need to kind of engage us a little bit before and give us enough time to talk about this and actually come up with a good collaborative effort. Thank you.

Craig Blackmore: Thank you. Dr. Yam.

Dr. Yam: Hi. Thank you for allowing me to speak. So, I'm a neurosurgeon in Walla Walla, Washington, and I encounter a lot of patients with degenerative disc disease. It is a common disorder that we all see and I think one of the difficulties that we all encounter with it is that, like has been brought up many times, it is rarely seen in isolation. You rarely see a degenerative disc patient that has back pain alone and oftentimes, it is the loss of cartilage, the loss of disc height, the compression of the foramen, the compression of the disc into the canal that causes symptoms in patients, and it is these things that I think oftentimes get neglected in many of the studies that we look at and a great example of this is all four of the randomized control trials that are presented today that are old data, the Brox studies, the Fairbank study, and also the Fritzell studies all include patients that have complicated courses. If you look at the inclusion and exclusion criteria of these studies and not just at the overall summary of the studies, but if you actually look at the data and where the patients come from, if you look at Brox's two studies, they do not exclude patients with leg pain, and they later measure it. Why are they measuring these things that are supposedly not happening in their patients? Why is leg pain and radiculopathy included in patients with degenerative disc disease? Why do those two things go together in those large studies, which are, again, touted to be the source of information on uncomplicated degenerative disc disease, which I think is incredibly rare, again, and then, if you look at the Fairbanks Study, they include patients with or without leg pain. Again, how does a degenerative disc disease patient have leg pain if it's uncomplicated? And if you look at Fritzell's study from 2001, which also is one of the foundations of the ICER Report and also Dr. Franklin's information, that it also includes patients with back and leg pain. So, I think what really needs to be looked at here is, what are we actually talking about? All of the evidence presented today includes patients with leg pain and if you're

going to use this to somehow isolate out back pain and degenerative disc disease alone, none of this data is useful for that. So, I would really ask that the committee continue the current policy, leave it in place. It makes the most sense. The nonoperative treatments proposed as an alternative are not working for L&I, and let us, as a society, and let us, as physicians, try to help determine what the best course of patient care is in this complex disease. Thank you.

Craig Blackmore: Thank you. Is there anyone else present who wished to address the committee but has not had an opportunity to sign up? OK. Do we have a phone connection? So, in just a second we are going to see if there is anybody who has called into the meeting that wishes to address the committee, just give us a second to deal with the technical aspects here. Is there anyone who has called into the meeting that wishes to address the committee regarding lumbar fusion?

OK. Then we'll put the phones back on mute, and we're going to close the open public comment period, and we'll move on with the evidence report. And while we're setting up for that, I want to introduce our clinical expert, Dr. Shonnard. Thank you for coming. It is very important to the committee that we... we are not all spine surgeons. In fact, none of us are spine surgeons. So, it is very important that our decisions be in the appropriate clinical context. So, we thank you for coming and being willing to contribute that. We do not ask the clinical expert to make a specific presentation, but we will, doubtless, have questions for you throughout the course of our discussion, and we appreciate your input. So, thank you for being willing to be here.

Neal Shonnard: Thank you for inviting me.

Craig Blackmore: We also ask that really all presenters, including the clinical expert, tell us if there are any conflicts of interest or if anyone has paid for your services to be here. So, Dr. Shonnard, did you have any conflicts of interest to declare?

Neal Shonnard: I don't and...

Craig Blackmore: Thank you.

Neal Shonnard: ...I pay for everything.

Craig Blackmore: Thank you. OK. Let's, uh, let's proceed.

Daniel Ollendorf: OK.

Craig Blackmore: Dan.

Daniel Ollendorf: Um, so I guess, um, I should first refer to Gary's map of the country and say that after this meeting, I'm going to go back to Boston to get my lumbar fusion, but... just kidding.

So, um, we are here to talk about our evidence review, examining the comparative clinical effectiveness and comparative value. This is, as was

mentioned before, re-review of a previous systematic review done for the Health Technology Assessment. We'll provide some background on the condition, although Dr. Franklin already has to some extent, as have the public commenters. I'll talk about the topic in some context, go over our literature search strategy, describe the results in terms of quality and type of evidence, as well as they key questions that were set forth, and finally, our evidence ratings and the rationale behind them.

So, as has been discussed, low back pain is extremely common, chronic low back pain. Lifetime prevalence can range as high as 60 to 70% in industrialized countries. It often presents as a temporary condition with a quarter to half cases spontaneously resolving. Conservative therapy and the various forms of that is often used as a firstline approach, and I'll talk about some of those forms a little bit later. The condition is considered chronic when low back persists for at least three months, and as we have already discussed, the economic impact of low back pain is substantial, in large part due to its effect on the working class and its detrimental impact on productivity.

So, degenerative disc disease, a condition in which one or more damaged vertebral discs can cause pain in the lumbar spine. It is not limited to the lumbar spine. It can also occur in other areas of the spine. This is a natural process of aging. So, some feel that the term disease is a bit of a misnomer. Many individuals never develop overt symptoms of degenerative disc disease, and has been mentioned, this is often something that Carson Odegard-occurs with other spinal diseases or disorders. Importantly, the presence of degenerative disc disease correlates poorly with the presence and severity of low back pain, making it difficult in many circumstances to actually attribute the symptoms to the condition itself.

So, lumbar fusion, there are many in the room who could talk in more technical detail that I can, but this is a family of procedures designed to stabilize the spine by fusing two or more vertebrae together using a variety of approaches, in terms of instrumentation, as well as bone grafts or bone morphogenic protein, designed to eliminate motion in the fused segment that is causing the problem, and the hope is to decrease or eliminate the back pain created by that instability or motion. It is used to treat a number of indications, including spinal deformities, fractures, and other chronic conditions, and the controversy and really the reason we are here today is to talk about degenerative disc disease in the absence of other clear indications for spinal instability.

So, in terms of context, more broadly than just the State of Washington, there is still an increase that is being observed in the number of lumbar fusion surgeries in the U.S., two-fold increase has been observed in a nine-year period, 2000-2009, but across that time, other studies that have attempted to measure the presence and severity of low back pain have not seen an increase of that magnitude. So, the state commissioned ICER to update a previous Health Technology Assessment conducted in 2007 that focused primarily on four RCT's that, again, were described in both Dr. Franklin's presentation and public comment. These were all XUS RCTs. Our update includes an additional RCT, which is also XUS conducted in Japan, some new observational studies, and

studies that were intended to, in many cases, pool data from the existing RCTs and follow those patients for longer periods of time.

So, we don't have to go into too much detail on the key questions. The major contrast in this review was fusion surgery, as compared to various nonoperative approaches to care that said we did not exclude the possibility of comparative studies for fusion versus minimally invasive treatments that would go beyond nonoperative spinal injections or other minimally invasive procedures, electrothermal therapy, etc. As you will see, we did not find any comparative studies. We did specifically exclude the studies that compared spinal fusion to artificial disc replacement, because artificial disc replacement was another topic thread for the Health Technology Assessment program. So, the decision to re-review that particular topic would be made separately.

So, in addition to measures of clinical effectiveness that are typically reported in these studies, these are several validated pain disability and function scales. We also looked at measures of treatment success, or successful clinical outcome. There has been a lot of research done to try to identify movement along some of these scales that would represent a clinically important difference or a change. In addition, there are a variety of measures that are more homegrown, studying specific measures of treatment success, and we looked for all of those.

We also looked for rates of adverse events and other potential harms during the perioperative period, as well as over the longer term for both surgery and whatever its alternative approaches were in available studies.

And then, as always, we attempted to look at differential effectiveness and safety of lumbar fusion across a number of existing factors or subgroups demographically defined, clinically defined, as well as factors that would be associated with the performance of the procedure itself, use of instrumentation, single versus multilevel fusion, etc.

Then finally, as is our charge, we looked at evidence on the costs and potential cost effectiveness of lumbar fusion relative to its alternatives.

So, let's talk about the scope in some more detail. The focus for this evaluation, similar to the original review, was on adults with chronic low back pain and uncomplicated degenerative disc disease. So, this was defined as patients without confounding spinal conditions, such as radiculopathy, greater than grade 1 spondylolisthesis, severe spinal stenosis, those with acute trauma, or systemic disease that affect lumbar spine. We recognized from the outset that many of these studies would have mixed populations. So, we made a decision to include mixed studies, only if outcomes were reported separately for individuals with chronic low back pain and uncomplicated degenerative disc disease or a preponderance of patients had such a diagnosis greater than or equal to 75%.

So, the intervention of interest included all major technical approaches to lumbar fusion regardless of technique. So, that could include various anatomic approaches, laparoscopic versus open procedures, or different types of

hardware utilized, as well as grafting. Comparators included conservative management approaches. These could have included individually-focused approaches, so focused on one modality, physical therapy, rehabilitation, cognitive-behavioral therapy, medication management, as well as multidisciplinary programs that included several components. As I mentioned, we also considered minimally-invasive treatments, radiofrequency ablation, electrothermal therapy, or other nonsurgical, minimally-invasive modalities, if comparative studies were available.

The outcomes, as I mentioned, these measures of pain, function, and disability, pain is typically measured using visual analog scales. That's what we most frequently encountered. There are two functional scales used in these populations, the Oswestry Disability Index, and the Rowland Morris Disability Questionnaire. As I mentioned, measures of treatment success or successful clinical outcome, however they were defined, changes or reductions in the use of opioid or narcotic medications, return to work and/or resumption of normal activities, mortality both during the perioperative period and over the longer term, other complications and adverse events, requirements for repeat surgery, and other retreatment according to the type of initial surgery, and studies that focused on cost and cost-effectiveness.

We looked for studies published between January 2000 and October of 2015. We posed no restrictions on the inclusion of randomized control trials and comparative studies. For our case series, we limited these based on some quality criteria, because we were interested in information from case series on the longer term. We looked at studies that were conducted over two or more years of followup with a hundred or more patients, 80% or better retention of the sample, and again, a preponderance of patients with uncomplicated degenerative disc disease, or findings stratified by indication.

In terms of what we identified, we found 19 publications in total. As I mentioned, five RCT reports, four from the original review and one additional, two secondary analyses of those RCTs and six longer-term followup studies focused on those RCTs. We also looked at two prospective cohort studies, including the study mentioned by Dr. Mirza, and an additional poor quality retrospective, as well as three case series. There are other data that I'll talk about that are included for contextual purposes. So, these may be large retrospective database studies, for example, that examine harms, but in those studies, again, it is very difficult to tease out a truly uncomplicated population from populations with other confounding indications.

What we found, in terms of these studies, is that we did find no studies comparing fusion to minimally-invasive treatments. We found, this was mentioned in the public comments, that most of these studies included patients who had a significant duration of chronic pains that they've been dealing with this for a very long time. There are issues with these studies and not uncommon to any comparative study looking at surgery versus a nonoperative form of management, in that there were relatively high crossover rates in many of these studies. So, patients initially randomized to nonoperative care who ended up getting surgery. Some patients randomized to surgery who elected

not to undergo the procedure, etc. And of course, this is a problem that is more difficult to manage the longer the followup is. There were some indications of heterogeneity of populations across the studies and, in fact, some imbalances between treatment groups at baseline, again making some of the conclusions problematic to arrive at. Of course, the interventions themselves, the type of fusion employed, and the type of nonoperative management used, were also defined variably.

So, I apologize for the small type. This is the way we start in the executive summary of our reports with our overall assessment of the strength of evidence for each key question, and then we'll focus on some slides that talk about the details of the studies that informs the key question.

So, our two major comparisons available to us were fusion, as compared to intensive or interdisciplinary rehabilitation, and fusion compared to physical therapy or exercise alone. We found moderate evidence in terms of the comparison to interdisciplinary rehab, suggesting no differences in pain, function, or return to work in the short or long-term, again complicated in some studies by high cross-over rates and variable definitions of the interventions.

In terms of the studies comparing fusion to physical therapy or exercise alone, there was moderate strength of evidence suggesting some incremental benefit of fusion over these individual modalities over one to two years of followup, one example being a faster return to work in some studies. However, differences appear to diminish, as followup lengthened in these comparisons. Then, as I mentioned, no studies comparing fusion to other minimally invasive comparators.

So, here is just kind of a brief rundown of the five RCTs, the four original ones are listed at the top. The fifth one, the new one, newer one from Japan, is the last one. One thing to point out is that the population in the Ohtori RCT is a little bit different. There are some differences across the studies and populations, but there is a bit of a difference here in that, while pain duration was similar, age at randomization was lower in comparison to the other studies. The patients were about ten years younger, and no patient in this study had any prior surgery. So, another challenge with looking at some of the data from the other RCTs is that some patients had prior attempts at surgery and others did not. In fact, in one of the Brox RCTs, all patients had prior surgery. In those studies where a portion had prior surgery, the studies did not stratify the results by those populations. So, that was a challenge, as well. Back to the Ohtori RCT for a second, however, the comparator in this case was patient self-directed exercise, as well as strengthening and stretching... muscle strengthening and stretching done by a hospital-based physical therapist. Most of the other studies, even the studies that had an individual modality, had clinician-supervised nonoperative care, and so one component of this was patient directed. Another difference in the Ohtori RCT is that patients were randomized only after examination using discography and discoblock injections. So, discography is a technique used to provoke pain in certain anatomic areas. Discoblock is used to induce pain relief in some of those anatomic areas, so patients had to have had a positive test for both, meaning the pain was

provoked on discography and pain was relieved on injection, to be able to enter this study. One important concern, and it is something the authors described as leading to the relatively low sample size, is that half the patients originally enrolled refused to undergo the exam, discography or discoblock. So, there is a potential concern about volunteer bias in that particular study.

In all of these RCTs, I think as was mentioned during the public comment, some of the entry criteria are vaguely described, and so the Brox RCT, for example, did not exclude patients with leg pain, but did exclude patients who had clinical signs of radiculopathy. So, it is very difficult to understand exactly how those criteria were applied. One of the concerns with the Fairbank RCT is that no every patient got fusion. They were most... the preponderance of the patients did, but there were other surgical procedures used in a small percentage of patients.

So, again, these are a mix of RCTs, all of them done outside of the U.S. They vary in sample size. In some cases, there were nominal differences in baseline characteristics. So, I was looking through the Ohtori criteria, or the Ohtori baseline characteristics this morning. It may have been something that was, it was not statistically significant, but that could have been complicated by the small sample size. There were nominal differences in visual analog scale rating, or pain, so greater than a point on a ten-point scale at baseline. These studies did not do a lot of multi-varied adjustment to try to control for those differences. So, that's kind of an overall gestalt of the randomized evidence.

So, this is actually a result from a previous systematic review that examined final improvement in Oswestry Disability Index across the five RCTs, and I think this came from a Cochran review if I'm not mistaken, no. A different, review, OK. And you see here that overall, there is not a statistically-significant effect on the ODI across the RCTs. You do see some variability. Really, the study with the biggest marginal improvement was the Ohtori RCT. So, there has been some discussion and editorial and commentary that possibly this provocative testing before randomization might have honed in on a population that would benefit, but again, a small RCT with some of the design challenges I mentioned.

We also produced our own meta-analysis that actually focused on improvements ODI across the three RCTs that had an intensive conservative treatment group. Here, you also see a non-significant difference, but the confidence interval around that difference is much wider, because while there is some variability in the estimates, all of them cross... all of their confidence intervals individually crossed or nearly crossed zero. So, that really kind of hones in our... on our conclusion of no material evidence of clinical benefit in comparison to these intensive programs in these RCTs.

So, as I mentioned, there were followup studies conducted. These studies were conducted over one to two years of followup, and then there were additional studies conducted to examine these cohorts over longer periods. In some cases, pooling data across multiple RCTs, which, again, given differences in populations has its own challenges, these studies produced 4 to 13 years of followup information, and none of these longterm studies found any statistically-

significant differences between groups and measures of pain or function. There was an additional good-quality prospective cohort study conducted by Mirza and colleagues finding that functional outcomes favored surgery at one year of followup. So, a significant and clinically-important change on the Rowland Morris Disability Questionnaire at one year of followup and the challenges, potential challenges with this study is that a certain percentage, about a fifth of the population, did not receive fusion as their surgical approach. In addition, a conservative group was treated at physician discretion. So, there was not a standardized program of treatment in the conservative arm, and the physician... and the authors noted that fewer of 5% of patients got any sort of behavioral educational component to their nonoperative care.

So, we looked at return to work as another outcome. We identified this in seven studies. In the two Brox RCTs that were conducted in Norway, there was actually a percentage of employed individuals who returned to work, found to be numerically higher in the conservative group over the fusion group, but this was not statistically different in one RCT, and the numbers available at that time point were too small to be tested, according to the authors in the other RCT. Mannion pooled data from Brox over four years and I think the Fairbanks study was included in the 11-year followup, as well, and found non-significant differences in return to work over those longer periods of followup. In Fritzell, there was a statistically-significant difference, and this was a study compared to physical therapy alone in favor of the fusion group. In a secondary analysis, it was found that shorter duration of sick leave prior to treatment was also associated with better work status at followup in both groups. So, it wasn't necessarily a differential affect, but an important thing to note. In longer-term followup of this study, the original study followup was two years, there were no significant differences found at 13 years. Again, complicated by some of those changes, particularly high crossover and attrition of the cohort.

Other outcomes, in quality of life, there were quality of life measures available in four studies. NO significant differences between groups in three of the four. I think the one that produced a significant difference was the Mirza study. Again, that was comparing... a prospective cohort comparing mostly fusion surgery to conservative treatment at physician discretion. Patient satisfaction was assessed using a variety of instruments in eight studies, variable definitions, no significant differences between groups in seven of the eight, and the original Fritzell study found that significantly more patients would undergo surgery again, but in longer-term followup from that study, the direction of the affect changed to the conservative group, numerically only, not statistically significant.

Other outcomes, mental health, in particular depression, was evaluated in five studies. Two of the RTCs found no differences. A secondary analysis of Fritzell reported that having a great level of depressive symptoms at baseline was predictive of improvement in the conservative group but not in patients undergoing fusion. Long-term followup of Fritzell, that was the 13-year followup, did not find any significant differences between groups, and the Mirza study did find significant differences in favor of lumbar fusion in these patients.

So, onto treatment success. So, here the challenge was that a lot of the research and development around clinically important differences on scales like the ODI and the RDQ happened after these RCTs were conducted. So, work by Carrigy and others suggesting that there were certain numerical changes on those scales that would suggest clinically important difference was available in some observational studies but unfortunately not in the RCTs. So, in the RCTs, when treatment success was measured, it was typically a study to find a measure, and this was something that was either patient reported or was observer reported or clinician reported in terms of whether the treatment was a success. And kind of mirroring the findings for the scales... the changes on the scales themselves, there was no difference in patient or observer rated success rates in comparison to fusion to intensive or interdisciplinary rehab. There were higher rates of success or clinical improvement reported in comparison to fusion to single modality treatment, in this case one RCT looking at physical therapy, as the comparator. I believe the Mirza study also measured treatment success and found improvement there, as well.

So, as I mentioned, two of the five RCTs had no measurement of successful outcome, and in three RCTs, results favored surgery in Fritzell, but no differences observed in either of the Brox RCTs comparing to interdisciplinary rehab and studies predated those measures. The studies that did look at a minimum clinically important difference included the Mirza Study, which results favored surgery, and a case series of fusion, which was really intended to find demographic or clinical factors that would be predictive of surgical success, and in that particular cohort of patients, none of the factors that were examined were found to be significantly associated with the success measure, unfortunately.

So, moving on to harms. So, here, we were looking primarily at perioperative and longer-term mortality, where available, overall, complications and subsequent treatment. So, in terms of mortality, this, again, was a challenge. This was a measure that was either reported as having not occurred in the period of followup in these RCTs or was not actually measured or reported on at all. In other studies, other database studies that we used for contextual purposes, we found perioperative mortality rates, in-hospital mortality rates, ranging from 0.2 to 0.3%, so a relatively tight range by procedure type. In terms of overall complications, and this is again sometimes a challenge with surgical literature, there was not sort of a standard method applied across these studies to look at complication severity. Those studies that did report severe complications reported those in the range of 1 to 3%, overall complication range was 9 to 18%. In terms of subsequent treatment, and in some cases this was difficult to tease out between reoperation and surgical revision, whether it's a different procedure used or a version of the same procedure, and I think Dr. Franklin actually already presented these data. From our evaluation, we found across our studies a mean of 12.5% over a mean of five years of followup, a wide range, however, 4 to 32%. I'll show you a graphic to see how this plays out over time.

So, as I mentioned, the rating of complication severity was done inconsistently or not at all in many of these studies, and harms of a certain type were not

reported with consistency across the studies, as well. These studies, obviously, were powered to detect differences in clinical effectiveness measures when you see that most of them were small in sample size with the exception of Fairbank and Fritzell. We looked at subsequent treatment, but most of the studies that reported on this measure reported on it over the longer term. So, it's... and if there is subsequent treatment in the shorter term, it was difficult to see that, as well.

So, as I mentioned, the... there were no deaths reported in the available RCTs deemed related to surgery or to its alternatives in our primary evidence base. In the Mannion long-term followup study that pooled data from Brox and Fairbank, there was a 7% mortality rate over eleven years in the patient receiving surgery and 0.8% mortality rate in the patients receiving conservative management. The authors did specifically state that there was no way for them to determine whether deaths were conclusively related to surgery or not. That's the one longer-term data point on mortality we have from the RCTs.

Subsequent treatment, so I've already kind of talked about the average statistics. Not surprisingly, studies of shorter duration had a lower reported rate of reoperation compared to a limited number of studies with longer followup periods. In terms of a particular concern with adjacent segment degeneration, so this is the clinical situation in which segments that are not part of the original fusion then begin to degenerate, potentially requiring additional surgery or other treatment. We did not find this specifically called out in any of the studies in our primary evidence base. We did find one case series looking at repeat surgery and finding that a third of subsequent procedures were performed due to this reason, so degeneration adjacent to the primary fusion level.

And there is just graphically, again, a limited amount of data that reoperation/revision, as displayed over years of followup.

So, let's turn to subgroups then, in terms of differential effectiveness and safety, according to these factors. We looked first at intensity of fusion. So, looking at single level versus multilevel fusion or high versus low levels of instrumentation. Some researchers describe this as complex versus simple, or actually describe both as complex versus simple. We found no discernible evidence of differences in effectiveness, according to this measure, and we did find, in retrospective study, again primarily contextual, because many of these studies looked at fusion as a procedure regardless of indication and did not necessarily stratify by indication, finding higher complication rates with greater levels of intensity. In terms of type of fusion, whether it was the anterior approach or posterior or transforaminal or combined, there was some evidence... the evidence was mixed generally, particularly on effectiveness. Some evidence suggesting a higher complication rate with anterior approaches. In terms of conservative management intensity, so the aspiration here and it actually was an aspiration that ICER had itself when we did our own little back pain appraisal in 2011, was to identify whether there were discrete components of conservative management or interdisciplinary rehab that were most closely associated with success. And there was really no way to do that from the available evidence. It was difficult to find any discernible patterns in terms of

actual individual components of these programs that were most closely tied to success. As I have already described in terms of the more intense programs with multiple components, there was better performance in comparison to fusion than the single modality approaches, but there is also mixed evidence, to be perfectly honest, in systematic reviews comparing outcomes for interdisciplinary rehab versus physical therapy alone. So, in some studies there are benefits shown for interdisciplinary rehab, and in some studies there is not. So, it still remains a challenge.

In terms of demographic factors, age... not surprisingly, age is generally associated with poor clinical outcome in many surgical populations. Again, we were looking primarily for differential rates that would be explained by one or more patient factors. We did not find that here. We did find some evidence that there was greater return to work in younger patients but also a higher level of disability claims in these patients. Gender, no clear patterns of impact by patient gender. And in terms of worker's comp, I will go through some detail on this, but the available evidence suggests that having worker's comp status, as opposed to other insurance status, is associated with poor clinical outcome, lower return to work, and higher costs.

In terms of psychological factors, I already presented the results on depression. There was mixed evidence available there. There was some evidence suggesting that the presence of neurosis or severe personality disorders was associated with poor outcome and oftentimes that particular factor is used as a criterion in patient selection for surgery.

Lifestyle factors, there has been a lot of research suggesting poor surgical outcome in patients who are smokers and who have higher BMI. Unfortunately, these factors were not evaluated specifically in the studies available to us.

We also did look at race/ethnicity and surgical setting, and we did not identify studies that performed this stratification, unfortunately... or these stratifications.

So, let's go into a little bit more detail here. Surgical intensity and approach, one cohort study examined primary versus revision surgery but found no statistically significant differences for any outcome. One RCT compared different fusion procedures with and without instrumentation and did not find any significant differences. And as I mentioned, these broader systematic reviews that have included multiple populations have generally reported higher complication rates with complex versus simple fusion.

In terms of conservative management intensity and approach, interdisciplinary programs described variably may provide better outcomes than unstructured or less intensive approaches, as displayed in the clinical data, but as I mentioned, we do not have enough information to identify specific components that would be associated with success.

We did not identify any studies in the surgical setting. We talked about age, gender, and race, and we talked about psychological factors already.

So, worker's compensation status, this was negatively associated with work status following fusion in available studies, but this was not the case for conservatively-treated patients. Pre-surgery work status, whether the patient was working versus not before treated, rather than worker's comp status in another study might have influenced this outcome after fusion but did not have effect in conservatively-treated patients. We did find one study looking at the RDQ and found... it was a poor quality study, so not part of our primary evidence base, but had found that smoking negatively influences treatment outcome regardless of what the intervention is, not a huge surprise there. And no studies identified that looked at BMI.

So, cost and cost-effectiveness, the concerns around variable definitions and approaches played out over this particular key question, as well. There are some cost-effectiveness studies available, but they each have their challenges. So, let's go through some of those challenges now.

We do know that based on cost studies done in the U.S. that hospital costs alone can approach \$100,000 in the U.S., particularly for more complex forms of surgery. Costs are obviously lower for simple forms of surgery. There were two economic evaluations conducted in conjunction with the RCTs available to us, the Fairbank comparison of fusion to multidisciplinary programs yielded a cost-effectiveness estimate of greater than \$100,000 per QALY adjusted life gain. That was only over the two-year followup duration of the trial. So, typically in most developed countries, a cost-effectiveness ratio that exceeds this over a lifetime is potentially challenged on its cost-effectiveness. So, at two years, that remains a challenge. There was another comparison in the Fritzell RCT of fusion to physical therapy, but the data are reported in detail in our full report. I am not presenting them here, but they're very difficult to compare across other evaluations, because the metric used was cost per one unit improvement on some of these scales, whether they be pain or function. So, it's difficult to compare to cost-effectiveness for other interventions.

There was one study that was kind of interesting, also U.S., but assessed a metric known as willingness to pay. So, through validated psychometric techniques, tried to identify cost thresholds that patients who would be undergoing different surgical approaches would have in terms of what they would be willing to pay to undergo that surgery. And then in this particular study, they compared that to the actual costs for the actual surgery itself found that the threshold for their willingness to pay exceeded the actual cost of surgery for other forms of surgery, discectomy and decompression alone, but their willingness to pay threshold was lower for lumbar fusion when it actually costs to deliver the procedure.

Then, finally, there were two other evaluations, again reported in detail in the report but not described in detail here, because the comparison was not to an alternative form of treatment but to their presurgical state... the patient's presurgical state.

So, our ICER evidence rating matrix, as most of you have seen before, is intended to assign a letter rating to the comparative clinical effectiveness on the Y axis and... to the comparative value on the X axis. Comparative clinical effectiveness is really a measure of net health benefits. So, that includes considerations of both effectiveness and harm compared to value is based on the available evidence for cost and cost effectiveness.

So, our judgment, and again it is our judgment, so it's... that's all it is, is that because we found that in the available evidence there was no data suggesting incremental clinical benefit for fusion in uncomplicated degenerative disc disease in comparison to intensive or interdisciplinary rehab, but a greater potential for harm versus conservative management, our rating was inferior. And while economic evidence is limited, the suggestion is that this is a very high-cost intervention in the U.S. and juxtaposed against its potential for clinical benefit in this comparison, we termed it a low value service in patients with uncomplicated degenerative disc disease. In comparison to less intensive conservative management, we found the results to be comparable, because while there is still a greater potential for harm versus physical therapy or exercise alone, for example, there does seem to be some short-term incremental benefit, particularly around measures like return to work, but again, because of its high cost, we considered it a low value service.

So, let's turn to what practice guidelines say. I think that you have already kind of heard through public comment that American Association of Neurological Surgeons and North American Spine Society support fusion for uncomplicated degenerative disc disease after attempts at conservative management. American Pain Society, ISASS stands for something that I don't remember, but we can look it up, and the National Institute for Health and Clinical Excellence in the U.K. recommend intensive rehab after failure of general conservative measures and prior to consideration of surgery. And I think as Dr. Franklin already presented, this is not recommended in the absence of spinal instability by the Bree collaborative or the Washington Department of Labor and Industries.

Coverage policies, we found no national coverage determinations or local coverage decisions that would have affected the State of Washington from CMS. In terms of private payers, most of the national payers do not cover lumbar fusion for uncomplicated degenerative disc disease or cover it with restrictions, an example of one being 12 or more months of structured conservative management. As Dr. Franklin also presented Regence, and I'm not sure if he presented Premera. That's another Blue Cross plan in the Northwest, do not consider fusion medically necessary for uncomplicated degenerative disc disease. Health Net, on the other hand, does provide coverage after six or more months of conservative management but for one or two level fusion only.

And this is an appendix that just talks about our quality criteria. It's part of our standard slidex. We don't need to go through it here. I'll take any questions.

David McCulloch: Thank you for that review, Dan. The... as a non-expert, you mentioned, I think it was your slide six, that there's been a greater than two-fold increase between

2000 and 2009. How many of these are being done in the U.S. per year? Can you give me... maybe the expert can... how many per 100,000 of the population. And then second, and how does that compare with Germany, Canada, and Australia?

Daniel Ollendorf: I'm guessing someone has done that work, and I'm not sure that I know it off the top of my head, but we can certainly look it up while... while I'm taking other questions.

David McCulloch: Well, and it... you've told me there is more than a two-fold increase between... from what to what?

Daniel Ollendorf: Yeah. Understood. Annie, why don't we look at that specific study and if there's any other studies that make international comparisons, let's see if we can find them. I also realized that I...

David McCulloch: I'm... I'm... I'm absolutely flabbergasted. In a bunch of experts, you can't say how many of these surgeries are being done per 100,000 of the population in the USA this year compared with five year, I mean, I... surely.

Craig Blackmore: Maybe during the break we can even look at the Dartmouth Atlas and see the range around the U.S.

David McCulloch: Thanks. That would be...

Craig Blackmore: OK.

David McCulloch: ...helpful.

Chris Standaert: Sorting through that data is somewhat tricky because most of these studies talk about lumbar fusion rates, in general. And trying to sort out lumbar fusion if you look at their articles on treatment of spinal stenosis, then the rates of lumbar fusion are going up in the spinal stenosis population. And lumbar fusion is going up in every population. And the tricky part is, we're only talking about a subset of this. And that's... I asked the same question of Dr. Franklin before. How do you tease out how many are being done for what we're talking about?

David McCulloch: Right, I, I...

Chris Standaert: And in the papers I know of, in the literature it's really hard to do that, because they just don't separate them that way. They talk about them and they, they go through Medicare and look through... for fusion rates in general. So, maybe...

David McCulloch: ...I, I, I get that, Chris, but I mean, I, I don't imagine that spinal stenosis is ten times more common in the U.S. than it is in Germany or...

Chris Standaert: No. The surgical rates are higher, though.

David McCulloch: ...right, right, but I want to get a sense of how, how much overall surgical rates for...

- Chris Standaert: Yeah.
- David McCulloch: ...spinal fusion at all really.
- Seth Schwartz: I have a question about sort of what we're talking about when we're talking about chronic disease. So, I think that when you see the definition that it is greater than three months of therapy, or sorry, greater than three months of pain for...
- Daniel Ollendorf: Persistent pain.
- Seth Schwartz: ...versus... for persistent pain, but when we look at all the randomized trials, we are looking at... these are, I mean, the minimum was, like, eight years of, of pain. And I just, I, I'm wondering very strongly if we're talking about the same patients here, you know? A patient with three months of pain, I can see how they might respond to treatment, but a patient who has eight years of pain, it seems to me like it might be a different disease. And I didn't really see a lot really separating out those, the populations based on duration of symptoms. I think I heard a little bit about it, but it wasn't very good. And I'm curious if there's any more information that's been presented to us on patients who have had pain for say, less than a year versus those who have had pain for five or ten years in terms of their response to therapy, either conservative or surgical management.
- Daniel Ollendorf: Yeah. So, that... again, that's something that was not specifically part of the scope of our review. None of the studies that had the comparisons of interest made that stratification for us. So, we couldn't actually look at where there might have been a mean duration of pain, we would look at those who had, you know, two or less years of pain versus two or more. That was not something that was available to us. There may be other studies out there that might have stratified the fusion population by duration of pain or duration of symptoms, but that's... that wasn't (inaudible).
- Seth Schwartz: How about even things like duration out of work. I mean, similarly I can see if someone has been out of work for three to six months, their likelihood of returning to work is going to be higher than if they'd been out of work for ten years regardless of treatment.
- Daniel Ollendorf: Right.
- Seth Schwartz: Is there anything on duration of time out of work?
- Daniel Ollendorf: There was a, a little bit of evidence suggesting that that was, in fact, an independent predictor, regardless of the intervention, but again, not a lot of detail and stratification in our primary evidence base.
- Chris Standaert: In the inclusion criteria of these studies, for the Brox and the Fairbank, I think it was one year of pain at least. I think Fritzell was two if I got it right. I'm trying to remember the date, but they're in that range.

- Daniel Ollendorf: We can double check.
- Chris Standaert: They're not... there isn't...
- Daniel Ollendorf: Yeah.
- Chris Standaert: ...they're not out looking for people at eight years of pain. They're looking for people with more than one year of pain and roughly... but in that population they had some very chronic patients, clearly.
- Seth Schwartz: But there was no sub-stratification.
- Chris Standaert: No.
- Seth Schwartz: Looking at those. I mean, it seems like they could do that. I mean, two of those papers have almost 300 patients in them. It seems like outcome. I wonder if there's... I'm surprised there's not some breakdown on it.
- Craig Blackmore: Kevin?
- Kevin Walsh: Can we go back to the fourth slide that was presented by the triad of neurosurgeons? Among the many pejorative statements that were made regarding Dr. Franklin's work, ICER, and the Bree collaborative was the assertion that the information here was cherry picked and that these valuable studies were not included, and I wondered if you could comment on...
- Daniel Ollendorf: Not on our presentation, the... society presenters. Kevin, I think I know at least part of where you're going. The SPORT trials were not included in our set because the one SPORT trial that used fusion as a comparator focused that procedure on patients with greater than Grade I spondylolisthesis. So, patients with spinal stenosis in the SPORT trials received discectomy, not fusion. That's the SPORT trials. I know they listed other studies, as well. Right there. So, some of these other, cost-effectiveness data. So, the Mirza study was obviously included in our set. I mentioned the SPORT trials. The control groups of the ADR trials. I have to say, I don't know what the ADR trials are.
- Chris Standaert: Those are, those are studies on total... on lumbar disk replacement.
- Daniel Ollendorf: Oh.
- Chris Standaert: And the studies were ran (inaudible)...
- Daniel Ollendorf: (Inaudible)
- Chris Standaert: ...trials of lumbar disk versus fusions. They didn't have a nonoperative group, and they're comparing fusion to disk replacement not to . . .
- Daniel Ollendorf: Got it.

- Chris Standaert: ...nonoperative care.
- Daniel Ollendorf: Right.
- Chris Standaert: And they're advocating for the use of the control arm.
- Daniel Ollendorf: Right.
- Chris Standaert: So, the fusion arm of those studies.
- Daniel Ollendorf: We already described our, our rationale for why those were not included. And then, in terms of the registries, I know that our clinical expert has some experience with the SCOAP registry and can speak to that potentially, but again, based on our contrast of interests, fusion as compared to either nonoperative management or minimally invasive treatment in patients with uncomplicated degenerative disc disease, I'm not seeing an indicator that there is one that we missed, if that was your question.
- Kevin Walsh: OK.
- David McCulloch: So, can I ask the expert, if we have all these SCOAP registries, all these... surely we have some data from that to say, how many patients are on these registries, and what... what proportion of patients who get spine surgery in Washington State are in a registry. So, do we have those numbers? Can we do some extrapolation? I mean, I just want to get a sense of how... how common this is.
- Neal Shonnard: So, I'm Neal Shonnard. I'm the director of spine SCOAP. And, I have some degree of understanding of this field. I'm a spine surgeon. So, from a conflict of interest perspective, I do this kind of work. I'm speaking as an expert. I'm a committee member for the American Academy of Orthopedic Surgery on safety. So, I draw up safety parameters nationally. I'm a member of the International Consortium of Health Outcome Measurement, which develops registries across the world. And spine SCOAP is incorporated in their data platform. Lastly, I'm the director of spine SCOAP. In spine SCOAP, there are presently 27,784 patients who have had spine surgery who we have outcomes on. So, there's a fairly robust data set of Washington State residents who have spine surgery, since 2011. So, if you have specific questions, I will try to answer them when the data is present to answer the question you raise.
- Chris Standaert: Neal, is any of that data published? I don't, you haven't published any?
- Neal Shonnard: Yeah. Yeah. So, we have criteria. We will not release data that is not appropriate or mature. So, as you might imagine when you start a registry, you go through the growth phase and the initial first year some folks will not enter data reproducibly, because they're doing it for the first time. So, you don't use that data, but by the time you get into the second and third year, you're through the growth, and you are now getting into verifiable, auditable, useful data. So, from that perspective, we have a great deal of useful data. There are some populations where we don't have data well represented, and you heard comments this morning from Dr. Franklin that they do not have baseline or

followup outcomes on the nonoperative treatment. It's also important to understand for the operative treatment, only 5% of L&I patients have complete data for baseline and followup because they're not mandated. They're not required to enter that data. And it is critically important to have baseline. It's critically important to have complete data in order to understand the problem. On other payers, we have remarkably complete data. So, from the standpoint of adverse events, from the standpoint of risk profiling, from the standpoint of the things that make surgeries successful and the things that make surgery unsuccessful, we have a great deal of robust data, and I can comment on it if you wish.

Craig Blackmore: So, I guess to Dr. McCulloch's question, do you know what proportion of the 27,000 would... at least roughly, what portion of the 27,000 would be in our definition here of discogenic or uncomplicated discogenic pain?

Neal Shonnard: So, the way that the registry is designed, the registry is designed to specifically address fusion. So, 100% of fusion cases that are entered are tracked; 30% of the database carries nonsurgical, nonfusion surgical procedures. So, you commented about diskectomy. You commented about spinal stenosis and laminectomy. Others have commented about disk replacement. Those are not fusion procedures; 30% of the registry tracks those data sets, because it is important to have data in order to make safety, quality, and efficacy decisions, but because the predominant issue here is lumbar fusion, 100% of those that are entered that are fusion are tracked. Now, there are some hospitals in the state, 34,654 cases were done in the time interval between 2011, second quarter 2011 and present when we... when we gathered this data to look at it, and we only had 79, 80% of data on that, because there are some hospitals who do not participate in SCOAP. We can tell you about the folks who do. We can tell you safety, we can tell you efficacy. We can tell you adverse events. We can tell you that if you're in SCOAP the rate of risk drops each year you're in. So, if you join SCOAP in 2011, your present rate of going back to the operating room, going into the ICU, having and adverse event, is 4%. If you joined in 2012, it's 7%. If you joined in 2013, it's 9%, and what that means is, the longer you're in SCOAP, the safer the procedures become for your hospital, and that is fusion, diskectomy, laminectomy, disk replacement procedures. That was not the specific question you asked, but can you give me a specific question? I can tell you if the data is there to answer your question.

David McCulloch: Well, for me, that helps, but is this SCOAP registry, is that national or is that for Washington State?

Neal Shonnard: So, the SCOAP registry was... it was the brain child of a former member of this august group. Dave Flum was once a member of this august group, and...

David McCulloch: So, is it Washington State or national?

Neal Shonnard: It's Washington State and a single hospital in the University of California's system, and we're trying...

David McCulloch: So...

Neal Shonnard: ...to grow it nationally.

David McCulloch: ...so, again, I feel as if I'm asking an incredibly simple question. And I'm not, I'm not trying to be awkward. So, you said something like 57,000 from 2011 in about four years. So, about 10,000 per year in Washington State. Is that about right?

Neal Shonnard: We have 8,000 in spine SCOAP per year as an annual number.

David McCulloch: OK. So, I'm just...

Neal Shonnard: But, we don't allow 100%.

David McCulloch: ...yeah, I get that, but I'm just trying to do the math to the... to the national... there must be 400,000 of these operations being done in the U.S. per year?

Neal Shonnard: Well, that varies because of geography.

David McCulloch: Well, I know that. California is bigger than...

Neal Shonnard: No, the rates of. So...

David McCulloch: Well, I know that as well.

Neal Shonnard: ...OK.

David McCulloch: But I mean, but roughly speaking, we collectively, neurosurgeons and orthopedists in this country must be doing about 3 or 400,000 of these a year.

Neal Shonnard: I can't comment on that. I don't know that data.

David McCulloch: Common sense.

Daniel Ollendorf: And is there any more information from that study.

David McCulloch: It has to be, ball park.

Daniel Ollendorf: It looks like we have more information on the study that reported rates from 2000 to 2009. Is it possible to pass the mic over there?

Female: So, there were 380,000 patients who underwent surgical treatment for...

Daniel Ollendorf: Nice guess. Keep going.

Female: ...so, yes, about 400,000 patients who underwent surgical treatment for lumbar degenerative disc disease between 2000 and 2009, and that was a two-fold increase.

Craig Blackmore: So, that's in a ten-year period.

- Female: Yes.
- Daniel Ollendorf: So, the 380,000 was in 2009, and the number in 2000 was 190,000 roughly. Or was that 380 across the entire nine year period?
- Female: Across the entire nine-year period.
- Chris Standaert: And that's just for degenerative disc disease.
- Daniel Ollendorf: Just for degenerative disc disease.
- Craig Blackmore: Oh, OK.
- Chris Standaert: Yeah. And, so the SCOAP registry has everybody who got fused for whatever indication, which is very different from, like, and this is our... part of our dilemma is going to be this... differentiating these things out, but we're talking about degenerative disc disease.
- Neal Shonnard: I'm sorry. Is that data from the Dartmouth Atlas? Is that where you're pulling the data?
- Female: No. That was the study that Dan quoted on slide 4, I believe.
- Daniel Ollendorf: What's the data source though...
- Female: Oh.
- Daniel Ollendorf: ...for those numbers?
- Neal Shonnard: Because, I believe Dartmouth Atlas...
- Female: It was NIS, clinical data derived from NIS data was used.
- Daniel Ollendorf: That's the nationwide inpatient sample. So, that's a... the healthcare cost and utilization project collects. There is mandatory collection of data from all U.S. hospitals. And so, it was basically cases of lumbar fusion with a principle diagnosis of degenerative disc disease without other complicating diagnoses.
- Female: I can also speak to the rate for the United States and spinal surgery compared to other countries. So, the United States performed spine surgery at roughly twice the rate of most developed countries and the most recent formal comparisons is that the U.S. is roughly twice that of New Zealand, Australia, Canada, Norway, and Finland. And the spinal surgery rates in the U.K. are about one-fifth of the U.S. rate.
- David McCulloch: Thank you.
- Craig Blackmore: So, if I might ask... a different track but a question about the Ohtori study. You said something that I'm... I don't know if I caught it entirely, about not all of the

individuals in that study were willing to undergo the discography or the selection process.

Daniel Ollendorf: Mm-hmm.

Craig Blackmore: So, was that after randomization or was that before randomization? And is there an intention to treat analysis, and I mean, how is that all?

Daniel Ollendorf: It was intention to treat, but randomization did not occur until after the exam. So, they... so patients dropped out because they did not want to undergo the exam. After the exam was done, if patients did not want to meet either the provocative test or the relief test, they were also excluded, and then they were randomized after that.

Craig Blackmore: OK. So, it's a selection issue, but it's not differential between the two arms?

Daniel Ollendorf: No. It doesn't seem to be. There is no assessment of the characteristics of the patients who dropped out, but. Question over here?

Craig Blackmore: Any other questions?

Gregory Brown: Yes, I have a question about the inclusion criteria for... somebody mentioned that these studies had included leg pain patients or back pain with leg pain or back pain alone.

Daniel Ollendorf: Mm-hmm.

Gregory Brown: Do we have any data in your study, which studies included this... this criteria, or, because that would actually, in the outcomes, you know, if you're tracking leg pain or low back pain with leg pain, I mean, it could be quite... quite different, so.

Daniel Ollendorf: Right. Yeah, so I mentioned briefly the, the challenge with the Brox study was that there... there was mention that patients with leg pain were allowed in, but patients with clinical signs of radiculopathy were excluded, which I'm not a clinician but that doesn't seem to make sense to me. The Fairbank study was the other RCT that does appear to have allowed patients with leg pain, but there is no stratification available. So, we couldn't just focus on the patients who only had back pain. The other studies either were not clear in their describing entry criteria, or they did not include those patients.

Seth Schwartz: Can I ask a question about misclassification bias here, along those same lines? It seems to me that for isolated degenerative disc disease with no other symptoms, the... conceptually, we think surgery is less likely to be beneficial in those patients, but more likely to be beneficial in these patients with selected other problems that you're addressing. What I'm hearing is that the patients who then would be more likely to benefit from surgery are being included in these trials, sort of accidentally. So, it seems like the bias there would be to actually favor surgery, but we're still seeing no benefit. Is that... can you just comment on that?

Daniel Ollendorf: I think that probably does make sense, yeah. And again, we do have mixed results that were primarily driven by the comparator in these studies. So, the two studies that had some of this misclassification concern are Brox and Fairbank, no benefit seen in Fairbank, but small benefit seen in Brox. So, actually, I'm sorry. I'm wrong about that. No benefit seen in either, because the comparator was interdisciplinary rehab. It was Fritzell where there was benefit seen.

Chris Standaert: I mean, I do want to make this one comment on the nonoperative... this is what I... I'm, so... I'm a nonoperative spine provider. This is what I do. So, I've read these studies dozens of times. Just one comment, so you have language and... and, there is a problem on the rehab side. The Fritzell and Brox papers did a very intensive rehab program. It wasn't the same as the inpatient programs we have in the U.S. It was different. It was very exercise based. It was cognitively-behaviorally driven, but not necessarily having active psychotherapy as part of it, but the other studies you talk about all really have... they're not even a structured PT program. They're totally non-structured. I mean, look at Fritzell, the Fritzell paper, they simply said, we recommended a PT program, and only 46% of patients in that group got something they hadn't received before entering the study. The Mirza study, they say the nonoperative group received minimal new therapy. They're basically a natural history study.

Daniel Ollendorf: Yeah.

Chris Standaert: The Ohtori study, they said go walk half an hour a day.

Daniel Ollendorf: Right.

Chris Standaert: So, these weren't even what we would consider even a decent nonoperative structured physical therapy program. They are very minimalistic, and we wound up with the extremes. We wound up with a very intensive exercise program and a very minimalistic rehab program, and that's what made a difference in the studies. The rates of improvement in the fusion groups in Fritzell and Brox and Fairbanks were the same essentially. Their ODI dropped about 12 to 15.

Daniel Ollendorf: Yeah.

Chris Standaert: So, the difference in the studies, solely, is what they did nonoperatively. And again, the distinction of these languages of less intensive conservative management, it's almost natural history is what many of them... the ones that we talk about here . . .

Daniel Ollendorf: Right.

Chris Standaert: ...are close to natural history. They're not even close to...

Daniel Ollendorf: In fact,...

Chris Standaert: ...intervention.

Daniel Ollendorf: ...some of the studies themselves used descriptors like minimal treatment.

Chris Standaert: Yeah.

Daniel Ollendorf: Ohtori uses minimal treatment.

Chris Standaert: Yeah.

Daniel Ollendorf: And Mirza used minimal treatment, as a descriptor.

Craig Blackmore: OK, I... I think we're headed away from questions and towards discussion. So...

Gregory Brown: May I ask one further question?

Craig Blackmore: Yes, absolutely.

Gregory Brown: For our expert, question on clinical practice guidelines. Dr. Chapman, several times, mentioned that fusion was helpful in selected patients. Have any of the national societies, orthopedic or neurosurgical, published a list of who those select patients are?

Neal Shonnard: Yeah, the criteria that are in guidelines with regard to patients who fail conservative treatment protocols, which are not defined, except for a duration. Routinely, it will be a duration of three months, six months, but the content is not described. So, the... routinely what clinicians do is abide by the timeframe, use what is available in the community in which you live, because the notion of having a type of treatment, which does not exist in your community, is not an option, because the patients will not travel. They will stay home. Satisfying the criteria that are in the clinical guidelines for surgical treatment after the conclusion of the timeframe for nonoperative treatment is routinely what clinicians use as an overall guidepost.

Gregory Brown: I guess my question would be differently, and that is, is not what is the indication for surgery, but is there any evidence from the national societies on what are positive prognostic indicators for outcome from spinal fusion?

Neal Shonnard: For spinal fusion, that part is what we are presently doing in SCOAP. That's what's called appropriateness. You're looking to find the criteria of appropriateness, and the appropriateness is specific to the stratification issue you all have been going through here. You must stratify. You have to get these separate diagnoses separated from each other. You have to risk adjust in each category, and then you must track from baseline through followup, and that's what SCOAP is trying to accomplish. And it has not yet been accomplished.

Gregory Brown: OK.

Neal Shonnard: But, it's well on its way.

Gregory Brown: So, since we're discussing degenerative disc disease or discogenic pain today, for that specific diagnosis...

Neal Shonnard: Mm-hmm.

Gregory Brown: ...do the societies have any significant prognostic factors that they have identified?

Craig Blackmore: So, just... just to interrupt. The society guidelines are in your packet and in the decision tool in detail.

Gregory Brown: OK.

Craig Blackmore: It's towards the back of the tab under the coverage and reimbursement determination tool. There is a summary of the various society and other international guidelines. So, that may or may not totally answer your question, but it's there. OK. So, uh, we'll take a brief break of about 15 minutes and re-adjoin at 10:20 and launch into the more discussion phase. We still have the opportunity to ask questions of our clinical expert, of our scientific evidence vendor, and of our agency directors during that time period, but we'll adjourn for 15 minutes.

Alright. Let's bring the meeting back to order. Alright. So, the committee is all present. So, I will call the meeting back to order. So, we have... we have heard presentations... we've been through the morning's presentations, and now we move to the part of the meeting where the committee members deliberate and render a decision. We still have the opportunity to ask questions of our presenters, but this piece of the program is really focused on deliberation and discussion around the committee members. As we move into that, I just wanted to make a couple of comments. First, we have a couple new or returning committee members. So, it's worth thinking about how the committee works and what the committee's charge is, and our responsibility, and unfortunately in medicine, there is not or may never be perfect evidence on what we should do, but the committee has to make a decision. And we have to identify whether there is evidence of effectiveness, safety, and cost-effectiveness and in the absence of evidence, we should render a decision to not cover whatever that particular technology is. Now, what constitutes sufficient evidence is up to our deliberation. Obviously, if there were 17 perfect randomized clinical trials, they wouldn't come to this committee. So, we are always in the world of uncertainty, but it is incumbent upon us to require that there be evidence of effectiveness and safety, and hopefully cost-effectiveness. The second thing that I will say is related to this lumbar question that we're addressing, and this is a little different than most of the issues we address, because it's a re-review. So, the committee has already deliberated and made a decision on this issue back in, I believe, it's 2008. And as such, in a re-review, our charge is to look at the best available evidence, but specifically to focus on the evidence that has come to light since that prior decision. So, we would not make a different decision based on the same evidence base. If we were to change our decision, it should be based not exclusively, but primarily or largely based on evidence that has come to light in that timeframe. And then the final

thing I will say is more of a reflection, and that is that we as a committee make decisions to either cover or not cover, or cover with conditions. And one of the particular aspects of this decision is that in some ways, many of the conditions or a set of conditions have already been imposed on us by the key questions. So, rather than saying we will cover lumbar fusion if there is spondylolisthesis or radiculopathy, that is defined by the key questions. So, the key questions have already narrowed our focus to this one very small area or narrow area of being pain... discogenic pain in the absence of these other conditions, and I think we've already started to address that, but I think it's important to recognize as we go forward that we are... we are narrowed, and we are focused by what we're asked to do, in this case, which is a much more narrow topic.

So, that being said, we should begin our deliberation. Customarily, we start the deliberation by having one of the members of the committee sort of summarize where we are, just to give, not necessarily a, I think we should do this, but at least sort of encapsulating in thirty seconds or a minute where we are, what we know, maybe what some of the areas are that we need to delve into in more detail to understand this collectively. So, I will solicit a volunteer from the group to initiate the discussion. If I don't get a volunteer, I'll volunteer somebody. OK, Joann, start us off.

Joann Elmore: I wanted to volunteer Chris.

Craig Blackmore: I know you did.

Joann Elmore: I, actually, I want to start with the more general comment, and I appreciated your background, but I want to also say that this is a committee of volunteers. We are here to review evidence, and we care about the patients. I just kind of felt like I had to get that out there. There are a small number of studies, the designs are challenging. There is no clear criteria for this diagnosis. There is no good comparator. It varied by studies, very low in the prospective cohort of Mirza, and in addition to looking at evidence of benefit, we are tasked, as a committee to consider harms. And if you think about mortality from surgical procedures, 0.2% doesn't seem like a lot, but in 2018 in the State of Washington, in these payers, we had 888 patients that had this procedure, 0.2% we're talk... I mean, we're talking about individuals here. I mean, that's one to two patients. In addition, the reoperation rate is, I think, something that many of us need to consider when we think about the harms.

Craig Blackmore: Comments?

Chris Standaert: I mean, I agree. I think the harms are a significant issue, and I think the issue is complicated, as topics for us go, to actually be handed three good quality RCTs is kind of rare. So, we actually have data, which is interesting, because we don't usually have data. I think, if anything, I agree with Seth's point that it's biased towards the positive, because the studies are not purely discogenic low back pain, they include people who would have expected to improve more likely than those patients. I think one of the questions I have, I was in part of the committee when the first decision was made, and this position of people who failed a comprehensive rehab program can go on to fusion, I question. In part, I

think this idea that axial low back is resulting from a degenerative disc is largely a fallacy. We have a very hard time finding these people where we can prove that. Chronic axial low back pain is a very difficult... it's a biopsychosocial disease. There are changes in their biology. There are changes in their brain. There are changes in their central nervous system elsewhere. There are changes in their life. There is depression. There are also sorts of things that go with it. And degenerative disc disease isn't the disease. It's part of aging. And so, we... that whole component of it, and I think when you, we can even... if I look at the newer data and looked at the Mannion study and they track patients. It goes back to what Joann said that with surgical groups... they found that over 11 years in the Brox and Fritzell populations, of the patients they could track, which was less than half of them, or roughly half of them, but things stayed about the same. They had sustained drops in ODI and pain that were sustainable over 11 years, and one of the curious things in the surgical group, they had a higher proportion of people who did relatively well, but they also had a much higher proportion that did very poorly, and they sort of went to the extremes. You know, in the nonsurgical group, there weren't people who did really poorly. They were only in the surgical population largely. So, there's a... there's a harm there that people go, this goes badly. And if it doesn't offer significant benefit and it's not clear what we're treating, and it goes badly, then that's a concern, I think. So, I sort of wonder that a bit. And I think that arises out of, like Craig said, the idea that we follow the newer data and follow the studies out and see what we learn from them, but it's not a benign thing to say we're going to fuse you because you failed rehab, and there may be other reasons why they failed rehab beyond that. I also think the rehab stuff is important and what you do in rehab matters, and I find it somewhat disturbing that in Medicaid, for example, I believe my DSHS patients get approved for six visits of physical therapy that is only... they only pay them enough to come to Harborview. Nobody else takes it, and they don't pay enough for a psychologist to see them other than the psychology services at Harborview, which are flooded. And so, there really isn't an effective... essentially, they are disempowered from being able to access what we know will help them, which is a more comprehensive rehab program with some degree of psychological basis and some degree of structured exercise, but they don't have that as an option. So, opposed... and we can't mandate that the state do that, because that's not our... our charge here, but it is a bit of a problem that that option isn't there for them practically.

Craig Blackmore: I think, I mean, several of us were here in the previous decision and others are welcome to weigh in, but, I think one of our thoughts in having this sort of requirement that individuals go through a more comprehensive rehab program if it was available was that that might actually encourage the development and the funding of such programs. I... I mean, others who were here can reinforce that, recognizing that that availability may help, and...

Chris Standaert: (inaudible)

Craig Blackmore: ...and I don't have any way of knowing if, you know, if that sort of indirect hoped for effect was achieved.

- Chris Standaert: I don't know.
- Kevin Walsh: The rate of surgeries doubled. So, how can you argue that there's more conservative therapy, as a result of the decision?
- Craig Blackmore: Well, there's more conservative therapy. It's just whether it's prevented surgery or not is another deal.
- Michael Souter: And I think this is hugely (inaudible).
- Chris Standaert: This is hugely what? Sorry, Mike, I didn't hear you?
- Michael Souter: Muddied water. I have a significant problem, I think with kind of the (inaudible) that the rate of surgeries has doubled. (inaudible) And we have seen, you know, the (inaudible). Yes, OK (inaudible) the number of fusion procedures has gone up, but when you actually look at the top ten (inaudible) that were being used for this (inaudible) conditions here other than degenerative disc disease and a pure specific etiology that we're being asked to specifically decipher. So, with that data to delineate that there is, yes, a core (inaudible) of patients who are not getting appropriately treated for the condition that they have. I don't necessarily think that there's a problem to address here. I think that, you know, when you look at the balance of the evidence that's come out in the, in the intervening period since we made that decision, it tends to support that decision (inaudible). And I am not convinced at the moment, this is my personal position, I'm not clear I'm willing to... I am eager to hear from others, but I don't really see (inaudible) in a position to change.
- Craig Blackmore: Anybody else want to reflect?
- David McCulloch: Well, I wasn't here for the original decision, I'm flabbergasted in retrospect, no disrespect to the people here, that we came to the decision that was made last time. I mean, again, forgive me, but we in this country are doing something like 300,000 spine fusions per year for a variety... that would be enough that a significant minority of them would be for this condition. At \$50,000 per... that's about 15 billion dollars a year, and yet apparently nobody in this country, none of the neurosurgical societies, nobody from the government, there isn't one decent randomized control trial in this country? I mean, we actually have enough... it... it... it's so, I mean, we... we... even if there are four or five possible different surgical approaches, and even if we're not sure exactly what a multidiscipline, there ... there's ample patients in whom we could design, we, the U.S.A., could design several well-designed RCTs with a reasonable multidisciplinary thing plus whatever surgical thing you want, follow it out for three to five years with real outcome. This is absolutely knowable, answerable information, but in the absence of that, I have this great sinking feeling that we are doing hundreds of thousands of operations that are doing no good and potentially causing harm, and it should not be on the onus... it should not be on the onus of people doing that to prove that that's not the case. If this was a drug that cost \$10,000 a year, as there are plenty of them out there, you're going to be required to do a randomized control trial with hard outcomes, blah, blah, blah. I don't know why that is not mandating.

- Michael Souter: With all due respect, show me that we are (inaudible). Show me the data that says we are doing so many surgeries inappropriately for these patients. When you've looked at the list of conditions that were being done here, 90% of L&I are actually using (inaudible). You're looking at this list, you know, the tables and conditions of (inaudible). I don't see anything, apart from the rather, you know (inaudible) of lumbago, which is (inaudible).
- Chris Standaert: Antediluvian? Wow. Love it.
- Michael Souter: Well, I don't see anything else there that is, you know, germane or pertinent to the (inaudible) of patients who were delineated here. I understand your frustration at the lack of evidence base. And believe me, that was all recounted when we went first through this decision and process. We did the best we could with the available data. (inaudible) some signal and there does appear (inaudible) patients where there's a wealth of potential harms, and we all shared the concerns (inaudible). So, nobody wants to see an open door policy to just go in and just get your surgery. There is some form of check or appraisal, and we all went through these... these processes before, but the key (inaudible) just reiterate again, that I don't... I can't have any idea how many of these fusions... how many of these patients with degenerative disc disease. So, therefore, I don't know whether it's a problem we can answer.
- Kevin Walsh: But the onus is not on us. I, I don't understand, I don't understand your confusion.
- David McCulloch: Well, because I...
- Kevin Walsh: The, the onus...
- David McCulloch: ...[SS]...
- Kevin Walsh: ...the onus is on the... the onus is on the evidence to show us that there is a benefit. And in the absence of that, the mandate is we... we deny coverage.
- Michael Souter: Yes, in degenerative disc disease. But when we...
- Chris Standaert: Right.
- Michael Souter: ...actually have statistics applied to a much wider population without that, it's hopeless in that particular cohort group. Then, you know, I... if you could tell me that, you know, that 15% of the patients who were getting these procedures were actually... had degenerative disc disease, and not any of these other indications. Then I would say, that's fine. Let's exclude it. Let's...
- Kevin Walsh: But the evidence, but the absence of evidence doesn't... the absence of evidence does not mandate us to cover.

- Michael Souter: But there is evidence to show that fusion is appropriate in other indications. We are being asked specifically here about this particular cohort, no others. Craig said, the key question here is being (inaudible).
- Kevin Walsh: But logically...
- Michael Souter: It's not being defined. It's the population.
- Kevin Walsh: But logically, Michael, if these RCTs are including all-comers, I mean, people with other causes of low back pain and not just, not just degenerative disc disease, and they still I can't show any benefit over time, why would, how is it logically possible to conclude that in the sub-cohort of people with degenerative disc disease, there is benefit?
- Michael Souter: The populations in the studies and the exclusion factors talked about (inaudible) key population. There is a mismatch here going on between the (inaudible) with the population study.
- Kevin Walsh: So, you're positing, you're positing that people with all the other diagnoses of low back pain are going to have worse outcomes than the people with degenerative disc disease if they have surgery?
- Michael Souter: No. I'm not saying that at all. I'm not going anywhere near that.
- Gregory Brown: As a new, as a new member of the committee, could I ask for some clarification?
- Craig Blackmore: Sure.
- Gregory Brown: So, my understanding of our question today is, it's... it's mistitled as lumbar fusion re-review, but we are... we are only considering fusion for degenerative disc disease, correct?
- Chris Standaert: Mm-hmm.
- Gregory Brown: We, we didn't present evidence for deformity...
- Chris Standaert: Nope.
- Gregory Brown: ...instability, you know, spinal stenosis. So...
- Chris Standaert: Totally.
- Gregory Brown: ...there is no evidence on any of that. So, talking about 400,000 fusions a year isn't related to this. I don't know what percentage of those are just for degenerative disc disease, but I don't think that... I don't hear that between your conversation that that's we're discussing.
- Craig Blackmore: And on some level, it doesn't matter. It doesn't matter if it's 1 person a year or 50,000...

- Gregory Brown: Correct.
- Craig Blackmore: ...people a year, we're still charged with making a decision about what's appropriate for coverage.
- Gregory Brown: Right.
- Craig Blackmore: But, there is a body of evidence outside of our scope on other indications where, I mean, we're not here to discuss that evidence, but that evidence does exist, but that's not our question. So, radiculopathy, you know, spondylolisthesis, there's... there's... there are randomized clinical trials out there. It's not like lumbar fusion has been ignored, but the data pertaining to the problem as preconditions have defined it for us is what you see before you.
- Gregory Brown: So, so just in a pragmatic response. So, if a spine surgeon saw a patient and diagnosed them with radiculopathy from a disc herniation and degenerative disc disease, they could ask for authorization to do a diskectomy, as well as fusion, and the state could say if we agree with the question and deny coverage for the fusion, the state could say we authorize the diskectomy. We do not authorize the fusion. Is that...
- Craig Blackmore: Well, no.
- Chris Standaert: So, that, you... you're...
- Craig Blackmore: No. In that circumstance, that individual would not be covered, would not be included under our decision because of the radiculopathy.
- Gregory Brown: Right.
- Craig Blackmore: So, nothing we say today has any relevance for that particular patient. It's on-... it... it would be governed under whatever policies the agencies have in place for conditions that are excluded from our coverage decision.
- Gregory Brown: OK.
- Craig Blackmore: Because it's explicitly...
- Gregory Brown: Right.
- Craig Blackmore: ...in the key questions.
- Gregory Brown: Right.
- Craig Blackmore: Radiculopathy, those people are not included in whatever we say today.
- Gregory Brown: OK. I have a question for Dr. Shonnard. OK, in the real world, you get a patient that... that would be a candidate for surgery with discogenic... well with uncomplicated degenerative disc disease. You're stating that the only criteria would be, well beyond the complications of, you know, structural instability or

anatomical problems or neurological complications. So, you've got this patient. So, when... beyond the scope of they failed this program, they still have chronic pain, you, to the best of your ability, have, you know, determined that it was a discogenic degenerative disc disease pain, low back pain, where would... I'm trying to get an idea of where they fall into your decision to...

Neal Shonnard: First off, you're... you're... you're striking gold on exactly... this conversation is striking gold on exactly what happens in the clinic. First off, the patient doesn't... it is rare that the patient comes in with single level, degenerative disc disease, no other abnormality, has acute lower back pain, and is presenting with no other abnormality. That is exceedingly rare.

Gregory Brown: OK.

Neal Shonnard: Maybe 5%.

Gregory Brown: OK.

Neal Shonnard: So, when you look at this conversation, Michael's point, David's point are really well taken. They're just on either side of the spectrum. These patients present with a multitude of problems and not a single degenerative disc disease entity, and in the multitude of problems, it is quite likely, and this is consistently seen in human behavior, that this system will be gained to make sure that one of the inclusion criteria are listed, doesn't take long to figure out what's on the exclusion list. And the whole issue then becomes a gaming. And that is really not what you're striving to do.

Chris Standaert: So, I mean, I don't want to argue that that happens, it certainly does. To Mike's point, so I mean, frankly, if nobody is doing this, and I think it is a rare occurrence, and I think... my surgical colleagues said it when they're up there. It's very rare that somebody does this, in this community, but to think this isn't being done around the state or around the country is very naïve, I think. And I think if we say no, and nobody's doing it, we don't change anything. We haven't inhibited anybody. We haven't stopped anybody from doing anything they think is reasonable. If they're not doing it and we say no, it doesn't matter, but you... it's clearly being done, and there's clearly a large group of people and body of people who talk about lumbar fusion and disc replacement and other things for axial low back pain. The Mirza study was done, in large part, in Washington State. That's where they started. They talked to us as part of the study. The inclusion criteria was, a surgeon thinks they need fusion for discogenic pain. We said we wouldn't participate, because we didn't know who those people were. Clearly, they were surgeons who knew, in their opinion, what discogenic pain was that would qualify them for fusion. So, people are doing it. I agree, we don't know how many. We don't know the number. It's really hard to tease out. The diagnoses get twisted. People manipulate the coding system. All this happens, but none of that we can control. We can control, do we think in people where... if somebody can find them with this disease, should they be fused or not. I think we can control... we can state what we think about that. I think that's fair to do. I think we've got all the evidence to do it.

Michael Souter: I take your point (inaudible) may be (inaudible), but I think that one of the other factors that was brought to us in previous discussions, and that's (inaudible) option was (inaudible) seemed to be an inequality of geographic access to the comprehensive pain clinic, exactly the issue that you were getting at before. And in some cases, we may have patients who just have no opportunity to have any other means of treatment, and I think that, you know, to completely shut the door on that, that would be a considerable (inaudible). That's why we (inaudible).

Chris Standaert: Right.

Michael Souter: (inaudible)

Chris Standaert: No.

Michael Souter: (inaudible)

Chris Standaert: I understand that. I go back to Joann's point that unfortunately, fusion isn't benign, and there are people who get worse. So, that whole argument of I... I... I wish I could, in some way, force policy change on the other side to require better rehabilitative care. So, and then not purely out of self... but out of concern for patients and exactly what you said. If you can give them the right path, they will do just as well, but at the same time, the devil's advocate side of, well, since you can't do that you can fuse them knowing that there is a group of people who really do poorly with fusion is, I find... it's... it... it opens up a door of risk that wouldn't have to be opened otherwise. And then there are, you know, once they go bad, once they get adjacent segment disease, once they get arachnoiditis, once the hardware fails, once they get more depressed, they get infected, they get... I mean, I see this every day at my clinic. It's... it's... it never ends, right? Their life is changed. And so, to open that door, it bothers me a bit.

Craig Blackmore: So... so... I'd like us to focus a little bit, not exclusively, but a little bit on what we've learned, since we made our decision seven or eight years ago. And I think what we've learned, and please help me, is we've got longer followup on the randomized clinical trial data, long-term followup. There's always some loss, but we do have longterm followup. And we have, perhaps, more reliable cohort/registry data that defines some of the potential complications better. Can I get some comment and discussion on the meaning of that new data, since it's not coming (inaudible)?

Gregory Brown: I don't think that RCTs can give us appropriate harm data. They are not adequately powered for any subgroup analysis to look for prognostic factors, and the only way to get that is, I think, at least that I've... is registries. And I think spine SCOAP is to be applauded as to trying to get this data and move us forward. I think that the only way to answer what this select group of patients is would be a registry of that type. I... failed back surgery syndrome, I would prefer to look at specifically adjacent segment disease. That is my biggest concern, and that is unlikely to ever to be captured in an RCT just to get enough followup without the attrition to the... to the cohorts. And so, I would, I mean,

from my perspective, failed conservative, with or without conservative management treatment, intense rehab program, that in and of itself does not mean that a fusion for discogenic pain is an effective solution. What I also heard from the presentation was that surgeons don't do fusions for discogenic back pain. So, I agree with Chris that if you're not doing it for that and our decision is restricted simply to discogenic back pain, that it still allows them to do fusions for instability for deformity, and other issues that... if we... as long as we restrict our decision to that, I think we don't have evidence of effectiveness for fusion for discogenic back pain.

Kevin Walsh: And, OK, so, to answer your answer, Craig, which is what's, what's the interim shown us?

Craig Blackmore: Yeah.

Kevin Walsh: I think the interim has shown us that the benefit disappears. The surgical benefit disappears over time in terms of function. That's how I interpret it.

Craig Blackmore: So, what we've learned is, we have longer followup that confirms or elucidates that there is no longterm benefit, and if there is a short-term benefit, it's a short-term benefit.

Michelle Simon: There's... there's...

Chris Standaert: And a relative, a relative benefit.

Craig Blackmore: A rel-, depending on the comparator.

Chris Standaert: Yeah. So, if you took... I mean, the study I keep looking at is the Mannion study, which is following the Brox and Fritzell people out for 11 years, and their... the benefit they received from surgery or nonoperative care was durable. They stayed flat. They didn't go back up, but they did not differentiate at all. There was no separation. They were identical, essentially. And I think what it did also show was that higher numbers of people in the surgical group did notably better, but higher also did notably worse, right? It split them. And then it also showed that whatever group you tracked, only 50-60% of the people got better at all, and there is a substantial group of people in this population that do not get better whatever you do to them, and this is even an as-treated group, so, people who crossed over. That's curious. When you look at, like, studies of, they are the studies on vertebroplasty and a less study on epidural steroid injections. They allow people to cross over to a certain point, and they track data without crossovers and they track with crossovers. And in those studies, the people who cross over didn't get any better. They didn't respond like the people who responded to the initial treatment. They just stayed where they were. There is a group of people with chronic low back pain who are not going to get better from us fusing them or exercising them. They're just not, and I think that's what we see. And I think that informs the decision of is it reasonable to allow this procedure, if people fail nonoperative care. I think it informs that to a degree.

- Seth Schwartz: Yeah, and that... that's what I wanted to comment about. When you look at the decision that you guys made, I wasn't on the committee at the time, it was you can't have surgery unless you fail this (inaudible).
- Craig Blackmore: Well, it was a little more nuanced. It was unless you fail or if it's not available, recognizing that it wasn't... it wasn't geographically available. So, we didn't want to have... we didn't want to say you have to fail, because some people weren't even able to get it.
- Kevin Walsh: Can I have you stop using the geographic term, please? Because this is a socioeconomic issue. It has nothing to do with geography.
- Craig Blackmore: Socioeconomic is also a discriminator.
- Kevin Walsh: It's as true in King County as it is in Yakima County.
- Craig Blackmore: OK. Fair enough.
- Seth Schwartz: Well, just to continue with that (inaudible). So... so, excluding the patients that didn't have access. If you essentially say that we're... we really only think that there's applicability in patients who fail the appropriate... whatever the appropriate intensive rehab is, but I'm not seeing any data of the patients who failed that. Are any likely to do better than the patients who didn't fail that. And that's... I guess that's kind of what I'm struggling with is with that as an exclusion or as a... as a condition for surgery, because I... I want to (inaudible)...
- Craig Blackmore: I... I don't want to...
- Seth Schwartz: ...know that there is some benefit here.
- Craig Blackmore: ...I don't want to go back to 2008. I want to (inaudible).
- Seth Schwartz: No. No, I'm not, but I'm just saying, in the data that we saw today ...
- Craig Blackmore: OK. That's fair.
- Seth Schwartz: ...looking in those subsets of the data, I'm just not, unless I'm missing it, I didn't see anything that...
- Craig Blackmore: OK. That's fair.
- Seth Schwartz: ...failing... having failed intensive therapy did not mean you were any more likely to do well. So, I'm...
- Craig Blackmore: So, in terms of what...
- Seth Schwartz: ...just trying to see how... how that's a good criterion for who we offer surgery to.

Craig Blackmore: ...in terms of what we've learned, we have followup on the randomized clinical trials. We have talked about relative differences that might have been present in the short term, or certainly not present in the longterm. We have seen no evidence saying that people who have or have not had more intensive nonintervention, nonsurgical interventions benefit from surgical, as opposed. And I think we've also seen some newer or updated information on safety that maybe helps us to better understand the safety profile of the procedure. Is that fair... resonate with the committee? So, I think those are the pieces of evidence that we have.

Michelle Simon: So, if I think about what's new, since the last time we did this topic, there is that one study. We have one new RCT, the Ohtori study, and it's 41 patients, but their inclusion criteria, there are some issues with that, and we know they did a poor job of their control group, because they've had them just walking for half an hour. Not necessarily the most robust program. So, I don't think that evidence is super persuasive to change our decision. I think also we know from the L&I program that they have implemented, we haven't seen, the data is not perspective, as we know, and it is difficult to assess, but it seems clear that they didn't increase surgery rates in the state from that program. So, that was, perhaps, part of our thinking when we made that first decision is that we create this program. We would have some folks go through and do this intensive interdisciplinary approach, and then we would see some positive outcomes from that, and we haven't really seen the data from that. Maybe there needs to be more studies on that regardless. It isn't what I was expecting to see. So, we didn't see that. We know, also from L&I data, that we have a two-year 64% disability ten years out. These are 41% people permanently disabled from this procedure. So, I think that needs to inform our decision, as we go forward. And if I look back to when was participating in this first decision, I would, at this point where I'm at sitting on the committee, I would say no cover based on what we've learned.

Craig Blackmore: Carson?

Carson Odegard: Yeah, a question for Dr. Franklin. I, in your slide you mentioned 64% disability after two years, and then additional disabilities from revision operations. In that... do we... do we have any data at all on people that were... that went through the program and went through the rehab program that are still disabled, or the ones that crossed over to surgery group that would have been... would have been included into that disability?

Gary Franklin: As I said before, we don't have, we didn't do a... we didn't collect, you know, self-reported pain and function data prospectively from these patients. I wish we had, but we didn't. It's kind of a real research project, and we didn't have the funds to do that, but there's a lot of data in the literature on systematic reviews of some of these other therapies. That's not the subject here today. You know, all I know is that two-thirds of our workers are still totally disabled on time loss. When we did those two studies, we asked spine surgeons what timeframe should we look at? What... how long would it be before somebody actually improved from these things, and they said most people should be bet-... much better within six months, one year would be kind of an outside limit, two

years would be, like, nobody would question that. So, we looked at the two-year timeframe in both of our studies, and both before the introduction of spinal cages and during and after the introduction of spinal fusion cages, the introduction of the technology didn't make any difference in the outcome, which was about two-thirds of our workers being on total disa... being... still continuously disabled two years after the fusion. I don't have any more data than that.

Carson Odegard: OK. Thank you.

Craig Blackmore: Other comments or questions? OK. Well, we can launch into the decision making process if we're ready and just give people an opportunity to jump in if they don't think we're ready, if they want to talk further. Alright. So, I'm going to ask the committee members to turn to the Health Technology Clinical Committee Coverage Determination Tool, which is in your packets towards the back of the tab... determination analytic tool. And, so this is a document that helps the committee step through the actual decision making process. The first part is a description of our charge, which is to determine if the technology in question meets the criteria being safe, effective, and providing value or improving... implying to cost-effectiveness. So, we make, really, three separate determinations on each of those before we make a final determination. First the staff have, for us, prepopulated the document to document the outcomes that we have considered in our determination, and those are on page three of your packet. So, we'll just take a minute and ensure that this document reflects the considerations that we have done. So, first under safety outcomes, we have mortality complications, adverse effects, and repeat surgery. Are there other safety outcomes that we have considered that are not on here? I think I would add the adjacent disc... or adjacent level disc degeneration that...

Chris Standaert: Adjacent segment disease?

Craig Blackmore: ...adjacent segment disease, which can be increased by fusion. Are there others that committee members are using in their deliberation that we should have on here? And then hearing none, moving on. Under the effectiveness outcomes, we talk about pain, function, disability, treatment success, use of opioids, return to work or normal activities. Other things we've talked about, which are maybe not explicit on here are things like effect on depression or other indicators of overall well-being, just sort of implied by some of these but maybe can be brought out explicitly. Any other effectiveness outcomes that we should note? OK. And then we talked about special populations and again remembering that our boundaries are restricted to this discogenic back pain group. Other special considerations we talked about, at least looking for data on, not necessarily having data, one is the conservative management, the type of surgery, age, gender, physiologic status, worker's comp status. Anything else that we?

Joann Elmore: The ICER report didn't find differences among smokers, but the L&I report from Dr. Franklin indicates the spine SCOAP has worse outcomes in smokers.

Craig Blackmore: So, we definitely could discuss that as part of our consideration. OK, any others? And then under the cost outcomes, we look at the cost of the

procedure, short term and longterm and cost-effectiveness, such data as there is, we would have included in our discussion. OK. It's also incumbent on us to note what Medicare has done and what other clinical guidelines exist, and there is no national or actually local coverage determination for Medicare. There are clinical guidelines that we've heard about and that are in your packet from groups including the American Association of Neurologic Surgeons, the American Pain Society, the Bree Collaborative, and several others, which are in here. And, so that really brings us to the first voting question, and I'll review this a little bit. Again, I'll just review it a little bit. So, the way this works structurally is, the committee makes a first nonbinding decision looking specifically at safety, cost, and cost-effectiveness and that's the yellow cards for those of you that are new. And what we're going to do is, I'm going to ask if the committee members believe that the lumbar fusion is more, less, equivalent, or unproven in effectiveness to start with respect to... with respect to the comparator. And I guess we would have to define the comparators here. So, I think what we'll do is, we'll do this twice. We'll do it once with the first comparator being usual care. And then we'll vote again with the second comparator being a more intensive multimodality, multidisciplinary...

Chris Standaert: Can we use the phrase minimal care that's actually used in the studies. Usual is a very vague word.

Craig Blackmore: Minimal care is fine. And then intensive care, is that? OK. So... so, we'll do that for those three. So... so, that's our first step. So, is there... so, the question. Is there sufficient evidence under some or all situations that the technology is effective when compared to minimal care? And then I need a vote of unproven, equivalent, less, or more.

Joann Elmore: Could you restate the question?

Craig Blackmore: Yes. So, is... is the lumbar fusion surgery in our defined population, is it effective when compared to minimal care, so not the more intensive care that we talked about but the sort of not a organized focused intervention. Does that? OK.

Josh Morse: OK. Hold up your card, and we'll record your vote. So, four equivalent, seven more.

Craig Blackmore: OK. And then the same comparator, minimal care if you will, and we're going to talk about safety. So, is surgery more, equivalent, less, or unproven in terms of safety when compared to minimal?

Josh Morse: OK, that's eleven less.

Craig Blackmore: And then same comparator cost-effectiveness.

Josh Morse: Five less, six unproven.

Craig Blackmore: OK. So, now, I'm going to ask the same question, but this time with the comparator being the more intensive nonsurgical intervention. So, is surgery

more, less, equivalent, unproven effectiveness when compared to more intensive nonsurgical?

Josh Morse: OK. I see ten equivalent, one unproven.

Craig Blackmore: OK. And then safety, with respect to more intensive.

Josh Morse: Eleven less.

Craig Blackmore: And cost-effectiveness.

Josh Morse: Four unproven, seven less.

Craig Blackmore: OK. So, committee members, using that information from your colleagues as a way of being explicit about where we are in the discussion, is there further comments, questions, discussion, before we move on to the second and binding vote? Anybody want to elaborate at this point?

Kevin Walsh: You split the question into two.

Craig Blackmore: Yes.

Kevin Walsh: Is it your intention that we are going to vote in the same fashion?

Craig Blackmore: No. We're going to vote once.

Kevin Walsh: Thank you.

Chris Standaert: I just have a question on language. So, the key question uses the phrase uncomplicated degenerative disc disease. I'm not convinced that degenerative disc are diseased, and we shouldn't be using that term, and I have never met anybody with chronic low back pain who was uncomplicated. So... so, I don't... I... we need a better working phrase than that, I think.

Craig Blackmore: I think we may have to... may have to have the agencies operationalize, but it would be valuable, perhaps, to put on the record suggestions for what that might look like. Do you want to elaborate?

Chris Standaert: Predominance of axial low back pain with... patients with predominant axial low back pain with degenerative changes in the absence of significant structural concerns in their spine, something like that. It's more wordy, but the structural thing is the problem. So is scoliosis and spondylolisthesis and, you know, and...

Craig Blackmore: And those are all...

Chris Standaert: ...the spinal stenosis...

Craig Blackmore: ...outside of this.

Chris Standaert: ...and yeah. They're all outside of it, right. They're the... they're the...

- Craig Blackmore: So, really, it's...
- Chris Standaert: It's almost like we can define the negative easier than the positive here.
- Craig Blackmore: And maybe that's what it is. It's low back pain that doesn't meet any of the criteria for exclusion from our decision.
- Chris Standaert: That works.
- Kevin Walsh: Well, the previous decision excluded spondylolisthesis greater than Grade 1.
- Craig Blackmore: And I believe that's how it's still written on here.
- Chris Standaert: I don't know if there's a rationale for that. There are definitely people with... but, I guess for back pain, there are people with certain radiculopathy with a Grade 1 spondy, you can get a radiculopathy from spinal stenosis or foraminal stenosis. So, like degenerative L4-5 spondylolisthesis rarely actually becomes Grade 2. They don't slip that far.
- Craig Blackmore: OK, so...
- Chris Standaert: But they become stenotic.
- Craig Blackmore: So, the population for this review, which is the population to which the decision applies, adults greater than age 17, chronic, meaning three or more months of lumbar pain, uncomplicated degenerative disc disease, patients with conditions, such as radiculopathy, spondylolisthesis greater than Grade 1, severe spinal stenosis, acute trauma, or systematic disease effecting the lumbar spine, for example, malignancy will be excluded. So, again, we don't have any, that's done. OK. Any other thoughts? OK. Then, we will proceed to the binding vote. So, based on the evidence about the technology's safety, effectiveness... safety, efficacy and cost-effectiveness, particularly the more recent evidence since our prior review, but encompassing all evidence, we will now vote that it be not covered, covered unconditionally, or covered under certain conditions, and if we vote for cover under conditions, we will then develop that further and rebuild. So, vote?
- Josh Morse: Eleven, nope, excuse me, ten no cover, one cover with conditions.
- Craig Blackmore: OK. To reconcile that decision with the existing guidelines, we need to... we need to state why we might have diverged, if we did. So, again, under the Medicare, there is no coverage decision. Some of these others, the American Association of Neurologic Surgeons recommended for patients with one or two-level degenerative disc disease without stenosis, if the chronic low back pain persists after conservative treatment. The American Pain Society recommends shared decision making in patients who have not responded to usual care. The Bree Collaborative does not endorse lumbar fusion for surgery in the absence of structural instability. The International Society for the Advancement of Spine Surgery supports fusion surgery in patients who are experiencing clinically-

significant pain and disability consistent with discogenic pain with some imaging findings and six months of structured conservative management. NICE recommends more intensive treatment prior to surgery with American Spine Society lists as criteria MR findings, symptoms for a year, no active psychological disorder, no smoking. And then L&I says if the patient has nonradicular back pain with Grade 2 spondylolisthesis. So, they would be excluded anyway. So, we need to be explicit in our justification for varying from at least some of these guidelines, although we agree with some of the others. And I would say, we've looked to the evidence and the more recent longterm evaluation of the clinical trials, there is not a benefit over these more intensive nonoperative therapies that we've been able to identify. So, that was a factor in our decision. Certainly, the data about harms that we talked about in some detail was a factor in our decision. Is there anything else that we want to make explicit in why we're different. We are more recent than some of these. The American Pain Society is 2009, for example, before some of the followup studies on the randomized trials.

Gregory Brown: So, even if the findings that the outcomes, or effectiveness of intensive multidisciplinary treatment versus surgery have similar outcomes, the surgery is certainly more costly. So, therefore, less cost-effective in terms of that.

Craig Blackmore: And it has different safety (inaudible).

Gregory Brown: Yeah.

Craig Blackmore: OK. OK. Do we need anything else?

Josh Morse: No. Thank you.

Craig Blackmore: OK. Then that will adjourn the lumbar spine discussion. Next item for discussion is tympanostomy tubes. We're ahead of schedule. So, let's take, we'll take a ten-minute break, give the group time to turn over, and we'll meet back here and start with... is... are the agencies ready to move on to tympanostomy tubes? OK. So, we'll do that. We'll take a ten-minute break, meet back here, and we'll start with the agency presentation.

Alright. We have a quorum, so we will continue with the second topic for the day, tympanostomy tubes in children, and we will start off with the agency presentation.

Robert Mootz: OK. I'm Bob Mootz. I'm with Labor and Industries, and the agency medical directors have decided that we have some concerns and questions about this procedure, and the issues that kind of drove us were there are some safety issues, because it is something done in kids. It is done under general anesthesia. There are some efficacy concerns, which are pretty high based on the state of the evidence, and there are some cost issues associated with it. Just the background... the procedure is used for a couple of different conditions, primarily recurrent otitis media... recurrent acute otitis media, which is defined as three ear infections within six months or four year infections within a year. This is the acute episode. It is usually painful. So, there is a lot of quality issues

for the kids suffering from it. Chronic otitis media with persistent effusion is a chronic state of it where there was always effusion in the middle ear. This is usually not painful, and it's defined as being present for six months in a unilateral ear or for at least three months in a bilateral ear. Then, there are other situations where these tubes are placed. There are some congenital disorders and challenges with drainage in eustachian tubes and that sort of stuff.

It is a pretty straightforward procedure. It's just a little tube inserted into the tympanic membrane, which allows air to get in and sometimes fluid to actually drain out of it.

Otitis media, as a condition, is extremely common. Most children have at least one episode in the course of growing up. It is usually self-limiting condition, and the... probably the biggest issue associated with this is, there is a large proportion of these cases, however, that do become chronic and recurrent. The etiology is thought to be bacterial or viral. There may be problems with mechanically draining and the eustachian tube blockages and some congenital disorder, such as Down Syndrome. They are angled very narrowly, so the drainage just doesn't happen well.

The impacts from having otitis media, in the short-term there's pain, fever, and disturbances of sleep and eating issues, and the quality of life for the kids suffering from it, as well as the parents working with them can be substantial. The longterm things that have been suggested as being important are that you have a decrease in hearing. So, there are concerns, being in kids, of developmental issues cropping up, learning issues, and language development issues that have been proposed, and these also have impacts on the quality of life for parents and kids, missed school, missed work on the part of the parents. There are also some impacts from the tube insertion, itself. Again, in the young kids, it is usually done under general anesthesia, which has some inherent risks, and the tubes frequently fall out after a period of time. So, they may need to have repeat procedures.

This is a quick illustration of the utilization in PEBB. There is roughly about 6 to 700,000 a year spent in the Public Employees Plan. The procedures themselves run around \$3500 to \$4000. In Medicaid, it's a much larger population, and it's close to 5 million that we spend in Medicaid on the procedure, and that's at a substantially more discounted rate.

This just illustrates that most of the slides, both in PEBB and Medicaid are done bilaterally, and this just illustrates the ages in which they tend to be done. So, the majority, vast majority, are between the ages of one and nine and most of them are on the one to four-year-olds.

Currently, our coverage policy in the agencies is, Medicaid covers them with no conditions whatsoever, as does PEBB. L&I and the Department of Corrections, well there's not too many incarcerated four-year-olds or construction workers. So, it's not really relevant in those agencies. The questions we have is, is it effective, and the data, and I'll defer to the Spectrum report for you to look at

that sort of stuff, but our read on it looks like there is some impact, some benefit for hearing loss. There is about a 3 to 7 decibel improvement in hearing loss with ears that have tubes in them versus those that don't, but over time, it appears that that diminishes. That affect diminishes.

Just for some context, this is just an indication of what different decibel levels are. So, 10 decibels is the sound of normal breathing. Twenty decibels is the sound of a mosquito flying around your head. On the other hand, you know, 100 decibels is more your rock concert, headbanger level. So, the 3 to 7 decibel improvement is a fairly small difference for having the tubes, and that's just what we're illustrating here.

On the quality of life, there was one study that you'll hear about that in children with sleep apnea there was some benefit, again, short-term. It didn't appear to be sustained longterm, and other studies showed that there wasn't very much benefit on quality of life elsewhere. There are no differences, particularly in speech and language outcomes compared to watchful waiting for otitis media with persistent effusion at any of the time points that were evaluated, and there is no difference in complications for people who get the tubes versus people who don't. Some of the things that have been talked about are persistent perforation and sclerosing of the tympanic membrane and such.

So, our concerns, as agency medical directors, is that it looks like ear fluid of short duration is likely to resolve spontaneously without intervention. We may actually be placing more tubes than are necessary based on our understanding of the evidence. Questions we have: Is bilateral tube placement always necessary if only one ear is impacted? They suggest that if you're placing them under general anesthesia and someone is chronic, you know, while they're already under it probably makes sense to do it bilaterally. There's probably not much of a cost difference, and it's a similar safety issue. Again, refreshing the point that general anesthesia on kids is a significant thing to think about. We think that the concerns about the longterm risks of otitis media, either the acute version or... the acute recurrent or the chronic version, are probably unfounded in terms of developmental disabilities, and in children with comorbid conditions, such as speech delay, there may be situations where it's appropriate to place the tubes. I'm not... I'm not sure how helpful the evidence is in guiding us that way, and so I think there's some opportunities, too, that really aren't the scope of coverage decisions, but short-term benefits versus risks should probably be made very clear with parents. So, that's really more in the shared decision making area.

So, we're really looking to you and your review and take on the evidence to help guide us. So, our... kind of... the way we're thinking about it is rather than no conditions at all, maybe we should be applying some conditions and some ideas that we are putting out as suggestions for you to consider based on your review is to potentially consider covering it for con-... with conditions for recurrent acute otitis media if there's more than the three episodes in six months or more than four episodes in 12 months. And also in otherwise healthy children with the chronic persistent effusion, consider coverage with at least three months of chronic effusion and a demonstrated persistent hearing loss. The level and

amount of hearing loss is something I'm hoping you'll... you'll discuss and consider. NICE has recommended that it be somewhere in the 25 to 30 decibel range of documented hearing loss. I point out that it is very difficult with audiology testing to actually tell how much hearing loss a 1-1/2-year-old has. So, again, we don't bring you the no-brainers. We're bringing you the kind of... the challenges we have.

We would also suggest excluding from the coverage decision some of the special populations. So, deformities and those sorts of things, and if the otitis media has other complications, like, you know, it occurs as a result of other more extensive infections, brain abscesses and the like. So, that's our... that's our take on it. If there's any questions, I'll try and handle those.

Craig Blackmore: Thank you. Questions?

Chris Standaert: The NICE recommendation, does that refer to a threshold of hearing loss where you have a 25 decibel threshold, or is it compared to a... loss compared to normal or compared to the unaffected ear.

Craig Blackmore: It's probably compared to the ineffective... unaffected ear or normal.

Seth Schwartz: It's not, actually. Its total... its hearing level.

Robert Mootz: Oh, it's a total absolute hearing level.

Seth Schwartz: It's a total...

Robert Mootz: OK, thank you.

Seth Schwartz: So, that... and that was my other comment about that 3 to 7 difference. Like, when you show the degrees of hearing loss of zero to ten as whisper, it's a difference. So, a lot of these children don't have...

Robert Mootz: Have, yeah.

Seth Schwartz: (inaudible)

Robert Mootz: Exactly. They're starting at baseline.

Seth Schwartz: Starting at 20 and 25 to begin with. So, it's, it's the incremental change on top of that.

Robert Mootz: Yes. Thank you.

Craig Blackmore: So, I'm going to ask a question, and I think I know the answer, but you gave us some data on utilization and do we have any ability to get more granularity around the time of symptoms, indication.

- Robert Mootz: OK, this is... this is just based on billing data, and there is no records review. So, there... there's... there's other granularity on things that aren't really relevant to it, so, sorry.
- Michael Souter: Just with regards to concerns about general anesthesia in children... sorry. Is that working?
- Chris Standaert: No.
- Craig Blackmore: Yeah. It's working.
- Michael Souter: I'll borrow Carson's. So, just with regards to the concerns in general anesthesia for children, are there any specific concerns or is it just, you know, theoretically?
- Robert Mootz: No. It's just general theoretically, and I'll guess you'll hear about, you know.
- Michael Souter: OK.
- Robert Mootz: The issues in the... in the, uh, evidence review.
- Craig Blackmore: Any other questions. Lunch isn't here, so.
- Seth Schwartz: Can I just make one comment about the... the anesthetic issue, which is that the level of anesthesia for these children is different than even for tonsillectomy. It's usually a sedation medication. It usually takes about five minutes. So, it's usually just an inhaled sedative for five... for five minutes. So, the level of risk is probably considerably lower than what you would see even for a tonsillectomy or a procedure that requires general... general with an intubation.
- Michael Souter: I was going to come to that later on. I wasn't sure whether we were wandering into the concerns about anesthesia for small children and cognitive function subsequently, but we can cover that later on.
- Craig Blackmore: OK. Any other questions? OK, thank you. OK. So, Christine, do you know. It looks like we're clearing. Is lunch imminent?
- Christine Masters: About five, ten minutes.
- Craig Blackmore: Five, ten minutes. Well, I hate to waste five or ten minutes. Spectrum has arrived it looks like. Are you guys ready? Our clinical expert is here. OK. Let's introduce our clinical expert. Actually, perhaps you might introduce yourself to the group. I thank you for coming.
- Carol MacArthur: I'm Carol MacArthur. I'm a pediatric otolaryngologist at Oregon Health Sciences University.
- Craig Blackmore: Thank you for coming, and we always ask this, but do you have any conflicts of interest to declare?
- Carol MacArthur: No.

Craig Blackmore: So, thank you for coming. The clinical expert is an important part of the process. We're not all otolaryngologists. So, you're here to help us put things in a clinical context. We have Spectrum. They are going to tell us about the evidence, but clinical context is also important. So, we're not asking you to make a specific presentation, but doubtless there will be questions through the course of the discussion. So, thank you for being here.

Carol MacArthur: Great.

Craig Blackmore: And, yep. Let's go for it. Yeah. So, procedurally, I'm going to, we're going to move the public comment period back so that it... we try to keep on the same schedule in case people were intending to come at that time. I don't want to cut them off. So, that's why we're rearranging is to keep that public comment period in the window we had prescheduled.

Robin Hashimoto: Hi. Sorry. Loud. I'm Robin Hashimoto from Spectrum Research. OK. So, as you've heard, tube insertion... sorry... slide advancement. Tube insertion is a very common procedure in children. It's the most common outpatient surgery that's performed in the children in the U.S., and tubes are inserted to help ventilate the middle ear space. It's done in children with either otitis media with effusion or with acute otitis media.

So, otitis media with effusion, or OME, as I will refer to it, is characterized by inflammation of the middle ear that is accompanied by fluid and it does not have any symptoms of an acute ear infection. This inflammation can be caused by upper respiratory infections and allergies and is compounded by an immature eustachian tube, which can impair the effective clearance of fluid that is in the middle ear. It is not surprising then, due to children's immature eustachian tube function, combined with their propensity to get frequent colds, that otitis media with effusion is a common condition in children, and while the majority of cases resolve on their own, 30 to 40% develop into chronic otitis media with effusion, which is that which lasts for at least three months.

So, otitis media with effusion can be asymptomatic, but there can also be a sensation of fullness in the ear and accompanied hearing loss. In general, otitis media with effusion is associated with a conductive hearing level of about 28 decibels, and that is consistent with mild hearing loss. The hearing levels are shown here on this chart. So, in green, the range from 0 to 20 is considered normal hearing levels, mild hearing loss ranges from 20 to 40 decibels, and that is the level that soft speech falls in. Normal speech falls within the next level, around 50 decibels. So, hearing levels that are between 41 and 55 decibels are considered a moderate hearing loss, and then it goes up from there.

So, with the hearing loss that is accompanied with otitis media with effusion, when it becomes chronic, there is a concern that the hearing loss could result in developmental delays related to language and speech behavior, academic achievement, as well as reduced quality of life for both the parent and the child.

Chronic otitis media with effusion can also lead to other problems, such as cholesteatoma, retraction pockets, or atelectasis, which I hope I'm pronouncing correctly, ear infections, middle ear cysts, and tympanic scarring. Patients with cleft palate, Down Syndrome, or other craniofacial disorders are at very high risk due to an impaired eustachian tube function.

So, the other condition for which tube insertion is indicated is recurrent or persistent acute otitis media, or AOM. This is your basic ear infection, and these, of course, are very common in young children. So, as you've heard, recurrent acute otitis media is defined as at least three episodes in six months or at least four episodes in twelve months with the most recent episode being in the previous six months, and then persistent acute otitis media is defined as persistence or recurrence of acute otitis media within a month of antibiotic therapy.

As for chronic otitis media with effusion, there is a concern with recurrent acute otitis media that impaired hearing could head to developmental delays, and recurrent or persistent acute otitis media is also associated with a reduced quality of life for both the parent and the child. So, risk factors for ear infections include the craniofacial disorders, as well as upper respiratory infections, exposure to large groups of children, such as daycare, and exposure to cigarette smoke.

OK. So, tubes are inserted in an outpatient procedure, typically under general anesthesia, and they are inserted by first making a small incision into the eardrum, and this is called a myringotomy. A myringotomy alone is one of the comparators that we'll talk about that was used in the report. Once the incision is made, fluid can be aspirated from the middle ear, and then the tube can be inserted into that incision. So, tubes are designed to fall out on their own, and they typically fall out within about 20... or about 15 months, and that's due to the accumulation of keratin between the tube and the surface of the eardrum. Checkups are typically performed periodically during the time which tubes are intact to evaluate their function, as well as middle ear status. Currently, there are over 100 FDA approved tubes indicated for otitis media, and they are made of varying materials and have various shapes and sizes.

So, as you've heard, the anticipated outcomes with tubes are an improvement in hearing levels by about 5 to 12 decibels, and the greatest benefit is expected early on. It is also anticipated that there will be a reduction in middle ear effusion, improvement in quality of life for both child and parent, and a decrease in ear infection incidence.

Adverse events that have been associated with tube insertion include otorrhea, which is basically fluid coming out of the ear that is typically transient, a persistent perforation after the tube falls out, blockage of the tube lumen by secretions, formation of granulation tissue around the tube, premature extrusion, which is often going to require reinsertion, tympanosclerosis formation, formation of atelectasis, or retraction pockets. Then there is also, of course, potential harms of anesthesia.

So, treatment alternatives are shown here. The comparator for which the highest quality evidence was found is watchful waiting, and this is basically when the child is monitored to see if the condition will improve on its own, because many cases do resolve spontaneously. Then, surgery, tube insertion, can be performed if the condition deteriorates, or if it continues to persist. Myringotomy is also a comparator of potential interest. This is basically done to relieve severe ear pain and drain the middle ear. It is done with a cold knife. It provides a very brief ventilation period and laser myringotomy provides a longer period of ventilation. Adenoidectomy with or without tonsillectomy may also be indicated in children who have frequent throat infections, as this can disrupt eustachian tube function and lead to chronic otitis media with effusion or recurrent acute otitis media and it is also, of course, indicated for children with some obstructive sleep apnea. Other comparators include antibiotics, other medications such as mucolytics or steroids, autoinflation of the eustachian tube, and then complementary or alternative procedures.

So, there are a couple of recent guidelines that provide recommendations on tube use. For chronic otitis media with effusion, the American Academy of Otolaryngology recommends tubed insertion in children who have chronic bilateral otitis media with effusion and documented hearing loss. They consider tubes to be an option in children with chronic unilateral or bilateral otitis media with effusion who also have symptoms attributable to otitis media with effusion, such as impaired balance, poor school performance, behavioral problems, ear discomfort, and reduced quality of life. They also consider tubes to be an option in children at risk for developmental disorders who have unilateral or bilateral otitis media with effusion that's unlikely to resolve quickly. Then they specifically did not recommend tubes in children with a single episode of otitis media with effusion that was of less than three months' duration.

For children with recurrent acute otitis media, and this is defined, as I had mentioned before, the same guideline recommends tubes in children who have recurrent acute otitis media with unilateral or bilateral middle ear effusion but they did not recommend tubes in children with recurrent acute otitis media without middle ear effusion. In contrast, the American Academy of Pediatrics 2013 guideline recommends tubes in children with recurrent acute otitis media regardless of the middle ear effusion status.

So, the key questions are listed here. They are your standard fare. They ask about the impact of tubes compared with watchful waiting or alternative treatment options in children aged 16 and younger with regards to efficacy, safety, differential efficacy, or safety in subpopulations, and cost-effectiveness.

So, regarding the inclusion criteria, we included studies of children aged 16 and younger with chronic otitis media with effusion or recurrent acute otitis media and patients who were treated with tubes and at least one of the comparators listed here. These are the ones I already went over. There were a number of outcomes of interest. They were clinical, functional, quality of life, and healthcare utilization outcomes. The critical outcomes were developed with clinical expert input, and those are in bold, and they include hearing,

cholesteatoma, speech and language development, parent satisfaction, patient quality of life. Then, the critical harms of interest were perforation with a focus on persistent perforation and chronic otorrhea.

Regarding study type, we included RCTs and nonrandomized comparative studies for key questions one and two, a case series designed to evaluate harms that met the criteria shown here were also included to evaluate harms. For key question three, which is the question on differential efficacy and safety, we included RCTs that stratified outcomes on characteristics of interest and that formally evaluated statistical interaction. Then, for key question four, we only included formal economic studies.

It shows the results of our literature search, and as you can see, a total of 66 publications were included. The majority of these come from 30 RCTs. There were also four nonrandomized comparative studies, three case series, and five economic evaluations.

The results are going to be presented in terms of the overall quality of evidence, and I am going to focus on the highest quality of evidence available and on the critical outcomes of interest.

The way at which we arrive at the overall strength of evidence is based on our application of grade and ARC's recommendations, and the four levels of evidence are shown here. So, we have quality ratings of high, moderate, low, and insufficient, and each quality rating should be interpreted in terms of the level of confidence we have that the evidence reflects the true effect. So, we graded the overall strength of evidence separately for each critical outcome, and we did it separately for each comparator, as well. We start with a baseline quality of evidence, RCTs start as high, and that baseline quality of evidence can then be downgraded if there are concerns surrounding risk of bias, inconsistency, indirectness, imprecision, and publication bias across the studies that provide evidence for that outcome. Then, after we take all of those factors into consideration, we arrive at a final strength of evidence rating, and for this report, we most commonly downgraded the quality of evidence due to risk of bias resulting from methodological flaws in the studies included, as well as for the risk of imprecision resulting from small sample sizes.

So, moving into the results, key question one asks about the evidence of the comparative efficacy and effectiveness of tubes versus other treatment options. In general, we pooled results when there were two or more RCTs of similar quality and that used similar comparators and outcomes, as well as followup times. In addition, we attempted to stratify results by age at treatment, but the mean age did not vary considerably between studies of the same comparators, so this did not end up getting done.

So, for key question one, a total of 30 RCTs and four cohort studies were included, and there were a total of 11 different comparators. These are the comparators that we identified for otitis media with effusion. Some of these present results by child and some present results by ear. Tubes versus watchful waiting provided the highest quality and the most recent evidence, and there

were a total of seven RCTs that were included. This was a comparator... the only comparator that provided moderate or high strength of evidence. The total number of patients across these trials was over 1300. Mean patient age ranged from about 16 months, 15 months, across to about five years across five of the trials, but there were two trials that only reported that patients ranged in age from half a year to 12 years. The studies included patients with bilateral or unilateral otitis media with effusion that had lasted at least two to four months. Hearing loss, which is defined there, was required in three RCTs. Another one reported that 71.5% had hearing loss at baseline, and then three RCTs did not require or hearing loss or did not provide details. One of the trials did require patients have disrupted speech, language, or behavior for enrollment. I do want to point out that the... you know, by nature of the comparator that the majority of these studies did permit tube insertion in the watchful waiting group during followup. Indications for tube insertion did vary considerably between studies. I think there was one study that didn't permit it. Some of them required that otitis media with effusion... was there a question? Sorry. Some of the studies required that otitis media with effusion persisted for another four to six months prior to tube insertion, and then other studies would allow tube insertion upon parental request. So, overall, there was anywhere from 0 to 8% of patients in the control group that received tubes during the followup periods.

So, the other comparators we identified and their evidence base is shown here, and no studies were identified on any of the other included comparator treatments, such as mucolytics, steroids, or autoinflation of the eustachian tube.

And this is the evidence base for studies of recurrent acute otitis media. So, as you can see, there was considerably less evidence available. We also identified one pretty small RCT that included patients with either a chronic otitis media with effusion or a recurrent acute otitis media.

So, I'm going to start with hearing levels, and this was the one outcome that was reported for all comparators identified. Overall, the results suggest that hearing levels were significantly better in ears with tubes versus those without between three and nine months' followup, and that time varied with comparator. This difference was not sustained but later followup time points.

So, here are the results for tubes versus watchful waiting for otitis media with effusion, and the results were presented in terms of mean hearing levels. Unfortunately, the vast majority of studies reported mean hearing levels rather than the percentage of patients who had returned to normal hearing. So, for the studies providing evidence for this outcome, the majority of patients did have hearing loss at baseline, and as you can see, there was moderate strength of evidence that tubes improved hearing by about 4 decibels at six to nine months based on results from three trials. By 12 to 18 months, there was moderate strength of evidence from the same trials of no difference in hearing levels between treatment groups. There was also one high quality trial that enrolled children between the ages of 2 months and 3 years that provided high strength of evidence that mean hearing levels were similar between groups at age six.

This shows the evidence on tubes... patients who had a tube in one ear and no procedure in the other. As you can see, there was low strength of evidence that mean hearing levels were about 6.5 decibels lower in the tubes group at six months, and then there was no difference at later time points through 120 months between groups, and that was based on low strength of evidence.

More of the same. This is results for children who went... underwent adenoidectomy and had a tube placed in one ear only. In the tubes group, hearing levels were about 3.5 decibels better than in the untreated ear at six months, but then there were no differences between groups... between ears at twelve months or later.

This shows similar results. Again, this is for tubes placed in one ear versus no procedure in the other ear in patients who had undergone adenoidectomy. So, there was a benefit at six months and none at later followups.

This is the remainder of the hearing results for the comparators of chronic otitis media with effusion. Most of them provide similar evidence. There was one trial that found that through 24 months, tubes patients had 7 to 8.5% fewer evaluations with hearing loss compared with patients who had received myringotomy alone. There was also one piece of evidence that showed that children with bilateral tubes compared with those who had bilateral myringotomy plus adenoidectomy. In the ear with better hearing, there was no difference between groups and the number of evaluations with hearing loss, but in the worse ear, those with tubes had 8% more evaluations with hearing loss in the control groups, and this was through 24 months.

So, these are the results. The first one is for patient... the trial with patients with chronic otitis media with effusion or recurrent acute otitis media, and here mean hearing levels were about 3 decibels lower in the tube's ear than the control ear through nine months. Then also at nine months, 32% of patients had hearing levels that were at least 5 decibels lower... better in the tubed ear compared with the control ear. No differences were found between groups at later time points.

For patients with recurrent acute otitis media, one trial found no difference between tubes and antibiotic groups in the percentage of time spent with hearing levels about 15 decibels.

So, the next outcome of interest is speech and language development. This outcome was... we only found evidence for this outcome for the comparator of tubes versus watchful waiting for chronic otitis media with effusion. Overall, the results suggest no difference between groups at any time point evaluated.

Here are the four spots. They showed the results of the pooled analyses, and as you can see, there was moderate strength of evidence, so no difference between groups in either verbal comprehension or in expressive language measured at six to nine months, and this was based on results from three trials.

And you can see at later time points, there was low to high strength of evidence of no differences between groups in any measure of language development.

The next critical outcome was parent satisfaction, and there was insufficient strength of evidence for this outcome. So, no firm conclusions can be made.

For the outcome of patient quality of life, there was limited evidence, and results were mixed. One small trial found greater improvement in quality of life in two patients at six months, but two other trials found no differences between groups. So, in the first row here, you can see that one trial provided evidence at both six and twelve months of no difference between group in a measure of quality of life called the TAIQOL, and this is the quality of life outcome measure that's focused on infants, in particular, and there was moderate strength of evidence and no difference. Another small trial compared tubes to myringotomy in patients who had undergone adenoidectomy, and these patients also had sleep apnea, as well as chronic otitis media with effusion, and the study found that patients that received tubes had greater improvement in OM-6 scores, another measure of quality of life, at six months than the control group, and there was low strength of evidence; however, this difference was not sustained to twelve months. In patients with recurrent acute otitis media, a sub-analysis of one trial found no differences between groups in ear-related quality of life. There was low strength of evidence for this conclusion.

The next outcome is cholesteatoma, and overall, there was low strength of evidence of no difference between groups at any time point measured. So, the results for patients with chronic otitis media with effusion are shown here. This outcome was relatively rare. There were only a handful of cases that were reported in the control group. You can see there's low strength of evidence across the board of either no difference between groups or that there were basically no cases. There were no cases of cholesteatoma in the studies of recurrent acute otitis media, and there was no evidence for any other comparators.

Before moving on to key question two, this actually was not identified as a critical outcome, but it was requested that we present evidence of acute otitis media recurrence in patients who have recurrent... who are being treated for recurrent acute otitis media, and this forest plot shows data from three trials that compared tubes to antibiotics, and as you can see, through six months the tubes group was 34% less likely to have a recurrence of acute otitis media compared with the group who had received prophylactic antibiotics.

For the comparator of tubes versus either placebo or no treatment, two trials presented evidence that acute otitis media recurrence occurred in significant fewer tubes versus control patients through both six and twelve months.

So, key question two asks about the evidence of harms of tube insertion compared with alternative treatment options, and the evidence based for this key question was similar to that of key question one. Most trials did report on harms. In addition, three case series were included. So, there were two critical harms that were of interest. The first was perforation. There was a focus on

persistent perforation, and there was low strength of evidence of no difference between groups in the formation of persistent perforation. Unfortunately, this was not clearly defined in trials, but generally seemed to indicate that perforation did not heal within a few months of tube extrusion, and it was generally treated with tympanoplasty repair.

So, the results for perforation are shown here in patients with chronic otitis media with effusion and overall, there were no differences between groups. In the tubes group, perforation occurred in 0% to about 13.5% of patients or ears, and then in the control group it occurred in 0% to 11% of patients or ears. Results for recurrent acute otitis media are shown here. So, for the comparator of tubes versus antibiotics and tubes versus placebo, perforation or persistent perforation occurred in 3.7% to 13.2% of tubed ears in patients and there were no results reported for the control group. Then, in patients with either chronic otitis media with effusion or persistent acute otitis media, one study reported that permanent perforation occurred in 4% of tubed ears and no control ears. There was one case series that we identified of 756 tubes patients, and it reported that persistent perforation after tube extrusion occurred in 1.3% of ears.

So, the other harms outcome considered to be of critical importance was chronic otorrhea, which was defined as that occurring three or more times a year. So, for this outcome, results were mixed. There was one trial that found that chronic otorrhea was more common in tubes than watchful waiting patients through twelve months and another small trial finding no difference between tube plus adenoidectomy versus myringotomy plus adenoidectomy groups through twelve months.

So, here are the results, and you can see for tubes versus watchful waiting, there was low strength of evidence. The chronic otorrhea was 19% more common in the tubes group. Two small trials reported that persistent otorrhea that required hospitalization occurred in 2.2% to 3.4% of patients. Another small trial found no differences between groups in the incidence of chronic otorrhea, and there was no evidence for any of the other comparators. That same case series of 756 tubes patients reported that chronic otorrhea occurred in 1.7% of ears.

Key question three asks whether there is evidence of differential efficacy or safety of tube insertion compared with treatment... with comparators of interest. Basically, we looked for any subgroup that was reported, and all of the evidence that we found was of insufficient quality in strength of evidence evaluations.

Key question four asks about cost-effectiveness of tubes versus other treatments, and we placed the focus on studies that did not use hypothetical patient populations. So, I'm going to talk about the one study presented here that was conducted alongside an RCT. So, this was a cost utility analysis. It was moderately- well conducted, and as I said, it was conducted alongside an RCT that was included for key question one of 187... 187 infants with chronic bilateral otitis media with effusion and hearing loss of at least 35 decibels who

were randomized to receive either tubes or watchful waiting. The analysis was conducted from a societal perspective, and both direct and indirect costs were used. The study found that tubes were more expensive than watchful waiting, and the only outcome used for this analysis was language development at 12 months. No differences were found between groups at 12 months, as I had mentioned. Thus, the study concluded that there was higher costs for tubes with no differences in effect with effect being measured only by language development, and the authors concluded that tube insertion should not be a standard treatment in children with persistent otitis media with effusion.

So, I'm going to conclude with a couple of slides with the evidence summaries and gaps in the evidence. So, we'll start with chronic otitis media with effusion. So, for hearing, hearing levels were 3 to 7 decibels lower in the tubes group than the control groups at three to nine months, and that's based on low to moderate strength of evidence. Then there was low to moderate strength of evidence of no difference between groups at later time points. Most evidence was related to mean hearing levels rather than achievement of normal hearing levels. There were no differences between groups in speech and language development based on low to high strength of evidence. However, evidence was only available for one comparator. There was no evidence on the impact of parent satisfaction. For patient quality of life, there were no differences between groups found at any time point between six and twelve months based on low to moderate strength of evidence. However, this evidence was only from two trials, and there was no longterm evidence. For cholesteatoma and persistent perforation, no differences between groups were detected. However, these were relatively rare outcomes and studies were likely underpowered to detect true differences between groups.

Then, this is the evidence summary for recurrent acute otitis media. For hearing, hearing levels were 3 to 9 decibels lower in the tubes group than the control group at two to nine months based on low strength of evidence. There was low strength of evidence of no difference between groups at later time points, and this was based on a very small evidence base. There were no differences between groups and... I'm sorry. There was no evidence for speech and language development, parent satisfaction, persistent perforation, or chronic otorrhea. Then, for patient quality of life, there were no differences between groups found at any time point with low strength of evidence. However, this evidence was derived only from one trial, and there was no longterm evidence. So, I can take questions now, or if we want to do that after lunch?

Craig Blackmore: I think we... we need to eat.

Robin Hashimoto: I think that... that sounds reasonable.

Craig Blackmore: So, we'll do that and then we'll have you come back and we'll have more.

Robin Hashimoto: Fantastic. Thank you.

- Craig Blackmore: So, let's go... I've got ten after twelve. Let's take a half an hour and... and have lunch.
- So, I'll call the meeting back to order and, excuse me, we'll... we'll resume. We've heard the presentation from Dr. Hashimoto, but we didn't really have an opportunity for questions. I don't think we need you to stand up there, but we'll take a few minutes to see if committee members have questions about the content of the evidence report.
- David McCulloch: So, I had one. Nice... nice presentation. This is probably a question for the clinical expert. I've no doubt that 3 to 5, or was it 5 to 7 decibels difference is statistically significant. My question is, I've no idea in the clinical significance of that amount of change in hearing.
- Carol MacArthur: Yeah. So, it... it absolutely does make a difference. Granted, remember that that's the average of the improvement...
- David McCulloch: Mm-hmm.
- Carol MacArthur: ...in hearing, but, you know, we see kids that benefit greatly with that amount of change. And I think, on average, in general, you... you see a little bit bigger change, especially acutely when you put those tubes in. Then, remember that decibels is a log rhythm-, log rhythmic scale. So, 7 decibels is actually a big change. It's not just 7% more. So, it can... it can make a big, big difference. So, yes, I think it's clinically significant.
- Chris Standaert: I had a bit... I had the same question, because I looked through the report, and they said that your community has not agreed on an MCI idea, since they have no literature, right? So, if you go to the spine literature, it talks all the time about the minimal clinically-important difference in the report. So, they went looking for this to get at that decibel rating that would be clinically significant and they couldn't find it. So, they couldn't find a consensus in the... in the community. Is this by, I mean, I assume there's a margin of error in the tests, too, right? So, if 3 or 4 decibels is when the margin of the error that tests statistically, doesn't that make it tricky to figure out what actually just happened here?
- Carol MacArthur: I think most... most of the testing is quite accurate. If the audiologist is not sure, they won't report a level. So, I think if you talk to an audiologist, they are very interested in getting a kid hearing in the normal range.
- Chris Standaert: Mm-hmm.
- Carol MacArthur: And anything below the normal range can actually cause pretty significant problems. There is one thing hearing in a quiet environment, like a... a sound booth or a hearing test, or a room like this, but most kids live in a noisy world. So, even a 5 to 10 decibel decrease in hearing in noisy kindergarten or preschool makes a big difference for some of them. And I think probably one reason there is no accepted standard of one number is that, you know, kids brains are all different. So, for some kids, they can go around hearing at 40 decibels and their

speech and language is normal, because we see that. And other kids, if it's 25 they're suffering and you fix it, and they make great strides. So, I think there's... it's not just hearing. It's that kid's brain, too, you know? Their ability...

Chris Standaert: Right.

Carol MacArthur: ...to use that information.

Michael Souter: And I've got a kind of related question if I can. Sorry, Carson. I'm hijacking your microphone again. The... it strikes me that there is probably some crucially important times, as well, when that hearing loss may have more, you know, detrimental effects than at other times, and related to that is the duration both of hearing loss and the duration of improvement. In other words, can you give me any sense in this? I realize that this may be best (inaudible) towards a child behavioral psychologist, etc., but in your experience can you give me any kind of insights into either of those two events, you know, when it's most crucial that a child's hearing be there for both language development and socialization, which is the under... which is the kind of not mentioned part of this...

Carol MacArthur: Mm-hmm.

Michael Souter: ...aspect, and ... and then how long a change should be present for it to be meaningful and significant, because I'm not so worried about whether or not something's still there three years down the line if it's... if it, you know, is a short duration of... if it has covered a crucial period of development, if you see what I mean.

Carol MacArthur: Yeah. Yeah. Absolutely. So, I, I, I think that obviously, children beginning in infancy and into their toddler years, their brain is developing language skills and you, excuse me, all of you who have had kids, you can see that emerging language. So, the... those early years are critical for hearing things at normal levels and developing normal speech and language. So, I think, you know, that initial age of infancy to age four is probably the most critical. After that, if, let's say you started having a problem later, I think you'd be better adapted to not developing speech and language delay, but you'd probably, perhaps, have some behavioral issues from not hearing well, and then there's a ton of experience, for instance, with cochlear implantation for deafened kids that would tell us that the earlier you get a kid hearing, the better, so, and that...

David McCulloch: Well, while...

Carol MacArthur: ...and that matches up with the age of otitis media with effusion, basically.

Michael Souter: We just finished the response to the other part, so, which was the... the duration of treatment. Is there...

Carol MacArthur: Oh.

Michael Souter: ...any kind of particular crucial threshold where...

- Carol MacArthur: Yeah, so...
- Michael Souter: ...it's not useful, or... or...
- Carol MacArthur: ...you know, the... if you noticed in all these studies, pretty much that tipping point of having ear fluid seems to be about three months or longer is when you're going to get in trouble if you're going to. So, if you have fluid off and on for an under three-month time period, it's typically not associated with problems like speech and language delay or behavioral problems or educational problems.
- Michael Souter: But, in terms of actually having a hearing benefit that's sustained over a particular period of time. So, that... that's what I was more getting towards. Is there... a kind of minimum amount of time that you should actually have an improvement in hearing benefit for it to be useful or, you know, so if... if you got... basically, if you're tube falls out, six months later has it been a complete waste of time versus if it stayed in for a year, has that been possibly clinically effective?
- Carol MacArthur: Yeah, I... I don't know if there's evidence for that, but I have a lot of anecdotal stories I could tell, but yeah. I don't know if there's...
- Michael Souter: Sure.
- Carol MacArthur: ...evidence.
- Chris Standaert: I just want to redirect that to Dr. Hashimoto, the same sort of question, though, because I didn't see any data whatsoever that there is any effect on longterm speech, language, any sort of social cognitive speech function whatsoever that had been identified from the use of these tubes. I didn't see... you said there's nothing. So, I understand the anecdotal stuff, but the data we have says...
- Michael Souter: But some of that comes...
- Chris Standaert: ...that doesn't exist.
- Michael Souter: ...and the reason I was asking those questions is because it depends upon the population that's been studied.
- Carol MacArthur: Yeah, I... I would like to address that after.
- Chris Standaert: I didn't like (inaudible). It's an evidence question for me. Thank you.
- Robin Hashimoto: Yeah. So, speech and language, there was no difference between groups. As far as when that was measured, could you check on that? I don't remember off the top of my head. Sorry. We'll get that for you.
- Kevin Walsh: Slide 33.
- Robin Hashimoto: Slide 33.

- Craig Blackmore: Page 17.
- Robin Hashimoto: Yeah. So, there were two to three RCTs that found no difference, basically between six and eighteen months, and then there was another RCT that found no difference in a variety of measures of language development at different ages. So, some of these, you know, kids... kids that were older had pretty long followup, there. Then, another one found no difference at... at seven to eight years.
- David McCulloch: Just go back one slide to... yeah, yeah.
- Robin Hashimoto: Yeah, that's, those are the results for the six to nine months.
- Michael Souter: That said six to nine months post-intervention.
- Robin Hashimoto: Post-intervention, correct.
- Michael Souter: OK.
- Seth Schwartz: So, their mean age...
- Michael Souter: And their mean age around that time was in the... was in those age brackets, yeah. I misunderstood that. OK.
- Kevin Walsh: I think you're asking a really important question, Michael, because as a clinician that's always been the reason that I've been concerned about persistent otitis. And when I saw these numbers, I was kind of amazed.
- Carol MacArthur: So, you know, in the pediatric otolaryngology community, we've been aware of these studies, since they came out, of course, and it created a lot of angst amongst our group. So, one thing that everyone needs to understand about these really nicely designed studies that have the high level of evidence is that they are randomized control trials, they were designed to study a very uniform population of children and compare them with controls that were also, you know, very much matched. So, they eliminated children with any comorbidities, any other challenges whatsoever. In addition, these children were screened, and as soon as the fluid was identified they were then followed and exactly at three months, usually that was the time period where they got tubes or watchful waiting. They got tubes. So, that makes a really good study and a paper with really level of evidence, but it is not really the real world of what happens in practice. So, what we... all of the thought leaders in my field kind of... the way we make sense of this is that the child that comes to our clinic is not one of these children that has exactly three months of fluid with no other medical problems or comorbidities or socioeconomic challenges, etc., but they are often a group of kids that we don't know how long they've had fluid. We know it's at least three months, but it may be longer. They often have other struggles, and they certainly come in with speech and language delay, behavior problems, you know, social issues because they can't hear. And then our community, along with audiologists, really feel it is very important for a lot of

these children to hear better. So, we... we think that this is a great... these are great studies, and they're really well designed, and the evidence is strong because the groups are so well designed, but I don't think it reflects the real world. So, that's kind of how we put it together.

Kevin Walsh: And since most... and since 40% of children live in the po-... live in the poverty level in the United States of America, it would be reasonably easy to do that study.

Seth Schwartz: I just want to comment on that too. I think that... that's an important point, the point about this being really a screening test. So, these... the children that are enrolled in that... in that speech and language study were not kids that came to otolaryngologists for...

Carol MacArthur: Or pediatricians.

Seth Schwartz: ...or pediatricians for hearing problems or any other things. They were basically healthy kids who were... who they decided to look in the ears and then they said, ah, you have fluid or you don't have fluid. So, it's a very... it is a very different (inaudible). The question is, is screening for fluid effective, and the answer is screening for fluid is not effective at all, but in children who are presenting with underlying problems, because that's why they come to the physician, they're not hearing well or they're having other issues. Those patients are not included in these trials.

Chris Standaert: But should I have reason to believe that there aren't thousands or hundreds of thousands of kids who are totally healthy otherwise who have fluid in their ear who get a tube stuck in because they have fluid in their ear, which is what this population is?

Robin Hashimoto: That's...

Chris Standaert: The... are you telling me that's not who's getting tubes? So, you have this data that says these are not the people... they did these beautiful RCTs that didn't study anybody who's clinically seen ever anywhere?

Robin Hashimoto: So...

Chris Standaert: I find that hard to believe.

Robin Hashimoto: So...

Chris Standaert: It seems like, you know.

Robin Hashimoto: The, so, two of these three trials that are shown up here, the Rovers and the COMET trial both required hearing loss for patients, and then the COMET trial did require disrupted speech, language, or behavior, one of the three.

Chris Standaert: So, they are symptomatic in some way.

- Robin Hashimoto: And then the... the Rach... or Rach trial didn't require hearing loss at all and did not provide any details.
- Craig Blackmore: Is there any detail on length of symptoms before they got enrolled in the trial?
- Carol MacArthur: They didn't have any symptoms, because they were screened and they... they didn't have any symptoms to be entered. They were screened.
- Craig Blackmore: So, I'm sorry. We just heard that the entry criteria for the trials were hearing loss or otitis media with effusion sort of behavioral issue.
- Carol MacArthur: Well, we can probably check that, but what I understand in general.
- Craig Blackmore: We'll have them check it.
- Louise Kaplan: Could I ask another couple questions? In the slide eight, it talks... and in many of the comparators, myringotomy was a comparator. So, how often is myringotomy often done? I... I'm just curious, because I don't typically see children who are getting myringotomy, because... and I noticed a lot of this data was really old, and I'm thinking it used to be done more often, but it's not usually done anymore.
- Carol MacArthur: Yeah, myringotomy is essentially never done. It used to be done in the office by pediatricians quite frequently, and for a lot of studies, it has been done as a comparator to a tube, but it's not a very effective intervention for hearing improvement or resolution of symptoms.
- Louise Kaplan: So, that's one we can sort of disregard?
- Carol MacArthur: Yeah. Yeah.
- Louise Kaplan: OK. And then there was one other question. In the American Academy of otolaryngology head and neck surgery foundation under the guidelines, it says tubes are an option in children at risk for developmental disorders with unilateral or bilateral otitis media that is unlikely to have resolved quickly. Is there a definition of quickly? Is that three months, one month, six months? It seems rather vague for a guideline.
- Carol MacArthur: You know, so I think what that guideline is giving the clinician a little bit of wiggle room to not wait the three-month time mark before deciding to put a tube in. If you have a Down Syndrome child, for instance, and you know that by virtue of their patho... their physiology of their eustachian tubes, they are not going to clear, and it's November, and you're in the middle of winter, then you can make a decision to put a tube in sooner than the three-month waiting period. So, I, I think it's vague on purpose.
- Seth Schwartz: And there's actually more information in the guideline, in the subtext under that talking about use of a flat tympanogram. So, tympanometry is another test that's done to look... to see is there fluid or is there a normal eardrum, that sort of thing, and for the children... and there is actually some studies that have

shown that for children who have flat tympanometry... flat tympanograms their effusion is likely to persist for three months or longer, as opposed to kids who have normal tympanometry, it might clear quickly.

Louise Kaplan: Thank you.

Craig Blackmore: So, I'm going to... I'm going to have to interrupt on a procedural issue. We have been delaying on opening the public comment period because it was prescheduled as being from 12:50 to 1:10 and we did not want people to have expected to comment in that time and have missed it, but we are now in that window. So, I would like to now open the public comment period and then we'll have to return to this discussion.

So, the question is, is there anybody who is here with us today that had wished to address the committee on this topic. I don't believe we had anybody preregister, and nobody has signed up. So, we will... we will go to the phones here in just a second and see if there is anybody who has called in. Do you want to unmute for us and? So, is there anybody on the phone who wishes to address the Health Technology Clinical Committee on the topic of tympanostomy tubes? Now is your opportunity to do so. OK, hearing no comments, we will mute the phones again, and we will close the public comment period. We will return to the discussion.

Robin Hashimoto: Let me, before we continue, answer the question that was asked before regarding the duration. The majority of these studies did not report the actual duration of the condition or... of hearing loss. However, most of them did require there had to be otitis media with effusion that had lasted for at least three months, some of them were four months, some of them were two months, and then the same with hearing loss. If hearing loss was required, it was required for about the same period of time. So, for the... the COMET trial, if we were going back to talk about speech and language development, was hearing loss for at least three months? Another trial did the same thing. Then, the other did not report hearing loss but said that bilateral otitis media with effusion had to be present for at least three months, so.

Gregory Brown: Did they say how much hearing loss to qualify?

Robin Hashimoto: Yeah. So, hearing loss was variably defined, or the hearing loss required. The COMET was 25 to 70 decibels hearing levels. So, that's mild to pretty severe hearing loss, and other ones ranged from hearing levels starting at 20 decibels to starting at about 35, so.

Craig Blackmore: Other questions?

Louise Kaplan: I have one other question about the cost analysis. In your slides, the one cost report that you have is based on 1998 dollars. So, is that the only... is it a study that is that old that it that it only used 1998 dollars and there is nothing more recent in terms of cost?

Robin Hashimoto: There were some studies. So, as far as studies that were performed using data from real patients, that's correct. Let's see. The cost-effective analysis was published in 2001, and then let's see here. We have four other economic evaluations that evaluated only hypothetical cohort studies. Some of them were older and some of them were... were more recent, and the conclusions were kind of across the board, and I can go over those if you would be interested.

Louise Kaplan: If it's, yeah. I... I would be interested.

Robin Hashimoto: OK. So, one of them was done by the U.K. National Institute for Health and Clinical Excellence, NICE, in 2008, and it was a cost utility analysis. Tubes was evaluated compared to tubes plus adenoidectomy, hearing aids, and no treatment for patients with otitis media with effusion of at least three months. Hearing loss was not explicitly stated as a baseline characteristic. Children... the hypothetical children were younger than... than twelve years. Let's see. So, basically, the study concluded that tubes was the optimal treatment strategy, because it was associated with better hearing and lower costs. So, again, that was 2008. There was one from 1994, and it was evaluated, the cost to clear the effusion within six months, and they basically found that, you know, the first treatment should be steroids plus antibiotics, and then different antibiotics after a few weeks, and then referral to tube insertion after another few weeks if the patient still had persistent effusion, and these were patients who had persistent otitis media with effusion after acute otitis media. Then, the other two were also from the 1990's. One was from 1991, and the other was from 1996. The one from 1991 was a cost utility analysis of patients with recurrent acute otitis media, and it compared tubes with antibiotics, and the study found... concluded that acute and prophylactic treatment with antibiotics was preferred as an initial strategy, and then tube insertion was reserved for failure of antibiotic treatment. Then, the last one was a study of patients with either chronic otitis media with effusion or recurrent acute otitis media, and that was from 1996. They found that this study actually, let's see. What was the outcome? OK. So, they looked at the impact of chronic effusion on hearing loss and developmental issues, and they found that overall medical therapy was more expensive than tube placement for otitis media with effusion, and tubes were considered to be the more cost-effective option for children with severe and recurrent otitis media with effusion that had failed to respond to conservative treatment.

Louise Kaplan: Thank you.

Robin Hashimoto: So, yeah. So, of the costs, of the five cost studies, only one was done in the last ten years.

Craig Blackmore: That's a lot of data to wade through. It's more than we usually have, because there are actually RCTs. Any other questions or comments?

Seth Schwartz: I just wanted to make a comment about the... the short versus longterm outcomes. I think what we're, what we're seeing is that the... there's some differences in the short-term and that the... the differences in the longterm are

not as conclusive, and I think that that correlates with the nature of the disease, which is that children are effected with this for a few months, you know, somewhere from three to six months to a year or something, and after that, in otherwise healthy children, it may not have a big impact, but to disregard what happens during that six-month period is... is... you can't really just throw it out, as far as the longterm outcomes, because you're talking about a child who's not hearing for six months. That can be a pretty significant outcome. If you imagine dealing with your own child for six months when they can't hear, that's... that... that can be a factor. So, just... I just wanted to make that comment about the long versus, longterm versus short-term outcomes, even if it may not impact their longterm development, most people who care for kids recognize that they can still be a... a meaningful outcome, even at six months.

Craig Blackmore: We haven't commented on the safety component, which may be relevant. Does anybody want to, anybody have any questions about that or understanding about that?

Michael Souter: I want to go for a comment about that.

Craig Blackmore: Yeah.

Michael Souter: Just in terms of the effects of general anesthesia upon the developing brain, that there's been a lot of concern about that in the last five years or so due to really what was characterized as animal data... animal models, and it has mostly been done in rodents. There have been some attempts to try and get it done in a primate model, but really those were unsuccessful. So, in rodents, it seemed that if you give certain anesthetic agents, which are not usually the common ones that you tend to use, then there's been some concerns for neurologic consequences with that. Some neurons may be dying. Now, what's been under-appreciated, perhaps, at that time was that the brain tends to discard neurons that you don't need anyway. There is a... you know, there's a concept of neuronal pruning that occurs in the formative years. You... you develop and you strengthen what you need and you throw away what you don't, and so there's been some concern, now, that what was being observed at that time was actually merely part of an observed, you know, what would be an expected process to occur. It's still up in the air. There are still... I think it's a very controversial issue, but just last month there was data presented from European studies, which is really looking at the registry model, looking at children who are being exposed to general anesthetics versus local anesthetics at this formative stage in their development and looking at their outcomes, and thusfar, based on about, you know, five years worth of data, there does not appear to be a difference. Now, that will need to be substantiated over kind of longer term, but I think it's a... it's a much more open question, I think. There's a lot of people querying whether this is really a significant as was previously thought. So, I just want to throw that out there. There is a U.S. registry and development, again, as well, but they're about a couple of years behind the European one.

- Craig Blackmore: So, I don't know if this is... I guess it's probably a clinical expert question. One of the complications, or outcomes cited is otorrhea, and I'm trying to understand the importance of that.
- Carol MacArthur: Oh, sure. Yeah, so otorrhea is basically what happens when you have a tube in your eardrum, and you get an ear infection, the pus comes out. So, in general, the... the number of episodes of otorrhea that a kid is going to have in the year following tubes is usually less than the number of times they would have had antibiotics for ear infections but... so... but the concern of otorrhea isn't that it causes longterm hearing damage or changes to the eardrum. It's... it's really more of a management issue. So, you know, it's treated topically with antibiotic eardrops versus oral antibiotics. So, there's that theoretical advantage actually that you can treat it topically versus systemically, but other than that, it's really just... it causes some clinic visits. There's dollars spent in seeing a kid with otorrhea, but other than that, I don't think there's any real concerns. It's not a longterm issue.
- Gregory Brown: Can I ask a type 2 error question on power. So, if they were, was it COMET I think you said had a range of 20 to 75 decibel hearing loss to be enrolled in the study. Is that... but anyway, one or both of them had some range like that. So, I'm trying to find changes from someone that's got a 75 decibel hearing loss in the same group that you have someone with a 20 or 25 decibel hearing loss. It's going to be really hard to measure a change, I would think, across mixing a group that much.
- Robin Hashimoto: I guess I'm not sure what the question is, but that study reported the mean hearing levels between groups.
- Gregory Brown: OK.
- Louise Kaplan: COMET?
- Robin Hashimoto: Yeah. Yeah, and it's... it's correct. It's 25 to 70 at baseline.
- Carol MacArthur: Was that the only study that included it up that high, to 75, because 75 decibels would imply that there is an additional sensorineural component, because the maximum conductive hearing loss you can have from fluid is 60 decibels, and you hardly ever see that ear fluid. It's typically 30 to 40. So, that would imply that some of those kids in that group must have had also additional sensorineural hearing loss. So, that would be... so that kind of muddies the waters, I think, of that particular study.
- Craig Blackmore: Which... which one is that? That's... which trial is that?
- Joann Elmore: They... they're talking about...
- Carol MacArthur: COMET.
- Joann Elmore: ...the COMET trial, and I've been sort of here reading through, since I'm the one that always asks to get the original papers. There were three papers that talked

about speech and language outcomes, and this is so important for these kids. The COMET one, they actually did require that the kids had to have 25 to 70 decibels, at least three months duration also. So, this was pretty significant and of a, you know, a three-month duration of hearing loss, and this is the one that did have sort of a marginal improvement in outcome. The other two studies that are in our packet, the Rovers and Rach, these ones, they did not require any hearing loss at baseline. Their outcome...

Robin Hashimoto: Rovers did. Excuse me, Rovers did.

Joann Elmore: ...50% of them had no or minimal complaints. They only had to have four to six months bilateral otitis media with effusion. They didn't seem, in Rovers, to have to have... at least in the one article I looked at, to have any hearing loss at baseline, even though their outcome was language. Maybe I'm wrong, because I... I did a quick review and you're our expert, but...

Robin Hashimoto: Right. Right. We have the inclusion criteria as being...

Joann Elmore: ...and then that...

Robin Hashimoto: ...yeah.

Joann Elmore: ...was... Rovers was 187, but if you don't require them to have a hearing loss at baseline, this isn't as relevant for us, because we're contemplating making that one of the criteria, and then the other article by Rach, 43 kids, and that was done in the 1980s, and I don't see that they had a requirement for hearing loss at baseline. So, I would ask you to look into that for those two to see if... if I'm correct in my (inaudible).

Robin Hashimoto: Yeah. You're correct on Rach, and I'm going to just double check Rovers right now.

Craig Blackmore: What about TARGET? I'm looking at slide 25, and it's got Rovers, COMET, and TARGET.

Robin Hashimoto: TARGET required bilateral otitis media with effusion for at least three months and hearing loss... or hearing levels of at least 20 decibels.

Craig Blackmore: So, if we try to summarize the inclusion criteria for TARGET, Rovers and COMET, they would be somewhere in the three to six months' range of otitis media with effusion and plus/minus, but mostly plus on hearing loss, or at least the higher threshold of hearing, and then COMET added the initial... had... had a higher level of hearing loss that... that some may have implied some more complicated clinical scenario. Is that fair enough?

Robin Hashimoto: So, part of the inclusion criteria for Rovers for children to even be considered for the trial, they had to fail three successful... three successive hearing tests. So, they did have hearing loss.

- Craig Blackmore: And then I... I guess I'm going to ask a similar question for the acute otitis media trials.
- Robin Hashimoto: Mm-hmm.
- Craig Blackmore: Which I think are El Sayed, Gebhart, and Gonzalez, if I've got that right. And I want to try to understand what they meant by acute otitis media as inclusion criteria for those studies.
- Robin Hashimoto: Yeah. So, if you happen to have the report, most of the acute otitis media studies are in table 23.
- Craig Blackmore: Which is slide... slide 23?
- Robin Hashimoto: No, table... in the actual report.
- Craig Blackmore: Oh, in the report, sorry.
- Robin Hashimoto: Yeah. So, which... which slide are you... or which...
- Craig Blackmore: I was looking at slide 40 looking at acute otitis media recurrence.
- Robin Hashimoto: ...uh-huh.
- Craig Blackmore: And, uh...
- Robin Hashimoto: Gotcha.
- Craig Blackmore: ...the list... so I've already listed three of the acute otitis media trials show that the recurrence risk was decreased, and I wanted to understand those populations a little better.
- Robin Hashimoto: Could we get that slide, please?
- Female: Which number again?
- Craig Blackmore: 40.
- Robin Hashimoto: 40. OK. So... so, these were studies that compared tubes to antibiotics. So, El Sayad the patients had at least three episodes of acute otitis media within six months. None of these studies required hearing loss. Gebhart was the same thing, and they specified that patients had acute otitis media episodes despite antibiotic therapy. Then, Gonzalez required at least three acute otitis media episodes within six months or at least four episodes within eighteen months.
- Craig Blackmore: Thank you.
- Louise Kaplan: I'd like to ask one other question, and I'm reflecting on this because I was struck by how old some of the references were. How, you know, some of these studies go back into the 70s, and I worked on the Navaho Reservation in the 70s

and otitis media was a very different experience for Navaho children than children who have otitis media today. Mastoiditis was a very common complication, and when I, you know, Chris you made the comment, you know, we have a lot of evidence, but I'm wondering if there's been enough progress in change in the causes, the risks, the clinical treatment, that some of the data from the 70s and 80s is really not relevant to what we see clinically today, because what I see clinically in primary care is a lot different than what I saw even in primary care 20, 25 years ago. So, I'm just wondering what kind of weight we really want to give to these studies that were done in the 70s and 80s, and that's maybe a question for... for our clinical expert.

Carol MacArthur: I mean, I guess that's a really hard question to answer. Some of the studies, like if you look at the Rosenfeld literature on otitis media, and he has, you know, written very extensively and has been responsible for the guidelines principally. He used that data from some of these studies in the 70s and 60s to get the natural history of acute otitis media and the natural history of otitis media with effusion.

Louise Kaplan: Mm-hmm.

Carol MacArthur: So, what we know is that the vast majority of acute otitis media in an otherwise healthy kids resolves on its own without antibiotics even.

Louise Kaplan: Mm-hmm.

Carol MacArthur: And we know that the vast majority of otitis media with effusion under three months' duration resolves on its own without any intervention. So, what we're really trying to get at is, in those two populations of kids, who are the kids that need our help, because the vast majority of them don't need us at all, even for antibiotics.

Louise Kaplan: Mm-hmm.

Carol MacArthur: And of course, what I used to see 20 years ago was that kids got antibiotics every time they had an ear infection, and now we withhold it and we wait for them to clear it on their own and, you know, about 80% of kids can get by without antibiotics actually, but, you know, if you look at Rosenfeld's data, it... there is like one in seven kids that you see that is eventually going to need intervention with antibiotics for an acute ear infection. We still... I don't have a... I don't think we have a great handle on which of those kids it's going to be. I'm sure it has something to do with their genetic background, how they respond to their innate immune system, how it responds to bacteria and things like that. So, I think it's a great observation. I think the one thing that has changed is that kids get fewer antibiotics for recurrent ear infections, and the... the... the population is aware of the fact that that's a good thing to withhold antibiotics, so.

Louise Kaplan: Thank you.

- Robin Hashimoto: I have a comment. Regarding the age of the studies, I just wanted to point out that there are definitely some older studies in here. Most of the... all but one of the recurrent acute otitis media studies are from the... all from the 80s, maybe some into the early 90s, but for the comparator where we have the strongest quality of evidence, for chronic otitis media with effusion, tubes versus watchful waiting, all of those studies that really contributed to those higher levels of evidence have been done since... well the oldest ones started in 1999, but they are much more recent.
- Craig Blackmore: Alright. Any other questions or comments? We've got...
- Chris Standaert: I have a question about one of the harms. You've got the issue of persisting perforation, and you said the... I forget which table it is. One of your tables you had one condition where they only reported data from the tubes, and they didn't report the non-tube kids. In the other one, you said they were similar, but the rates were up to 13%. I mean, did... kids with just a persisting effusion in their ear get persisting perforations at a rate of 13%? That just... is that normally what happens, because that seems like the rate they're reporting for the tubes, and then you said they were equivalent. So, it was slide 44 or 45. So, you didn't put the numbers on here, but you said them when you were talking, and I was thinking that... when you said one had, like, an 11% perforation rate or something in the non-tubed ears.
- Robin Hashimoto: Yeah. Just a second.
- Chris Standaert: Because 45 just doesn't... they don't report the control. It doesn't give you any idea of what the natural history would be from that.
- Seth Schwartz: I would just point out that real quick...
- Robin Hashimoto: So...
- Seth Schwartz: ...before you say, I would just point out that those are, I think, the acute otitis media trials, and acute otitis media is different than otitis media with effusion. So, acute otitis media is with inflammation. It's not just kids with pus behind their eardrum, and there is a significant incidence of spontaneous rupture in those kids. So, they sometimes can get perforations. The otitis media with effusion population is much less common to have spontaneous rupture.
- Chris Standaert: OK. Thank you.
- Robin Hashimoto: Actually, those... those higher levels of perforation in the control group come from the trials of tubes versus watchful waiting, and you have to keep in mind that a lot of those kids who are in the watchful waiting group ended up with tubes.
- Carol MacArthur: Like, that 13% number is a crazy number to me, as a clinician. So, I wonder if a lot of those were... so looking at that number that 13% does not make any sense to me as a clinician. It's way too high. So, I'm wondering if because they were in a study and they were followed and so holes were identified but then maybe

they spontaneously closed, because certainly that happens. We don't see them, and they come back and it's already closed. So, I wonder if it's even meaningful, that number, because it's certainly not what you see clinically.

Seth Schwartz: I think you also present, and this is for the vendor. I think you also presented that... the case report of 700 cases or something, and the incidence was, like, 1.7% or something like that. Is that right?

Robin Hashimoto: Yeah, just a second.

Seth Schwartz: Yeah. I think that... that's a much more realistic number.

Robin Hashimoto: Yeah, 1.3. So, and I wanted to point out, we... we called out persistent perforation when the study called it out. Otherwise, it was just reported as perforation. So, we don't know, you know, how long that really lasted after the tube fell out. It could have... it could have been completely, you know, quickly resolved.

Carol MacArthur: The other factor about the perforation is that there are certain longacting tubes that are associated with up to a 20% rate of perforation when they come out. So, maybe that's what that number means, but those tubes are not the typical type that you put in. So, yeah, that number is kind of alarming.

Chris Standaert: Question, are there behavioral restrictions or things about pools and water with kids with tubes? My experience as a parent watching parents with their kids with tubes, they are excessively cautious with them and anything to their ear and water, and I'm trying, in my head, to figure out if these things are really totally benign, and I find it hard to believe sticking something in anybody that shouldn't be there is totally benign, just having done this for awhile, and, you know, the data... the... the perforation thing would be an obvious thing, but then this... this issue of sort of, is it, like, better or worse because they have tubes. Again, I see lots of kids with tubes where... like... I mean, they... they walk around, and it's like they have, like, you know an invisible halo around them where the kids don't... nobody wants anything to happen to their head or their ears, and I... I don't know if that's just my neighborhood, and people are overly concerned? I mean, it's, like, we have a generation of this, or what?

Carol MacArthur: So, in the Academy guidelines, there is a recommendation against use of earplugs for swimming or bathing because that's no longer needed, and there are very good studies that looked at use of earplugs for swimming in kids with tubes, you know, earplugs or no earplugs, and the rate of infection is the same. So, our... our guidelines now are to not do any earplugs for water exposure.

Craig Blackmore: So, it's your neighborhood.

Chris Standaert: So, don't restrict the kid, yeah.

Carol MacArthur: But it... it's hard to get all of that.

Seth Schwartz: Yeah. It's just the OCD subset you hang out with.

- Chris Standaert: Apparently, yeah.
- Gregory Brown: Yeah, I have a question about the types of tubes mentioned that there... somebody mentioned that there's different manufacturers, different styles, shapes, and sizes. What's the... the common tube used or does it... is it based off of the particular condition?
- Carol MacArthur: I would say the vast majority of tubes placed are a collar button style. It's kind of a generic style. It's meant to extrude about a year later and associated with a low perforation rate. Other than that, all those 100 tubes, I think a lot of that is preference.
- Gregory Brown: OK.
- Carol MacArthur: Physician preference. And then with the caveat that there are certain conditions where you want a longacting tube and then you put something that's meant to return much longer that's got longer phalanges and things like that, but for the vast majority of kids, it's just this simple design and there are slight variations on that.
- Gregory Brown: So, the difference in risk is mostly a perforation risk?
- Carol MacArthur: Yes.
- Gregory Brown: Yes. OK. Thank you.
- Michelle Simon: I just... I had a question about adverse events. I'm looking a slide ten, and we... we have addressed a few of these adverse events, the otorrhea and persistent perforation, but there are several listed here, and is there just no data on this, the atelectasis, the premature extrusion, granulation tissue, and maybe somebody could speak to that.
- Robin Hashimoto: Well, so it was... these weren't identified as critical outcomes. So, I don't have summary information for you. Unfortunately, they were identified. It was kind of all over the map. I'd be happy to pull out some information on ones of particular interest.
- Carol MacArthur: I think... Robin could correct me, but I believe there's no data on those other outcomes. I think what we struggle is as doctors who put tubes in is, you've got a kid that has a bad eustachian tube function that leads them to get fluid that leads them to get the tube. So, when you have a lot... an outcome a couple years down the road of a retraction pocket or a atelectatic, which means it's just kind of sucked in and thin, would that have happened without a tube, because the eustachian tube function isn't normal. And certainly, you see it go both ways. So, I think it's going to be really hard to sort out causation by a tube, because number one, it's a not very common outcome and it... it's just going to be really hard... and big enough to study kids to find out does tube... do tubes really cause these things, or were they going to happen anyway?

- Craig Blackmore: Alright. Any more questions, or should we begin our deliberation? Alright. So, again, I need somebody to start us off with a summary of where we are, volunteers? Somebody other than Seth.
- Seth Schwartz: Somebody other than me.
- Craig Blackmore: Alright. Well, I picked Joann last time, so this side of the room. Michelle do you want to start us off?
- Michelle Simon: Um, well I don't know if I can start off the summary, because I'm... the part that I'm really struggling with is my training and background is to try to solve root causes of problems, and if I look at the evidence here that we've been presented, this is about what seems like the underlying cause would be inflammatory eustachian tube disorders that are being treated by making a hole in the eardrum. So, that's a symptom to me that they have this condition to begin with. So, that's... it's frustrating when we look at data that, to me, isn't actually asking the question I would like to ask. So, we've got some... plenty of data, actually, I think, for a change. There's actually quite a bit of data, and I think if we look at this as just in and of itself as a treatment, does it solve the problem? I think it does solve the problem for the question that's been asked. Does it solve the underlying cause? I don't think it does that. So, that's frustrating to me.
- Craig Blackmore: OK. Does anybody want to build on that or agree or disagree?
- Joann Elmore: I'll build on that but with the request for Seth to sort of help... help us with the big picture, because we're... we're looking at otitis media with effusion and then this acute otitis media and there's data on hearing. The data on hearing looks as if there is an improvement early on but not long-lasting. So, the... the big question for you is, how helpful is that to have six months of better hearing? Then, all of the other things, both the benefits, the... the speech and language... the important things like parent satisfaction, patient quality of, you know? Those things... the... there is either no evidence or it's insufficient, or if there is evidence, it's called no difference but low quality. So, that's my summary of where we are, and I need help.
- Seth Schwartz: I think one of the issues that gets confusing is this difference between acute otitis media and otitis media with effusion, and the reality is they're two different diseases that... that have a similar treatment. So, it all kind of gets lumped together. So, for acute otitis media, which is the acute otitis media, the outcomes of hearing is almost not an important one, because those kids, once their infections go away, they... hearing is not an issue. It's more related to the infectious problems that are... and complications from the infection that you're dealing with. So, what the important outcomes there are, complications from infection and does... do the tubes decrease the risk of having infections. So, the data we saw from the trials is that it does over a six to nine-month window decrease the risk of infections. Long-term, it has no effect, which is exactly what we would expect. When the tube is in, they get fewer infections. Nine months to a year later, the tube is gone, the infection rate returns to the same as... as baseline. So, you can decide for yourself how important you think it is to reduce a few episodes of otitis media. We would love to have the quality of life

data say, oh, it's a dramatic difference. The reality is, it is very, very hard to assess that. So, the trials are all of low quality. So, it's hard to prove it, but I think as our expert will say, if you talk to those parents, many of them will tell you, it's better but that's not good data. So, that's acute otitis media. I'd say there's randomized trials that say you're going to have fewer episodes of infection and the complication rates aren't a whole lot different between the two groups.

With otitis media with effusion, you have a different question, which is how is the otitis media with effusion affecting kids, and if it persists with hearing loss, those kids have hearing loss. Now, there's two questions there. How much does the hearing loss matter on a short-term basis versus how much does it matter on a longterm basis, and what we're seeing is, there is not good data that it makes a big difference in a longterm... in the longterm for otherwise healthy kids. So, you're... but it seems to make a difference in the short-term, which is, again, one of the things that's pretty expected. You... you put in the tube, the fluid's gone, their hearing is going to be better to some degree, and then the tubes are going to either fall out, or the natural history is such that eventually the... the effusion would clear up. So, the two groups are going to kind of equalize over time. So, I think that's what we're seeing here is that there's not a lot of good data... for otherwise healthy kids, there's not a lot of good data that it makes a difference in the longterm, but it probably does make a difference in the short-term, in terms of their ability to hear, but again, we're not seeing quality of life data in the short-term to say, oh yeah. It makes a huge difference in our lives, but that's hard data to gather, and it's hard... and so those are going to be the low-quality studies. So, I think that's where I'd summarize where we are.

Chris Standaert:

So, you know, I look at this stuff, and I mean, tubes have been around since, I mean, they've been around, what, since I was a kid, certainly for a long time. I mean, I, you know, I hear everything you're saying. The data is not overwhelming, right? I mean, the long-term differences are nonexistent. Short-term, they're talking 3 to 7 decibels, as I'm reading about how audiometric testing works and things like that. They don't go up by 1 decibel at a time. They go up by 5 decibels and go back and it's a little fuzzy. So, it's not dramatic. And I... I have no doubt that there are kids with either anatomic or medical circumstances where they are going to be at sustained risk of hearing loss, which is problematic, and they are probably the ones where this... this has the most bang for the buck, so to speak versus the idea that at the moment we have no... there is no restriction. Oh, and... and I imagine, you know, I know the world I live in. I imagine there are people who walk in and my kid says his ear is stuffy and there is an effusion, it's been there. They're going to pop a tube in, and I don't know if that's you. I don't know that this would be the (inaudible) surgeon do that, but I'd be willing to bet that happens, and I don't know that that's beneficial, and I don't know that it addresses the causes. There's other things that maybe they could counsel the parents about that might help them versus just sticking tubes in them. So, anyway, I find it... it's interesting. It isn't... the data isn't overwhelming for an intervention that is this deeply rooted, which we see often. I think, in my own head, the idea is sort of where is... how do you call out these kids who, you know, probably really have structural or

medical or other reasons why, or clearly have shown that they are recalcitrant to just sort of spontaneous healing in some way where they just are so at risk for recurrent otitis that it's well worth it to have them in to cut their otitis rate by 20 or 30% so they don't get sick so often. That's what I think.

Gregory Brown: So, I guess my... my... I had a comment not a question earlier, and maybe a better way to phrase that is, what we're really asking is if they have a hearing loss or deficit for six to nine months, does that put them back on their development curve, or whatever, language, and do they ever catch up? And my concern is that there is so much variability in child development that... and you can't, you know, do it... what's the term, where you alternate your treatment, you know, because they're going to... they're going to develop. You can't restart development or, you know, randomize the development part. And so, is the... do they have a persistent difference in development, but it's small enough that you can't find it in the variability of normal child development?

Chris Standaert: Right.

Gregory Brown: And...

Chris Standaert: I agree. I'm not totally sold... the question we're asking is sort of, does... will just sticking a tube in at three or six months make a difference in that? So, that, that's really quite... technically, that's the question we're asking, right?

Gregory Brown: Correct.

Chris Standaert: Which hovers around that longer-term question, yeah, but does that prolonged hearing loss cause a problem, and the correlate here is, well, if we stick a tube in, do we solve that in some meaningful way.

Gregory Brown: Correct.

Chris Standaert: And again, I'm not... I don't know that I saw the answer to your question in the data, you know?

Michelle Simon: Well, if you go back to slide 33, which is about speech and language, at least in otitis media with effusion, it does somewhat answer that question, at least from the data we were presented, and there's really no difference down the road, longterm.

Craig Blackmore: So, the question is, how sensitive is the Reynell test or the Schlichting test. Is 393 patients sufficient to have power to detect some meaningful difference in these kids? I think that's what you're asking.

Carson Odegard: I have a question about recurrent acute otitis media. I mean, I understand that it's not indicated for, you know, one episode of acute otitis media and antibiotics would take care of it, but on recurrent acute otitis media, what... what is the... the timeframe there, and how many episodes are we talking about, and also, are these kids tested on each episode to find out what the deficit is, the hearing deficit? Do we... do I ask the expert?

- Carol MacArthur: Are they tested for hearing or for bacteria or?
- Carson Odegard: Hearing.
- Carol MacArthur: No, because typically with recurrent acute otitis media, hearing isn't the issue. For some, the fluid persists in between episodes, but their issue is primarily just antibiotic exposure over and over again.
- Carson Odegard: Over and over? OK.
- Carol MacArthur: And just the burden of disease of, you know, recurrent infections. So, the... that's why I think the criteria are, you know, pretty good that tubes may be indicated if you've...
- Carson Odegard: Mm-hmm.
- Carol MacArthur: ...had, you know, four infections in six months. That seems to be a point at which that burden of that disease on the child and the family is meaningful to make an intervention.
- Carson Odegard: Within a six-month period?
- Carol MacArthur: Yeah.
- Carson Odegard: At that occurrence? OK.
- Seth Schwartz: Yeah, it's kind of what's in the... what's in the guideline. The... the... from the American Academy it was... and they... the criteria became increasingly stringent. So, you saw that was even stronger than the criteria from the AAP guideline...
- Carson Odegard: Mm-hmm.
- Seth Schwartz: ...which is that it's three in six months, four in a year with one in the last six months, and the presence of fluid at the time of diagnosis, and that was one of the things, because there is some question about accuracy of diagnosis for...
- Carson Odegard: Mm-hmm.
- Seth Schwartz: ...each individual episode, and so the, you know, many instances this was seen... someone saw the (inaudible) yesterday and was diagnosed with otitis media, and they come to see you the next day and their ears are totally normal, did they really have an ear infection yesterday? And so... so the... the... that was where that kind of recommendation came from, which is that if they come to you and they have fluid in their ear still, then you can say probably they have... this is a real problem for them, as opposed to kids who have had three episodes in the last six months, but their ear is still perfect, you're less concerned about the longterm effects on them, or... or the significance of it.

- Carson Odegard: OK. Alright. Thank you.
- Michael Souter: Can I just ask one point just to Josh, really, procedurally. If we make any decision here, what population will that affect?
- Josh Morse: Well, I would go back to the SCOAP and the key questions.
- Michael Souter: No, but I, sorry. I mean by that, you know, the, you know, the state...
- Josh Morse: Which program?
- Michael Souter: ...which programs, because it's really, I think at our maximum, would be affecting the kind of the PEBB, because we don't have a mandate for effecting Medicaid.
- Chris Standaert: Medicaid. It affects Medicaid, which is the highest number by far, too, in this state.
- Michael Souter: Yeah, but do, are we binding on Medicaid?
- Joann Elmore: Yeah.
- Michael Souter: I thought we were only binding Medicare?
- Craig Blackmore: No.
- Michelle Simon: We don't do Medicare, that's federal. We're Medicaid.
- Michael Souter: Oh, OK. No, I'm looking at it the wrong way around. OK. Alright.
- Craig Blackmore: OK, have we... have we any other questions?
- Seth Schwartz: Can I just... can I just make one more comment to address Chris's point, which is that I think you're right in the... in the comment of, I think there really is a role for limitation of the use here. I don't know how abused it is in the kids that come in with just a, you know, a... you see them, they've had this... you see an effusion and automatically put tubes in. I don't know how frequently that happens, but I think the whole point of... of this kind of a literature review and what... what was done in the guidelines was recognizing, trying to pick out those kids in whom you're likely to make a difference versus those kids who it probably doesn't make a difference, because every kid, I think, you know, 90% of children will have had otitis media by the time they're age 3, and close to that by the time they're age 10 will have had an effusion at some point in time. So, and most kids turn out OK. So, it's really about trying to figure out who you're likely to make a difference in and who you're not. So, I think there is a role for... for limiting it a little bit. The question is, how do you do it, and... and so some of the criteria we've heard about, you know, persistence for greater than three months and that sort of thing, and presence of hearing loss. Those are some of the criteria that people tried to use to sort out who's likely to... in whom it's likely to make a difference and whom it's not, but absolutely, it's... it's not

beneficial in a healthy kid who's had an effusion for one month. I think virtually all of us would agree that's... you're wasting your time.

Louise Kaplan: Could I... could I ask just to build on this, in Medicaid and PEBB, is there any prior authorization that's required, or is it just...

Seth Schwartz: Unlimit4ed.

Louise Kaplan: ...so, there's no prior auth? OK. So, then we don't know, in this population that's covered by the state, which children who received tubes meet what criteria.

Chris Standaert: We have no idea.

Louise Kaplan: So, it could...

Chris Standaert: There are no criteria.

Louise Kaplan: ...it could have it for a month and... or they could have it for six. So, we don't know? OK.

Craig Blackmore: Yeah. And the other way to look at that is to say, we don't know what effect our decision will have.

Louise Kaplan: Correct. Yeah.

Craig Blackmore: But that doesn't mean we can't make a decision to...

Louise Kaplan: Absolutely.

Craig Blackmore: ...align where we think the evidence states.

Louise Kaplan: I understand.

Craig Blackmore: OK. I think, at this point, it would be useful for us to talk about how we would do conditions if we did them. So, I don't know if we're going to cover, no cover, cover with conditions, but I, I think it would be worthwhile talking about what those conditions would look like. Does any...

Seth Schwartz: That's a... that's a supposition and you feel that it's well-founded?

Craig Blackmore: I said, I don't know if we're in the cover, no cover, or cover with conditions.

Seth Schwartz: Well, we didn't discuss it last time.

Craig Blackmore: What's that?

Seth Schwartz: We didn't discuss conditions this morning.

Craig Blackmore: We didn't because it felt to me that... that we were reaching a consensus.

- Seth Schwartz: Can we do a straw vote?
- Craig Blackmore: Absolutely. So, I'm considering having us talk about consent... what conditions would look like. Can I have a straw vote on whether that would be a good approach? Thank you. So, I need somebody... well, we need a couple things. So, at this point, we will ask Christina to give us a blank piece of paper.
- Christine Masters: Alright. I'm going to have Chris (inaudible).
- Craig Blackmore: Well, we will have Chris give us a blank piece of paper, and look at this. It's gotten sophisticated on us, and then I'll ask the committee members to generate some ideas, as a starting point on what conditions would look like if that's where we end up. Does anybody want to take a first stab at that?
- Gregory Brown: Well, actually, may I request that we do like we did last time, take two sets of votes, so one for acute otitis media and a different one for otitis media with effusion?
- Craig Blackmore: I think that's a very valid point, yep.
- Chris Standaert: We have two separate things.
- Craig Blackmore: Yeah. So, we're going to treat these, absolutely. We're going to treat these as separate. So... so, we'll start with chronic otitis... we'll start with otitis media with effusion, OME, and I will ask for a volunteer to start us with what conditions might look like.
- Louise Kaplan: Craig, before we do that, I'm wondering if we want to walk through the safety, efficacy, etc., and see if we have concerns or not. I... I... I feel like we've almost jumped ahead one step that we haven't really...
- Kevin Walsh: Yeah, I... you... you didn't understand my question. I wasn't asking if we should have a discussion about conditions. I was asking if we could take a straw vote about whether we needed to have a discussion about conditions.
- Craig Blackmore: I thought that's what I asked, but...
- Louise Kaplan: Yeah, well, I...
- Craig Blackmore: I...
- Louise Kaplan: ...and I... I voted yes, but now that I'm looking at the discussion document in front of us, I feel like if we talk about conditions, we've already made a decision that we...
- Kevin Walsh: I agree.
- Craig Blackmore: No.

- Louise Kaplan: ...need to do something.
- Kevin Walsh: I agree.
- Louise Kaplan: Which, maybe we don't if we decide...
- Craig Blackmore: So, it was never my intent to force us into a decision. We have done this different ways in the past. Sometimes, we've had a vote first, like we did this morning, but sometimes, it is felt to me, and I've tried to get input, that defining the conditions would help us to understand what that would look like, and I'll admit that often I have done that because I felt that the group was headed in that direction, and that may have been premature on my part. And I don't want to force us down any particular channel. So, I'm hearing discomfort with that. Let's go back to... to the decision document and work our way through it.
- Kevin Walsh: So, I'll ask you all to look towards your coverage and reimbursement determination tool, make sure we're looking at the right one, and so we've talked about this before. This is a document to help us understand how we're going to decide, and the staff has prepopulated this document with the outcomes that we have identified as important in our deliberation. So, safety outcomes are listed on here, and I would ask you to look to those on page three. So, chronic otitis... I won't read them all. There is a list of them here. Are there any safety outcomes, which are not already on this list, which the committee is using in its deliberation?
- Gregory Brown: I need a clarification. I thought I heard from Michael that for general anesthetic, there is question whether it's harmful, but then Seth said they don't really use general anesthetic, they just use sedation, am I?
- Michael Souter: I mean, these really are, like Seth says, mainly these would be considered more as sedation, you know, moderately heavy sedation as opposed to general anesthesia. There are some kids who would require the general anesthesia for those, especially as you kind of get into some of the younger age groups, but for the most part, these are not heavy anesthetics, and my comment earlier on was really just to allay some of the potential concerns. I think if you read the... the evidence report, the concerns there illustrated are general anesthesia causing neuronal damage I think are overplayed somewhat in the context of what's the emerging evidence.
- Joann Elmore: Are you asking if anesthesia is even the correct term?
- Gregory Brown: Well, no. No. I mean, I... I'm not going to argue whether sedation is anesthesia or not. I'm not... like I said, I... I, I guess I... I did... I misunderstood your comment.
- Chris Standaert: One of the harm I wondered was the... in some of the treatment groups, the comparison groups, they were put on antibiotics. So, it was, like, longterm antibiotic prophylaxis versus tubes, and antibiotics have problems. So, in the acute, there are current acute particulars... idea of multiple antibiotic courses or prolonged antibiotics is not benign and the... the studies didn't really talk about

that, but I would have wondered that if I'd read... if I'd looked at those studies, so.

Craig Blackmore: OK. So, we're... we're delineating safety outcomes, and I'll specify this is for either one, safety outcomes for either otitis media with effusion or acute otitis media just to be clear. We will separate those out later. Any other safety outcomes with regard to antibiotics as a potential? OK. And then, in terms of efficacy, we talk about hearing loss. We talk about reduction in fusion, quality of life, and decrease in recurrence of otitis media.

Joann Elmore: Language and speech.

Craig Blackmore: So, language and speech would be important. So...

Gregory Brown: And really...

Craig Blackmore: ...socialization and development I think is related to that. I'm sorry, Greg. Were you going to say something?

Gregory Brown: ...no. I just want to clarify again, there... there was nothing on any of the studies on quality of life of the parent. Is that correct? I mean, the measures were all for the...

Craig Blackmore: I think the data we had didn't show a difference, but we didn't really have much in the way of data.

Gregory Brown: Yeah.

Craig Blackmore: And... and these are the things we're looking at. It doesn't mean we necessarily have good data on it.

Gregory Brown: Right. No. No. No. Right.

Craig Blackmore: These are things we're trying to weigh in our heads and, you know, it's not always, in fact, it's never as good as we want it to be. OK. Then, in terms of special populations, we... we've mentioned at least a little bit, some special populations and I just need to look back at the... how this is actually framed. Do we have any exclusions, because there's things like Down's and people with developmental...

Chris Standaert: Right.

Craig Blackmore: ...you know, craniofacial deformities and I... I just want to see in our key questions if we are excluding those individuals or if they are...

Chris Standaert: And I was wondering if they were excluded from the studies in the... in the report, that being one of the issues. So, if they weren't excluded from the review, but were they excluded... these RCTs excluded Down's and anatomic abnormalities or craniofacial abnormalities.

- Robin Hashimoto: Yes.
- Craig Blackmore: I think...
- Chris Standaert: Right. So, does the... the medical director said, we should exclude from conditional coverage of special populations in that category. That's largely on the basis that they weren't in the studies we looked at.
- Craig Blackmore: OK, so, but they haven't been excluded from our... our scope.
- Joann Elmore: Key question three.
- Craig Blackmore: So, the scope, the scope does not exclude people with sort of underlying anatomic issues. So, that would be a special population, and that includes Down's, but any other sort of, I mean, we might need some help from you guys on framing.
- Seth Schwartz: Yeah. I mean, there's some other... so, there's... there's two different circumstances. There's... there's children who are higher risk for... for effusion or for recurrent infections, and then there's children who are disproportionately affected by those conditions. So, one is children with Down's, craniofacial abnormalities or other things that might affect their underlying eustachian tube function. The second is children... so, children with an underlying sensorineural hearing loss, children with a... a preexisting speech delay. Those are two of the main conditions for children who may be disproportionately affected by even a smaller degree of hearing loss.
- Craig Blackmore: OK. OK. So, those are some special populations. We'll keep that in mind. We can talk about conditions later. Then, cost outcomes, we talked about costs and cost-effectiveness. Any other outcomes that aren't on here?
- Gregory Brown: Actually, the only study that we included was cost utility.
- Craig Blackmore: Cost utility as a... as a subset of cost-effectiveness? We can specify?
- Gregory Brown: Yeah.
- Craig Blackmore: OK. OK. And then we have this sort of exhaustive list of, well not exhaustive, but comprehensive list of... of other recommendations from the American Academy of Otolaryngology from the Darwin Otitis Guidelines Group from British Columbia, from NICE, Korean Society, American Academy of Pediatrics. So, there's a lot of different recommendations. There are more in here that I did not mention. I'm not sure I'm seeing a Medicare coverage decision. Is there a Medicare coverage decision?
- Christine Masters: There is not one.
- Craig Blackmore: There is not one. Here it is. There is not one. OK. So, that... so we'll discuss that. If we need to reconcile with these, we will do so. OK, so... so the next step, then, will be to our first voting question, and so I will ask you to pull your

yellow cards, and we will now vote a nonbinding vote on the effectiveness, safety, and cost-effectiveness of the use... this time we'll separate. So, we'll separate out acute otitis media from otitis media with effusion, and we'll vote... we'll vote on the effectiveness, safety, and cost-effectiveness of use of tympanostomy tubes, and we have to have a comparator, and I think the comparator here would be not using tympanostomy tubes, and we'll put the myringotomy aside, because it sounds like that's not a relevant comparator anymore. So, really, we're looking at conservative management.

Gregory Brown: Actually, I thought acute otitis media, the comparator was... it was multiple antibiotics.

Craig Blackmore: So, it... so, we would be saying tympanostomy tubes, I have trouble saying that, compared with nonsurgical intervention, which in the case of acute otitis media would be antibiotics, as usual care, and in the case of chronic otitis media with effusion would be watchful waiting, presumably, not... not draining the effusion.

Chris Standaert: (inaudible) Acute otitis media, we're talking about recurrent otitis media, right? So, I don't want to lose that word, because it... it clearly the... the data on acute otitis media as a single episode is very different from...

Craig Blackmore: That's... that's...

Chris Standaert: ...recurrent.

Craig Blackmore: ...that's a condition that we haven't defined. So, again... so right now, we are voting on whether this technology is more effective under some or any... some or all situations. So, if you think there is a situation where... and we'll start with acute otitis media. If you think there is a situation under which tympanostomy tubes are more effective than nonsurgical management or acute otitis media, you'll vote yes, even if it's not all the time, even if it's in some small subset, you'll vote yes, because you believe there is a situation where the tubes are better than not using the tubes for otitis media. Carson, do you have a question?

Carson Odegard: One thing. Are we considering this vote within a parameter of time?

Craig Blackmore: No.

Carson Odegard: So, we're including all the...

Craig Blackmore: Yeah.

Carson Odegard: ...evidence that says (inaudible).

Craig Blackmore: If you think there is a circumstance in there where it's better...

Carson Odegard: Oh, OK.

Craig Blackmore: ...then you're going to vote yes.

- Joann Elmore: If two of the articles showed more, like a short-term hearing improvement...
- Gregory Brown: So, you're voting... you're voting more not yes, correct?
- Craig Blackmore: Correct. This is not a yes, and... and it may be that we will define conditions later around what that situation is, or it may be that it's everywhere, or it may be that imbalance when we weight effectiveness versus cost-effectiveness we vote note, even though there was some effectiveness data under some circumstance. So, if you think that acute otitis media, the tubes are better in any or all circumstances, you would now vote more.
- Josh Morse: I just want to make sure I understand, because the scope... the scope is recurrent or persistent acute otitis media.
- Craig Blackmore: Alright, then I... I had misspoken it sounds like. So, I need to get my scope out. Where is the scope?
- Josh Morse: Right before the tool, you have the complete set of questions.
- Craig Blackmore: There's the scope. OK. So, I apologize. The scope is, let's start with B, recurrent or persistent acute otitis media. So, sorry. We are dealing with acute, not single episode. We are dealing with recurrent or persistent. So, effectiveness, we could have a vote.
- Josh Morse: Three unproven, eight more.
- Craig Blackmore: And then, what's next, safety?
- Josh Morse: Yes.
- Craig Blackmore: So, safety.
- Josh Morse: Seven unproven, four equivalent.
- Craig Blackmore: And then cost-effectiveness.
- Josh Morse: Eleven unproven.
- Craig Blackmore: OK. And then we're going to do the same exercise for chronic otitis media with effusion. So, again, if it's better under any or all circumstances, you would vote more, starting with effectiveness.
- Josh Morse: Ten more, one unproven.
- Craig Blackmore: And then safety.
- Josh Morse: Nine unproven, one equivalent, and one yes.
- Craig Blackmore: Well, there's no yes.

- Josh Morse: I'm sorry, more. One more.
- Craig Blackmore: And then cost-effectiveness.
- Josh Morse: OK, hold on. Ten unproven, one less.
- Craig Blackmore: OK. OK. So, I, I'm seeing an absence of, alright. I'm, I'm seeing a predominance... I'm seeing a relative lack of less's out there. So, I'm going to think that it's probably a worthwhile exercise to formulate what conditions would look like, thinking that based on what we've discussed and what we've just seen that we're probably not headed towards a no coverage decision. We can still go there, but it would be prudent, I think, or worthwhile to generate what conditions would look like, and then have our final vote. Are people in general agreement with that approach? OK. So, we have a blank piece of paper. Blank Excel spreadsheet, and we're going to treat acute otitis media and otitis media with effusion separately, recurrent acute or persistent acute otitis media, and I... and I'd like to ask the committee members to give us a starting point, and we'll start with acute otitis media. What would a reasonable set of conditions look like, as a starting point for discussion? Does anybody want to?
- Michael Souter: Well why don't we start the ball rolling with just what the agency medical directors said with the, 'in otherwise healthy children.' I think that, to me, would be a good starting point.
- Craig Blackmore: So, explain that. I'm... I'm not tracking.
- David McCulloch: It was... it... agency slide 17, in otherwise healthy children with recurrent acute otitis media.
- Craig Blackmore: Yeah. OK. So, we need... we need to define that as a condition, which means the negative. So, we have to be... we have to say not otherwise healthy children, which we might...
- Chris Standaert: Exclude?
- Craig Blackmore: ...no, wait a minute. So, we will cover... so who will we cover?
- Chris Standaert: So, we can...
- Craig Blackmore: We'll cover not otherwise healthy children.
- David McCulloch: No. No. No. They're saying they recommend we cover, in otherwise healthy children, not patients with Down's etc., etc.
- Michael Souter: Yeah. Our decision would only apply to healthy kids.
- David McCulloch: In healthy kids, if... if there's more than three episodes in six months or more than four in twelve months. That, that's what they...

- Craig Blackmore: OK.
- David McCulloch: ...were saying.
- Craig Blackmore: And, but what about the kids who are not otherwise healthy?
- Gregory Brown: Well, aren't you going to have these group and...
- Chris Standaert: Right. And healthy... healthy is a tough word here.
- Gregory Brown: ...this group.
- Craig Blackmore: Is that, so is that out of scope? Is that what you're saying?
- Chris Standaert: Because we have anatomic abnormality. So, you... so, a Down's kid is not healthy, right? So...
- Craig Blackmore: So, we...
- Chris Standaert: ...I mean...
- Craig Blackmore: ...we have to make a decision about...
- Seth Schwartz: I... I would make a comment. I... I would make a comment here. These are two... two different circumstances again with acute otitis media versus otitis media with effusion. So, with otitis media with effusion, you're... there are... the anatomic considerations come into effect much more with... because they have a... those kids are at higher risk for having a persistent effusion. For acute otitis media, the bigger issue is, is it complicated or uncomplicated. So, I think the point was, if a child has mastoiditis or meningitis or some other... or they're immunosuppressed or have some other medical condition that would make it more complicated, then ... then... then this decision shouldn't necessarily apply, and since those kids should all be able to get it unrestricted, but in the otherwise healthy child, we might want to limit what the... what the... what the situation, or who we cover.
- Craig Blackmore: OK. So, the...
- Gregory Brown: So, are we allowed to start with the otorhinolaryngologist and clinical practice guideline (inaudible).
- Craig Blackmore: ...we can start with whatever we want.
- Gregory Brown: I mean, that... that's a professional organization that's put a lot of effort into some wording on who they recommend to cover. So, rather us trying to start from scratch, can we start there?
- Craig Blackmore: Well, and if we disagree with these national guidelines on some level, we have to justify why. So, it's not unreasonable to start with that or with the medical directors. We just need something.

- Seth Schwartz: So, what the medical director... director said is the same as what's in the AAP guideline, and virtually the same as what's in the AO... in the AAO guideline. The only difference is that this just says four in the last year, but those both say four in the last year with one of those being within the last six months. So, it's a little bit more stringent. In other words, if you had a child who had four episodes last January, and now it's December, they don't qualify, but if... so that's... so I would... I would recommend we add that to the restriction.
- Chris Standaert: I don't... I just want to back up one second on the acute otitis media thing to see if we can help me with the data here for a second so I figure out what to do. So, if I go to slide 40, and I go to... so, anyway I'm... the thing I'm getting is that it prevents infection, perhaps, recurrent infection, right? It lowers infection, but these studies are, like, one is six months, 42 kids. The other one has 200 kids. It's P- is 0.0447, that had 3/1000, 3/10000 of a point, that would have rounded up to 0.05, and it wouldn't have been significant. Right? So, this is not, like, wildly robust data that this does a whole lot. So, I'm just throwing it, in terms of prevention. These are small studies and that's not statistically... it crosses zeroes, negative 0.05.
- Michael Souter: There's a lot of sins get committed with that 0.005.
- Chris Standaert: I know.
- Michael Souter: 0.05 barrier, you know what I mean?
- Chris Standaert: Right.
- Michael Souter: And I think that's...
- Chris Standaert: Well, I'm just...
- Michael Souter: ...why we're here to exercise judgment, as opposed to just merely going by logic rules.
- Seth Schwartz: And I would comment is... back to the studies, as part of why the, the AO guideline is a little bit more stringent is because if you look at the entry criteria for the randomized trials, the one that actually... the... the trial that actually... I can't remember which trial it was, but the trial that actually presence of fluid at the time of entry to the trial had a... had a much bigger effect size than the ones that did not. So...
- Chris Standaert: That's the one with the 42 kids?
- Seth Schwartz: ...no. I can't remember which one... which one it was. Could you look at the entry criteria for those trials to see, because I can't remember which one it was, but there was a bigger effect size?
- Joann Elmore: So, do we want to require documentation of presence of fluid at these three prior... I can see people calling up over the phone Friday night saying, oh my

kid's crying, earache, and they'll just sort of it give it a presumed diagnosis and count that as one of the three.

Chris Standaert: I mean, theoretically, you'd have three, you know, documented symptomatic treated in some way, either through watchful waiting or antibiotics, but...

Gregory Brown: So, and...

Chris Standaert: ...I mean, if we're going that way.

Gregory Brown: ...no... nobody's spent any time in an Emergency Room in their residency and looked in ears that were absolutely normal and then got, you know, called the... the patient brought them into their pediatrician on Monday, and oh, it's all infected. You need antibiotics. Yeah, so, there's already a number of episodes, or suspect, I would say, but you have to...

Chris Standaert: I would agree.

Gregory Brown: ...start somewhere.

Craig Blackmore: And... and we've heard that you don't necessarily need antibiotics. So, it might not inappropriate to call up the pediatrician and have them say, probably otitis media, don't worry about it, but that means...

Seth Schwartz: But... but that... just to be clear, that's not what the trials say. Watchful waiting is truly watchful waiting, and all those trials that... what they did was those kids who did not resolve within 48 hours had to have close followup, and then they started antibiotics. So, it was the... so, the kids that resolved didn't get antibiotics. The kids that didn't did get antibiotics, and that's the way...

Chris Standaert: Are you talking about these two studies?

Seth Schwartz: No. No. No. The... the... no.

Chris Standaert: Which studies are you talking about?

Seth Schwartz: No. I'm sorry. What we're talking about, that... that comment about you don't need to treat each infection with antibiotics. So, I'm not talking about this data, the data on... on the concept of watchful waiting for treating an individual episode of acute otitis media...

Chris Standaert: Right.

Seth Schwartz: ...is based on true watchful waiting, which is you don't need to treat primarily, as long as they will have close followup. And then, if they don't resolve spontaneously, they do get antibiotics. So, it's not like you can just say we don't need to treat you at all. Anyway, it's a different population (inaudible).

Craig Blackmore: But, in terms of defining three episodes of otitis media, does that need to be somebody who saw the pediatrician and got antibiotics or can it be...

- Joann Elmore: No antibiotics, just documented.
- Craig Blackmore: Saw the pediatrician and documented something.
- Chris Standaert: Can we pull it from Robin? Can she give us the inclusion criteria for these studies? Do you have them? What were they looking at?
- Seth Schwartz: They were all done before watchful waiting.
- Chris Standaert: They probably were.
- Robin Hashimoto: Are you talking about the otitis media with effusion or the... you're talking about the acute otitis media?
- Chris Standaert: Acute otitis media.
- Robin Hashimoto: Right. OK. So, in general they required at least three episodes of acute otitis media within six months, some also extended that to at least four episodes within twelve months to eighteen months.
- Craig Blackmore: But did they define...
- Joann Elmore: How were they defining an episode?
- Seth Schwartz: You're not going to get that.
- Robin Hashimoto: Yeah. I don't think we're going to get that.
- Seth Schwartz: Well, logistically, it's really hard to do that and I, and I agree with Chris. I think the data is weak here. For... for acute otitis media, the data is weak. I think they're... I think there is data. I mean, I think there are randomized trials that show there is a small difference. It is a small difference, and it probably... if you could define the patients better, the difference would be bigger. In other words, if you were really sure that you were... you were offering the surgery to kids who really had recurrent acute otitis media, it probably is a real effect, but just logistically it's difficult to sort that out, and I think that's the challenge. We can try, but it... but the guideline wasn't able to do it. I think it's very hard to very... put very strict criteria on how you define an individual episode of... of acute otitis media, and I think it is probably both over and underdiagnosed, depending on who's doing it.
- Craig Blackmore: I think you also run the risk, maybe it's a theoretical risk of forcing people to go to the doctor. So, there are... so there are acute otitis media documented.
- Chris Standaert: They're not going to... they're not going to plot out how to get tympanostomy tubes, I don't think, you know? And if... I mean, the agencies are going to have a headache in how they get people to document this. They're going to have get documentation that somehow they knew this... this kid is known to have had

three infections. How are they going to do that? I don't know in their pre-auth process.

Kevin Walsh: Pull up ICD-10 codes, real simple.

Chris Standaert: Well, then they got to see the doctor, right?

Craig Blackmore: OK. So... so, back to the thing, Excel spreadsheet. Do you guys want to start with the agency's recommendations? Do you want to start with the national guidelines we've seen? Do you want to start with something else?

Joann Elmore: Let's start with Seth. I'm hearing that we... we should specify something better than otherwise healthy children to help the agencies. So, do you want to start us off?

Seth Schwartz: Well, I mean, I think I would probably use the term uncomplicated recurrent acute otitis media, in terms of where... when... when we're putting the restrictions, I think we... that... that term is probably the most appropriate one.

Craig Blackmore: OK. We need to... do we need to flip it around.

Seth Schwartz: Right. Right. Right.

Craig Blackmore: We will cover if...

Seth Schwartz: Yeah.

Craig Blackmore: ...not uncomplicated...

Seth Schwartz: Yeah.

Craig Blackmore: ...I mean.

Robin Hashimoto: Some of the guidelines used terms regarding children being at risk for additional developmental delays.

Seth Schwartz: That's for AO... that's for otitis media with effusion more than it is for acute otitis media, though.

Louise Kaplan: My read of otolaryngology academy's guidelines is it's addressing otitis media with effusion and not acute otitis media.

Seth Schwartz: It... it does both. They're separate.

Louise Kaplan: It does both?

Seth Schwartz: They're separated in that guideline very discreetly.

Louise Kaplan: Oh, OK. I'm sorry.

- Seth Schwartz: So, yeah.
- Louise Kaplan: I'm... I'm looking at (inaudible).
- Chris Standaert: And you wrote part of these guidelines?
- Seth Schwartz: I was the second author on the acute otitis media.
- Chris Standaert: Right.
- Seth Schwartz: So, take what I say with a grain of salt, but I have no professional bias, just that I... I was involved in that, so I know what it says.
- Gregory Brown: So, dictate.
- Seth Schwartz: I don't think it's... it... it really is talking... it's talking more about in... in... it sort of excluded those children... the complicated children as well with the sense that we're not trying to limit use of tubes, but it does not say specifically you should do it in kids who have complicated acute otitis media, it's just kind of left out there because it's going to be the right thing to do in those... in those children, but they are hard to define exactly who needs it. So, what we're talking about is really restricting the kids where there's a question of what the benefit is. So, I think... so, I don't know exactly how to state it in terms of the... the complicated children, but I mean, do we say...
- Craig Blackmore: No...
- Seth Schwartz: ...no limitations on children with complicated otitis media, with... with otitis... acute otitis media with complications? I mean you could say something like that.
- Craig Blackmore: So, conditions...
- Seth Schwartz: So, cover unconditionally...
- Craig Blackmore: ...would be...
- Seth Schwartz: ...in those children.
- Craig Blackmore: ...cover if there is a complication of otitis media and...
- Michelle Simon: With one?
- Craig Blackmore: ...for example, mastoiditis, meningitis.
- Seth Schwartz: I mean, and then... and then it would be certain populations, so immunosuppressed patients are excluded from these trials.

- Chris Standaert: The agency... so, when I think... I appreciate everything you've done, but we just need to go... just to make sure we're staying with our data to write what we got to say.
- Seth Schwartz: Yeah, yeah.
- Chris Standaert: Is all... so, and for some reason the agency directors called out exclude... they had a separate slide, exclude from initial coverage, special populations and otitis media with complications. So, we could just say, you know, for both... for everything, we could say before we can get to our conditions, say cover for otitis media with complications and cover for special populations, and then when they're called out, and they are separate and they're done. Then, we can go to recurrent otitis media and decide that... that they're already covered. These other kids... the other kids are already covered, but then we're talking about kids who aren't them. So, we've pulled them out separately.
- Craig Blackmore: So...
- Chris Standaert: And then we can say...
- Craig Blackmore: ...so cover if, and we're using the term complications. So, cover if otitis media with complications.
- Gregory Brown: Is it complications or comorbidities?
- Craig Blackmore: Well, we're starting with complications.
- Seth Schwartz: I think it's with complications.
- Gregory Brown: Oh, complications.
- Seth Schwartz: Yeah, because most comorbidities you wouldn't treat them any differently. I think, immunosuppression is probably the only one where they might be different, but you can say a special population or however you want to define that.
- Craig Blackmore: So, cover if otitis media with complications or immunocompromised/suppression? Is that?
- Seth Schwartz: Ask our expert, too, if she thinks of any other specific patients we should call out.
- Gregory Brown: Do you want to specify the complications?
- Michelle Simon: You said Down Syndrome, cleft palate, developmental.
- Seth Schwartz: Again, that's more for... for... for chronic otitis media than it is for recurrent.
- Gregory Brown: OK.

Seth Schwartz: The question is, are there any other special population for acute otitis media that you would...

Carol MacArthur: Facial nerve palsy.

Seth Schwartz: Facial nerve palsy.

Carol MacArthur: You've got meningitis.

Seth Schwartz: Meningitis.

Carol MacArthur: Mastoiditis.

Seth Schwartz: Yep.

Craig Blackmore: OK. So, the wording is...

Seth Schwartz: Brain abscess.

Carol MacArthur: I don't know, neonatal, and then I would put immunocompromised.

Chris Standaert: So, but those are complications, right?

Michelle Simon: Those aren't populations, yeah.

Chris Standaert: Those aren't, so... all we have to say is cover otitis media with complications and then we're done.

Carol MacArthur: Oh, OK. Yeah, you don't have to specify.

Chris Standaert: Right. So, get all that stuff out of there, just cover with otitis media... cover if otitis media with complications.

Seth Schwartz: Yeah.

Chris Standaert: And so, something not right about this, something else happened to the kid, it's done.

Michelle Simon: Right.

Chris Standaert: They can do what they got to do.

Craig Blackmore: But I think immunocompromise is not a complication.

Seth Schwartz: That would be a special population.

Chris Standaert: Do we know anything about that?

Seth Schwartz: No, they're... I mean, they're excluded from all the trials. It's... there's no data. The point is that none of the data we've looked at applies to them. We can

decide what you want to do with those patients, but I, none of the data we've looked at applies to that population.

Craig Blackmore: I'm comfortable covering people with... immunocompromised.

Chris Standaert: No. I guess do... do we have a, like, we've had this trouble before. So, either we have to give a comprehensive list of people who are going to be at risk, so we need immunocompromised, we need cancer, we need whatever else they're going to have, you know? Or, we go back to sort of where Mike started saying otherwise healthy kids and let people decide and so we're... we're two sides of a coin here, and it might be easier to do what Mike was saying earlier, just say otherwise healthy kids... otherwise healthy kids with uncomplicated clinical courses.

Craig Blackmore: If you can phrase it.

Chris Standaert: I just did.

Craig Blackmore: So, what's the condition? Cover if...

Chris Standaert: Cover if ...

Craig Blackmore: ...not otherwise healthy?

Chris Standaert: ...cover in... in...

Joann Elmore: Otherwise healthy children.

Chris Standaert: Otherwise healthy children.

David McCulloch: With uncomplicated...

Chris Standaert: With uncomplicated...

Joann Elmore: Recurrent...

Craig Blackmore: OK. So, if you say that, you're saying kids who are not otherwise healthy do not get coverage. They are only allowed to get coverage if you meet those criteria.

Michael Souter: You can put another sentence at the end saying children outside of these...

Joann Elmore: Otherwise (inaudible).

Michael Souter: ...of this population should be covered.

Craig Blackmore: OK.

Seth Schwartz: I... I think, you know, we're... we generally try to be pretty loose with the terminology, as far as how we classify those things, because there may be a lot of conditions to which it applies, whereas I think here, we're really talking about

an isolated population of kids with immunosuppression. I mean, there really aren't a lot of other kids that... that you would necessarily want to stick tubes into. So, I mean, I think it... you could safely say immunocompromised, or you know, it's something that compromises their...

Craig Blackmore: Immunocompromised or other...

Seth Schwartz: ...or who would be disproportionately affected by this. I mean, I don't... you can...

Craig Blackmore: ...other severe... or other systematic medical disease or something that would rule out kids who were not otherwise healthy.

Chris Standaert: Without complications or the presence of immunosuppression or other systemic disease at risk... putting them at risk.

Craig Blackmore: Something like that, and then...

Chris Standaert: So, go back up to that first line. Cover if only with complications and just add on to that.

Seth Schwartz: Yeah, since the special populations would be the immunosuppressed or the (inaudible).

Craig Blackmore: Either way.

Chris Standaert: So, cover if otitis media with complications or individuals with immunocompromise or other medical conditions putting them at increased risk of complications from infection.

Seth Schwartz: Perfect.

Gregory Brown: Don't we also want the or?

Chris Standaert: Otherwise...

Seth Schwartz: Yeah, that would be the second part. This is... we're defining who the...

Chris Standaert: ...for complications...

Seth Schwartz: ...who are...

Chris Standaert: ...of infection.

Seth Schwartz: Who our limitations don't apply to.

Craig Blackmore: So, these guys get coverage?

Chris Standaert: Of infection.

- Craig Blackmore: So, if you meet that criterion, you're in. And then the next criterion is, what did we decide, three in twelve months or four in twelve months, or?
- Seth Schwartz: Three in six months, four in twelve months.
- Craig Blackmore: With one...
- Seth Schwartz: At least one episode within the last...
- Craig Blackmore: ...is that... do you want to just... it just fell off the cliff. Do you want to use the wording, start with the wording that the AOAA, the otolaryngologists came up?
- Seth Schwartz: Which is that.
- Craig Blackmore: Which, I can't find the AAON.
- Seth Schwartz: It's three in the last six months or four in the last year with one in the last six months.
- Craig Blackmore: OK.
- Seth Schwartz: And then... and then the additional criteria for the acute otitis media guideline, which was above the AP guideline was with the presence of effusion at the time of evaluation.
- Craig Blackmore: OK. So, let's start...
- Seth Schwartz: But we can decide whether we want to include that or not. That was... that's a separate.
- Craig Blackmore: So, can you just say that to Chris and have her write it down?
- Seth Schwartz: Yeah. So, it would be in otherwise healthy children.
- Craig Blackmore: We don't need that.
- Seth Schwartz: Oh, you got that, OK. Sorry. With three episodes of acute otitis media in the last six months, or four in the last twelve months with one occurring in the last six months. So, again, that's... that... that's up for discussion here. I mean, we... I mean we didn't get to look at a lot of data to support that today. So, I mean, you guys can weigh in on that.
- Craig Blackmore: I'm happy with... this seems complicated enough. I don't... what do you guys think?
- Josh Morse: Does the first sentence cover otitis media? Is that supposed to be acute otitis media, recurrent form?
- Seth Schwartz: Yes.

- Josh Morse: Because it's underneath this header here.
- Seth Schwartz: Yes.
- Josh Morse: I just want to make sure it's right.
- Female: Do you want the recurrent on there?
- Craig Blackmore: What's the recurrent?
- Michelle Simon: The word recurrent.
- Chris Standaert: Actually, with... you're getting meningitis from the... you're... you're going to...
- Gregory Brown: Right.
- Chris Standaert: ...even one instance, you're going to pop the tube, and it's not recurrent in those.
- Gregory Brown: Yeah. You're not going to wait for three, right.
- Chris Standaert: If you have a complicated infected... a complicated infection, you're going to put the tube in. You're not treating for recurrence. You're treating that one infection.
- Craig Blackmore: So, that's the first condition, and then the second condition is three episodes of acute otitis media in the last six months or four in the last twelve months with one in the last six months. Do you guys want to add the visible fluid?
- Gregory Brown: Let's take a vote. I would like to add the fluid.
- Chris Standaert: I would like to add it. At some point, somebody's got to look in the ear and see that there's clear fluid and otherwise, what's the point?
- Kevin Walsh: You're not seeing fluid. You have to do a... you have to do a tympanogram.
- Seth Schwartz: No. You can see fluid. Well, I mean there's... there's questions about the diagnostic accuracy of seeing it, but I think the point... the point there... so, in the acute otitis media guideline, the point was, or in the tube guideline was that when they are evaluated by the otolaryngologist for surgery to determine if they're a surgical candidate, at the time of that evaluation, they have to have the presence of fluid. And typically, that will involve an assessment with a microscope or some other thing that is... that is accurate or a tympanometry. You can... I mean, how you document it is... is not specified, but.
- Craig Blackmore: So, is there enthusiasm for including that language?
- Chris Standaert: Mm-hmm.
- Louise Kaplan: Could I... could I just ask you?

Craig Blackmore: OK.

Louise Kaplan: What you just said was for acute otitis media?

Seth Schwartz: For recurrent acute otitis media.

Louise Kaplan: Recurrent. OK. OK.

Seth Schwartz: Yeah.

Craig Blackmore: OK. You're going to have to help Chris put that in.

Seth Schwartz: So, and you say and the presence of an effusion at the time of assessment for surgical candidacy.

Craig Blackmore: Yeah, go ahead.

Carson Odegard: Do we need the word last?

Craig Blackmore: Last? Where?

Gregory Brown: Yeah.

Carson Odegard: You have to last here for... for?

Gregory Brown: I... I think you do. Otherwise, you know, they could be four and that may be when they were two they had four episodes, but if you're evaluating them when they're four, you don't want to count those episodes.

Craig Blackmore: Three... three episodes in the last six months or four in the last twelve months with one in the last six months.

Gregory Brown: Yeah.

Craig Blackmore: Oh, you're saying we could leave out the word last?

Michelle Simon: I don't think so.

Gregory Brown: With one occurring in... in the six months?

Carson Odegard: Because none of the guidelines... even the recommendations from the agencies don't say (inaudible), and it doesn't say (inaudible).

Craig Blackmore: I like last.

Seth Schwartz: The AAO guideline does say that.

Carson Odegard: It's great. It defines it.

- Seth Schwartz: Right.
- Carson Odegard: About the six months.
- Seth Schwartz: Again, I think... I think the point is that we're trying to be more restrictive than... than less here. So... so I think that would be more restrictive language.
- Craig Blackmore: OK.
- Chris Standaert: Do we need to say the whole twelve-month thing, or can we... it gets complicated. Can you just three in the last six months?
- Seth Schwartz: Well, no, because then what if you had...
- Joann Elmore: It says four...
- Seth Schwartz: ...what if you had three 7 months ago, and then you just had one a month ago. That... the... technically those patients would qualify, where under the...
- Chris Standaert: But, do they really... I mean, they had one in the last six months, do they really need to get tubes in their ear, you know?
- Seth Schwartz: Well, you... you can't necessarily... I mean, the point is that those are the criteria for all of the randomized trials that we looked at. So, basically, the...
- Chris Standaert: Right.
- Seth Schwartz: ...data we looked at, you can say the difference is small, but if we're actually trying to go by the data, the data is included.
- Chris Standaert: That's what they said, though? I think she read them before and it said something like that, yeah.
- Seth Schwartz: Yeah. It's, that... that's the... that was within the entry criteria for the randomized trials we looked at.
- Craig Blackmore: OK, so...
- Gregory Brown: Like you said, some of the trials were twelve and some were eighteen months actually. I think there might have been (inaudible).
- Seth Schwartz: It might have been less restrictive.
- Craig Blackmore: So, Chris, can I get you to move everything with the word with over to the left so it's the same... there you go. And then, if we put a bullet point or some way to annotate before the word 'cover' before the word 'with' indicate, yes. I wanted (inaudible). She's ahead of me. Good. Are there any other conditions that we might apply in the acute otitis media recurrent?
- Gregory Brown: The presence... presence instead of presents.

- Seth Schwartz: It's almost Christmas. We can spell check it later. I guess the only... this probably doesn't apply in kids, but the only other guideline I can think about, well, it doesn't apply.
- Craig Blackmore: OK. Is this...
- Gregory Brown: That's good.
- Chris Standaert: That's good.
- Craig Blackmore: OK. So, then let's look at otitis media with effusion.
- Josh Morse: The only detail is the recurrent used to also include in the parenthesis recurrent or persistent.
- Seth Schwartz: So, we didn't really talk about that. It gets a little bit more complicated when you include persistent, because persistent usually you're referring to kids who have one episode that doesn't clear with multiple rounds of antibiotics. So, that's a little bit of a different situation.
- Chris Standaert: Wouldn't they have an effusion?
- Seth Schwartz: They do have an effusion, yeah.
- Chris Standaert: Right. So, it'd be in our next group.
- Seth Schwartz: Right, but they may not have had three episodes in the last six months. They may have had...
- Chris Standaert: No, but (inaudible) gone on for three months.
- Joann Elmore: If they have it for three months they would be.
- Seth Schwartz: But they... but... well that's the question so. If... would you... so, the difference is with, otitis media with effusion is without inflammation. I mean, that's the differentiation. So, acute otitis media has the presence of inflammation. So, kids have associated symptoms. With otitis media with effusion, it's just fluid. So... so, the child who has an acute infection that you give... that he doesn't resolve without antibiotics. You give him antibiotics, he doesn't resolve. You give him another round of...
- David McCulloch: That's complicated.
- Seth Schwartz: ...antibiotics, he doesn't get a...
- David McCulloch: Wouldn't that be complicated?
- Seth Schwartz: It's just... no, it's not. Well, you can define it that way, but it's not. I mean, in... the trials don't define that as a complication. It's just a persistent infection.

- David McCulloch: But wouldn't you say that it... it's a... it's a more complicated (inaudible) acute otitis media?
- Chris Standaert: I don't think we have any data on when to put tubes in the setting of a non-clearing acute otitis media.
- Seth Schwartz: Right. That... that's what I'm saying. We didn't... we didn't look... first of all, there isn't any data on it. Second...
- Chris Standaert: That's what I mean.
- Seth Schwartz: ...of all, we... we... we didn't look at it. So, I mean, that might be the one other population you'd want to call out is the persistent... for persistent.
- Craig Blackmore: So, are we... are we including persistent as a complication, I guess, is the question?
- Chris Standaert: I would lead that to the audiology... otolaryngologist to explain to the medical directors of the complications. We have no data. We have no data. We don't even know if it works. We don't know when to do it. We have no idea. We have no data at all. It wasn't part of our scope.
- Seth Schwartz: Well, so just to cla-... I mean, maybe we can get our clinical expert to comment on that situation.
- Carol MacArthur: My opinion is, I wouldn't go there. It's not that common of a scenario, and I think it's... it's in none of the guidelines and persistent acute otitis media is not in the literature very much. So, I just would leave it alone.
- Craig Blackmore: OK. So, if that occurs...
- Gregory Brown: But the way it reads now with recurrent up in the main header title, then that's going to imply that number one is not a single episode. So, don't we need to take the recurrent out of the header so that it's clear that number one is for one acute episode with the complication where number two is (inaudible).
- Craig Blackmore: I... I think that's... I think that's a good idea.
- Chris Standaert: So, recurrent's in our scope. We could take number one out of that header and just make it its own thing, right? So, we just cover for acute otitis media with complications. Then, under recurrent otitis media, which is... our charge was not to look at acute otitis media. We're to look at recurrent otitis media. Then, we say this is when we cover an acute otitis media. So, we pull it out of that header.
- Gregory Brown: OK.

- Chris Standaert: So, we just have recurrent, because that's what we're supposed to be talking about. We're not supposed to be talking about acute, because then we get into this whole persistent, and we're not talking about that. We didn't look at it.
- Kevin Walsh: Just by definition, if you have that many episodes, it's recurrent.
- Michelle Simon: Right. Isn't it?
- Louise Kaplan: So, does...
- Chris Standaert: Just put acute otitis media, just call it (inaudible)?
- Louise Kaplan: ...the key, but the key question said...
- Chris Standaert: I like it.
- Louise Kaplan: ...recurrent or persistent evaluated separately. So, do you make a recommendation for recurrent and a recommendation for persistent?
- Seth Schwartz: Why don't we ask our evidence vendor if they saw anything at all on persistent.
- Robin Hashimoto: We didn't, and regarding the evaluated separately, that was meant to indicate the difference between otitis media with effusion and acute otitis media.
- Seth Schwartz: Yeah, I... I guess the only comment I'd have about it... I agree we have very little data on it, but I'm just saying, when you're in that clinical circumstance, basically the way it's written, you can't offer... like, it wouldn't be covered. If you had a child who had a six-month episode of otitis media, they don't have meningitis, they don't have facial nerve, you know, paralysis. They... they don't have an abscess, but they've had an infection for six weeks, you can't offer them a tube.
- Craig Blackmore: I think if we take out the word recurrent from the header, then we would leave it for the physician to say, this is a complication. I mean, does that seem like a reasonable way... you know, clinical practice, I'm putting these tubes in because this won't go away. It's complicated otitis media.
- Louise Kaplan: But if you put in recurrent or persistent, then if a child has a six-week long infection that doesn't clear, isn't that persistent?
- Seth Schwartz: I'm sorry. I didn't understand what your comment was.
- Louise Kaplan: Well, the question asked recurrent or persistent. So, Craig is saying take out both of those, but if you put them back in, and you have that circumstance where a child has an infection that doesn't clear for six weeks, wouldn't that be considered persistent and then fit the criteria?
- Seth Schwartz: Well, because they're persistent, but they still wouldn't fit those criteria, because...

- Chris Standaert: Because they have to (inaudible).
- Seth Schwartz: ...they don't have a complication and they haven't had three episodes. They just have one episode that's persistent, so...
- Chris Standaert: And from the data... we have no data on persistent at all. So, we just leave it out. Then, like I agree with Craig that the... the ENT folks can then go back and say... say, look, this hasn't cleared in three months. It's a complicated infection. We need to put... this is our only choice. We tried, you know, and they, you know, make that case under rare circumstance.
- Carol MacArthur: The reality is, is that they go back to the pediatrician usually three, four times, it's not clearing. So, it's kind of documented, as if they had had four infections. We know it's a persistent one, but that's (inaudible).
- Craig Blackmore: I... I... I don't think this is going to prevent somebody from getting a tube in that circumstance, and certainly for the record, that is not the intent of the committee. OK. Otitis media with effusion, again, we can start with our colleagues, the otolaryngologists, or we can start with a different source. We can make one up. What do you guys think?
- Chris Standaert: So, the only real benefit is short-term improvement in hearing that we saw out of our stuff. So, if there's no documented hearing loss, there certainly isn't much point in doing it from what I saw. So, that should be a criteria. What decibel level do you make it at? I don't... I don't know. We should add documented hearing loss, if we're going to cover it, to be a criteria. You don't think?
- Kevin Walsh: Well, over what time period, because most of the time it resolves.
- Craig Blackmore: We... we need a time period. We might want hearing loss, as well.
- Chris Standaert: Right.
- Craig Blackmore: But I think we definitely need a time period.
- Chris Standaert: I'm just approaching the hearing loss.
- Michelle Simon: So, the NICE... the NICE recommendations recommend three months, I think, right, with a 25 to 30...
- Craig Blackmore: Three months seems to be a...
- Michelle Simon: ...decibel.
- Craig Blackmore: ...standard. So, three months? Three months of effusion... documented effusion, effusion... I've heard a recommendation for a hearing test that says documented hearing loss or hearing... hearing loss, I guess is appropriate.

- Seth Schwartz: So, there's... again, just a little more background. So, NICE does give the... the decibel definition. The AO did not. They used the term hearing difficulties, and the reason for that... there were a couple reasons for that. Part of it is it can be challenging... in some of these kids it can be challenging to get an audiogram that is... that's consistent. So, if you have an 18-month-old who is not reliable, you may not be able to get a reading on (inaudible)...
- Chris Standaert: Didn't she say ...
- Seth Schwartz: ...or not?
- Chris Standaert: ...didn't she say audiograms are very reliable, and you can... I believe I...
- Seth Schwartz: They are in most kids.
- Chris Standaert: ...heard that, so.
- Seth Schwartz: But occasionally, you'll set up... well, anyway, you can come out of this, as well, but... so that's one challenge, and... and accessibility of... of... it may vary in populations, because certain populations may have limited access to... to hearing tests. I'm not saying we shouldn't use it. I'm just saying what the... the reason the AAO used the term hearing difficulties, as opposed to a degree of hearing loss was due to some of the challenges with audi... audiometry both access to and... and... ability to actually get it in some of these children.
- Craig Blackmore: So, you can... you can access surgery but not a hearing test? Is that... no. I mean, most CHCs have an audiogram.
- Seth Schwartz: So, it's... it... so there are some under-served areas that don't have audiometry. They may have screening audiometry or they may have, you know, other things, but they may not have an audio-... an audiologist available.
- Joann Elmore: But they have ENT surgeon that will put in a tube?
- Seth Schwartz: Some do. I mean, there's... I mean, again, this is going to be a limited...
- Chris Standaert: So, an ENT surgeon...
- Seth Schwartz: ...you could...
- Chris Standaert: ...should get an audiometrist and do what they're supposed... do... do their job, no offense.
- Craig Blackmore: OK. So, three months. So, persistent... maybe I don't want to use the word persistent, but duration of effusion of three months or greater, and...
- Seth Schwartz: And I would specify bilateral, because there's a difference between unilateral and bilateral that...
- Craig Blackmore: Bilateral.

- Seth Schwartz: ...general, yeah. For bilateral effusion present for three months or longer.
- Chris Standaert: You don't treat a unilateral effusion?
- Seth Schwartz: So, the... the... the effect of a hearing impairment in one ear is... is... over a short period of time is less than that of a bilateral hearing loss. So, generally, we'll observe patients for... for six months with a unilateral effusion before intervening versus three months for a bilateral effusion. And that's all... that's in the guidelines, as well.
- Craig Blackmore: OK. And then, something about hearing loss. Do we want to have a more concrete documented hearing loss, hearing... can I say loss? Does that mean decrease in hearing acuity? Or do I have to say decrease in hearing acuity?
- Seth Schwartz: I think you can say with hearing loss.
- Craig Blackmore: Hearing loss is OK?
- Seth Schwartz: I think you can say documented hearing loss. That's fine.
- Craig Blackmore: OK, documented hearing loss.
- Louise Kaplan: In the guidelines, it uses the word difficulties.
- Seth Schwartz: Yeah, and that... and that's what I was getting at, but I think, I mean, again, I'm not saying where I fall on that. I'm just saying that's what the... that's why they use that term, is it's sort of hard to define exactly, but if you want to be more stringent, I think, like the NICE criteria are more stringent. It's a documented hearing loss as opposed...
- Craig Blackmore: Yeah, and I...
- Seth Schwartz: ...to just difficulties with hearing.
- Craig Blackmore: ...I don't know that we need to define the number of decibels, but I don't know. Do we need to define the number of decibels? I mean, what's the? I'm not seeing any enthusiasm. I'm not seeing enthusiasm for that.
- Gregory Brown: I mean, in this ...
- Craig Blackmore: And so hearing loss.
- Gregory Brown: ...in this... in this aged patient group to... to have a rigid documentation requirement seems exceedingly difficult to me and... and you may have kids that absolutely need something, and you just can't... they're... they're not cooperative. They're whatever, I mean.
- Craig Blackmore: It's in the clinical trial inclusion criteria, but we don't have to say that. We may respect the difficulty in getting a precise measurement and just say any hearing.

Kevin Walsh: Are we going to vote on these separately?

Michelle Simon: Yes.

Craig Blackmore: We can.

Chris Standaert: I mean, I feel like we're doing this because the data show there is improvement in hearing acuity. So, if you can't document loss in hearing acuity, why are you doing it? That's my... that's my... and I'll say... you know, that's my... that's the way I look at it.

Craig Blackmore: The question is, do we define what we mean by documented hearing acuity as a certain number of decibels or a certain...

Louise Kaplan: That's what NICE does.

Craig Blackmore: ...(inaudible) NICE says you got to be at 20 or above.

Gregory Brown: So... so, Chris? Chris, for the (inaudible) guidelines, you had to have a venogram to document a venous thromboembolic event. I've never ordered a... a venography. So, I guess my point is, is just because the trials used a specific way to document something doesn't mean we have to put it in the criteria that way. It's...

Chris Standaert: No, but... but you... so, but if you're going to treat a deep venous thrombo, you want to find that you have a deep venous thrombosis at some point, right? You want to document that that's what you have. You don't have to...

Gregory Brown: Right.

Chris Standaert: ...do a venogram.

Gregory Brown: Right.

Chris Standaert: But we're just saying you have to document that there's hearing loss, because that's the (inaudible).

Gregory Brown: Yeah. No. No. No. I wasn't...

Chris Standaert: That's all. OK.

Gregory Brown: ...yeah. I wasn't disagreeing with the documented hearing loss. I was just saying don't set a threshold that you...

Chris Standaert: Oh, yeah.

Gregory Brown: ...have to, yeah.

- Michael Souter: I honestly don't know what basis we'd have for coming up with a figure. I mean, we've heard some, you know, 7 to 8 decibels maybe a kind of insignificant level, as, you know, as measured, perhaps, by somebody (inaudible) interpret speech, you know, socialize, etc., 25 to 30 decibels is a fairly significant grade of loss, I understand, but I'm just concerned that we haven't seen any data to justify, you know, either that as a criterion of longer-term performance. All we've got is that, OK, there's no difference in the development of language. That's all the data we actually have in the studies. There's nothing else that actually ties that decibel hearing loss to that, you know? And... and I think in the... in the absence of that, we'd just be fishing in the dark, and I... I would just be happier, I think, just to go with Seth's saying about, you know, hearing difficulties.
- Louise Kaplan: In the NICE guidelines, it specifies decibels, and so in the NICE guidelines are there... it has a reference to the guidelines. Do they have documented studies that they used to come up with this criteria?
- Seth Schwartz: They looked at the same trials we are looking at today.
- Louise Kaplan: Because they... they have a... a recommendation for when surgery is recommended.
- Michelle Simon: And the inclusion criteria for the trials we looked at today, what was the decibel hearing loss required? I don't remember.
- Gregory Brown: 20 to 70.
- Craig Blackmore: 20 to 70.
- Michael Souter: In some of them, not in all of them.
- Gregory Brown: Yeah, in some of them.
- Michelle Simon: So, 20 was the minimum.
- Chris Standaert: That wasn't the loss, that was the...
- Gregory Brown: And... and... (inaudible) required it.
- Chris Standaert: ...that wasn't the loss, that was the threshold, right? So, that wasn't the change from the other ear or change from expected. That was the threshold at which they could hear.
- Craig Blackmore: Well, we're talking about bilateral. So, it wouldn't have the other ear for comparison. So, I think that's...
- Chris Standaert: Right.
- Craig Blackmore: ...it's the threshold we're talking about, not a change because we can't...

- Chris Standaert: Right. I'm just, yeah, yeah. It's a change... and I don't know how they even just make or measure it directly, but yeah, the threshold is...
- Joann Elmore: Are you talking about bilateral? Because you haven't put that up there if that's what you're talking about.
- Craig Blackmore: Well.
- Seth Schwartz: It should be bilateral.
- Joann Elmore: But it's not up there.
- Seth Schwartz: Yeah.
- Joann Elmore: And I also heard unilateral at six months, even though we haven't seen data on that.
- Seth Schwartz: Yeah.
- Craig Blackmore: So, let's put bullet point three bilateral effusion... bilateral effusion.
- Michelle Simon: You put it in one.
- Seth Schwartz: So, just to be clear. I... I would put it in one.
- Michelle Simon: Bullet point one.
- Seth Schwartz: We... we're talking about for bilateral... the three months is for bilateral.
- Gregory Brown: Yeah, so...
- Seth Schwartz: We can decide whether we want to do anything about the six month, but I didn't... the guidelines, you know, clearly say unilateral for six months or longer.
- Gregory Brown: So, one should be...
- Joann Elmore: Do we even want to...
- Louise Kaplan: Covered duration bilateral.
- Joann Elmore: ...go there (inaudible) data.
- Craig Blackmore: OK. So, Chris, on bullet point number one, cover if bilateral... cover... cover of duration of bilateral effusion three months or greater, and then we can drop that bullet point three.
- Carol MacArthur: Am... am I allowed to ask a question?
- Craig Blackmore: Sure.

- Carol MacArthur: You might want to discuss whether you want to just cover bilateral, because that's... it is worth discussing versus covering unilateral and bilateral.
- Joann Elmore: That's kind of where I was wandering also.
- Craig Blackmore: Thank you. OK. Let's do that, but before we go there, I just want to finish up this point of Down's and craniofacial... can... can you give us the wording. We had wording from Seth and.
- Seth Schwartz: So, in several of the guidelines is the... in reference to at-risk children, and then there's two categories of at-risk children, children at... at increased risk of persistent effusion based on anatomic abnormalities, and that would be things... yeah, anatomic abnormalities, which would be things like craniofacial disorders, Down Syndrome, cleft... cleft palate.
- Craig Blackmore: Do we need to list those, or can we just say anatomic abnormalities?
- Seth Schwartz: I think you can probably just say anatomic abnormalities, which is probably adequate.
- Craig Blackmore: So, then the next line, B.
- Seth Schwartz: B would be children at disproportionate... at risk of disproportionate effects of hearing loss, such as speech delay, underlying sensorineural hearing loss, or cognitive disorders. No disproportionate risk from hearing loss, such as speech delay, underlying sensorineural hearing loss, sensorineural, N-E-U-R-A-L-. We can fix that. Yeah, and cognitive disorders.
- Joann Elmore: So, we haven't looked at data on this.
- Chris Standaert: So, yeah. Where's all this... we don't have... where is all this coming from?
- Seth Schwartz: The issue is that these are the kids who were all pulled out of all the trials. So, again, we're... we're saying we're going to restrict it in the kids that we've seen data on, but...
- Joann Elmore: So, does that mean...
- Seth Schwartz: ...these are the kids...
- Joann Elmore: ...that a kid that a mild speech delay that has a little bit of fluid for, like, two days, gets a tube put in?
- Seth Schwartz: No. I think that's... it's... but the problem is that there's... there... so, the issue is that there is no data on these children, because they were excluded from all the underlying trials. So, if you have a child who has speech delay and has a bilateral effusion, and you don't know how long it's been present, that may affect it more, or a kid with underlying sensorineural hearing loss having a mild hearing impairment for even a month could affect them. It's not saying you

have to put in tubes in those kids. It's saying you're evaluating them differently. Now, again...

Joann Elmore: So, you wouldn't wait to see whether they've had it for three months and?

Seth Schwartz: Generally, the thought is that the... the impact of the hearing loss is more significant in these children. So, you don't want to put the same limitations on them. Again, you guys can decide how you want to handle this, because we've not seen a lot of data on it. I'm just telling you, this is... because these kids were excluded from all the trials and the perception amongst the community that cares for them is... is that fact that they are disproportionately affected. That's why they've been called out.

Joann Elmore: No, that makes sense.

Chris Standaert: So, we... we can... we can do what the agency directors said and say these conditions do not... these... this decision does not apply to, and we call them out, and what that means is, they're not covered, it means the agencies can do whatever they want to with them. They can make them preauthorization required. If we say cover in these conditions, then they can't require preauthorization. They have to just pay for it. So, if we have no data on them, we shouldn't be saying one way or the other we could... we... if they were excluded from our literature, we can exclude them from our decision and let them decide what to do with them.

Craig Blackmore: Well, that's a little bit of a copout.

Gregory Brown: Actually, yeah. I...

Chris Standaert: No, it's not.

Gregory Brown: ...I have... I have...

Chris Standaert: It's not a copout at all. We didn't get any data on them.

Gregory Brown: ...well, but...

Chris Standaert: If they're excluded from the studies.

Gregory Brown: ...we're talking about Medicaid kids and when I've tried to get preauthorization for a procedure for even fracture care, just the paperwork alone will delay treatment, and... and I'm not comfortable with... with that.

Craig Blackmore: We... we have the data there is.

Kevin Walsh: There's a little difference in urgency here. That's not an analogous comparison, I'm sorry.

Gregory Brown: No, but... but... but the, no, but I mean, the... the point is is that it... it... it's... certain Medicaid...

Seth Schwartz: The issue is delay...

Gregory Brown: ...payers significantly delay authorization, and...

Seth Schwartz: ...and the issue is your concern about a delay. It does put them in a circumstance where they may have an increased delay just for authorization, may not be a good situation. So, anyway, again, you guys can decide what you want here, but I'll just tell you that I think that currently, there's no restrictions on those kids, and I don't think the intent of this review was to say, what do we do with these kids? We're really worried about... anyway... I don't think anybody wants to restrict... I mean, if you guys want to, we can talk about that, but I don't think that was the... the intent to bringing this up. I mean, you guys can comment, but...

Chris Standaert: We're not saying they have to be restricted. We're just saying the agency can do whatever they want with them. They can restrict them if they want to. They can not restrict them if they want to. We didn't get the data on them to talk about this...

Craig Blackmore: Well...

Chris Standaert: ...population.

Craig Blackmore: ...we got the data. We have all the data there is on these populations. Isn't that correct, Robin? You didn't... in your literature review, you got the data on these people. There isn't any, but you got it.

Robin Hashimoto: That's correct. There is no comparative data.

Craig Blackmore: So...

Seth Schwartz: Yeah. So, there's no randomized trials on these kids.

Craig Blackmore: ...there's no randomized trials.

Robin Hashimoto: And there... there weren't...

Seth Schwartz: That's a very different situation.

Craig Blackmore: So...

Seth Schwartz: There's a lot of data on these kids. There's just no randomized trials.

Craig Blackmore: ...procedurally, I don't like the... the... we are given a problem, and we say we're only going to answer part of it, and we don't want to answer the other part. So, if it was covered in our evidence review, the onus is on us to make a decision about it. If it wasn't covered in our evidence review, then we shouldn't, absolutely not, make a decision about it, so.

- Robin Hashimoto: There... there were no studies that met our inclusion criteria, as specified.
- Craig Blackmore: No clinical...
- Robin Hashimoto: On these pub-...
- Craig Blackmore: ...trial data in these (inaudible).
- Robin Hashimoto: ...right, or nonrandomized comparative data with the stipulations that we placed on them.
- Craig Blackmore: OK. So, therefore, I think we can't give it back to the agency directors. We have to make a decision, and... and... and, you know, one path is to say we accept that these children are at higher risk, and we see that there is a short-term benefit, maybe, in normal children and that short-term benefit may be of more value in these children. Therefore, we are going to cover them. Another decision might be to treat them the same as all the other children, but the randomized clinical trial data doesn't include.
- Kevin Walsh: Then why, I, I'm sorry. I understand the point you're making, Craig, but the... that's not what the state agencies proposed, and if they can live with the wording that they proposed, why are we disagreeing with it?
- Michael Souter: Because the wording they proposed is, in otherwise healthy children. They're not... that's what they proposed. That's what it says there, it reads. So, when we're...
- Michelle Simon: No, slide 19.
- Michael Souter: ...and given that we're not going down that road, then it means we've got to be explicit about making sure that our conditional coverage only applies to the population we're comfortable with.
- Michelle Simon: Mike, if you look at slide 19, they have further recommendations. Turn the page.
- Michael Souter: Yeah, exclude from conditional coverage. It's there.
- Michelle Simon: That's what we're discussing, use that wording.
- Seth Schwartz: We're not saying exclude from conditional coverage. We're saying cover them unconditionally.
- Chris Standaert: Exclude from the conditions of our, yeah.
- Joann Elmore: Of our decision.
- Michael Souter: Oh, it just depends on how many double negatives you throw in there.
- Chris Standaert: Yeah.

- Michael Souter: I mean, it's just a.
- Craig Blackmore: That's trying to get rid of the double negative. Exclude from conditional coverage, which means, presumably...
- Joann Elmore: Cover.
- Craig Blackmore: ...cover. And that's what we've done. Conditional coverage is one of these conditions.
- Gregory Brown: Yeah, I, you know, I didn't write it, but I think if... I think the intended meaning was cover without conditions for those two groups. I... I agree there's a problem with a double negative there, which makes it confusing, and it would be more straightforward if it said cover without conditions.
- Craig Blackmore: OK. We... have we beat on that enough?
- Seth Schwartz: I need to ask a couple of language questions.
- Craig Blackmore: Yeah.
- Josh Morse: So, does it cover in... under one or both of these, would that be outside of the one and two?
- Craig Blackmore: So, one... one and two should be and. One... no. No. No, under otitis media with effusion, yep. That should be... well maybe for both, definitely for otitis media with effusion it should be duration and documented hearing loss. And for acute otitis media, it should be or, right.
- Female: Which one was for or?
- Craig Blackmore: Up top. Those, one and two are or in that case. So, you're going to have to be careful how you write this out. That was a good question, and then, so... so may... maybe... maybe it would be better to remove... under otitis media with effusion, remove the number two, just not the whole thing, just the number itself, and then put the number two in front of at risk. So, now it's an or. You either have number one, which is duration and hearing loss. Or you have number two, which is an at risk child. And then having done all that, we haven't said anything about unilateral. Kevin.
- Kevin Walsh: Can we go four times?
- Craig Blackmore: You can go as often as you want.
- Kevin Walsh: No. I meant...
- Craig Blackmore: This is my last meeting. We can do, you know, we can (inaudible).

- Kevin Walsh: ...I just meant... I meant how many times can each of us vote? I meant, can we... I... I'm... I have a lot of trouble with this, because I feel like I don't want to exclude the children with special needs who are number one under acute otitis and number two under effusion. I don't feel that the literature supports the coverage of either of the others. So, I... I don't want to... I mean, I don't want to vote. So, if I vote no, don't cover, I'm voting to not cover anybody.
- Craig Blackmore: OK. We... we'll vote separately.
- Kevin Walsh: Do you understand my point?
- Craig Blackmore: I do. I do. I totally understand. So, let's get them all out there, and then we'll go through it. And so, the other one that has come up is the idea of unilateral versus bilateral.
- Josh Morse: Another point of clarity then. So, if complications under one seems (inaudible) children, and we put that in parentheses there, including at risk, is that the intent of... this... this number two also applies to acute otitis media?
- Craig Blackmore: No.
- Josh Morse: It doesn't? OK.
- Craig Blackmore: No.
- Seth Schwartz: I... I was saying, I think we have to comment on unilateral, because right now, those patients are excluded. I think we have to comment on them.
- Craig Blackmore: Right.
- Seth Schwartz: Because this also goes up to kids up to age 16, and while, you know... you know, you have a teenager with unilateral hearing loss, they're not going to be really happy about it, and it's just a different... in some ways it's a different population. We're not going to see a lot of data, but... we haven't seen any data.
- Craig Blackmore: Right. So... well, so Robin, do we have all the data on unilateral, such as it is?
- Robin Hashimoto: Yes.
- Craig Blackmore: Thank you.
- Chris Standaert: You didn't call out unilateral versus bilateral on those studies of otitis media with effusion. Are they all bilateral, or are they unilateral? Are they a mixed group?
- Robin Hashimoto: It's a mixed group. Some of them are bilateral only. Some of them could be either.

- Chris Standaert: And their criteria generally were three... the... you've read the inclusion criteria before, and they tend to be about three months. And so, we don't...
- Robin Hashimoto: Yes.
- Chris Standaert: ...so the data you haven't doesn't distinguish for us bilateral versus unilateral, but our inclusion criteria was about that three month mark on most of these studies.
- Robin Hashimoto: That is correct.
- Chris Standaert: So, we could just leave out the word bilateral and cover them both, because that's what our data says.
- Seth Schwartz: That's what the AAO guideline says. AAO says bilateral... three months for bilateral, six months for unilateral.
- Craig Blackmore: But we don't have any data to support that.
- Seth Schwartz: We don't have any data. I mean, that would be... if we... I... I'm fine with that because based on the data, that's what we have, but I think that's less restrictive than what most... than what most of the guidelines say.
- Chris Standaert: It's less restrictive, but I got to go with our data says myself.
- Seth Schwartz: That's fine.
- Craig Blackmore: OK. So, I'm hearing maybe we should include unilateral and bilateral under the three month. Does anybody want to present a contrary argument to that? Kevin?
- Kevin Walsh: There's no evidence.
- Craig Blackmore: Well, the unilaterals were in the study. They were a mix of unilateral.
- Kevin Walsh: That's why I'm... I'm saying on what basis are you... are you... are you parceling them out?
- Chris Standaert: We're trying not to.
- Craig Blackmore: The... the society guidelines do, but we haven't seen any evidence to support that. So, I mean... I'm hearing that we're going to treat them the same because we don't have evidence to differentiate. OK. OK. Can we save that? I know you're probably doing that all the time, but I would feel better. And then one other correction. I would like us, where it says at risk children, I'd like that to be in regular type, regular font.
- Gregory Brown: Can I ask a process question?
- Craig Blackmore: Yes.

- Gregory Brown: So, if there's, I mean, I work on the evidence based committee on the American Academy of Orthopedic Surgeons. So, the... a consensus statement can be made in the face of no data, and for us life or limb threatening, but, you know, here hearing threatening condition. So, if we have a condition where we have no data but we have a professional society that is a clinical practice guideline, are we not allowed to defer to their expert opinion?
- Craig Blackmore: So, we... we have to make a decision based on the best available evidence. The best available evidence might be the guideline, that might be all there is.
- Gregory Brown: OK.
- Craig Blackmore: But we also have an obligation to require evidence.
- Gregory Brown: Correct.
- Craig Blackmore: So, we have to reconcile those, and it may be if it is life or death, you say there's no evidence, but, you know, you use the N1, the case series or whatever it is, but in general, often, our standards of evidence are higher than the societies. Not always.
- David McCulloch: Yeah, most often. I mean, there are certain societies where I would absolutely not defer to, especially societies recommendations. The American Diabetes Association do not produce evidence-based guidelines.
- Gregory Brown: No. No. I understand that, but... but this is a unique condition where actually the recommendation from the professional society is more restrictive.
- Craig Blackmore: More restrictive, yeah.
- Gregory Brown: And so...
- Kevin Walsh: So, what?
- Craig Blackmore: Well, I think in this case the committee is saying the evidence is actually three months based on the trials, and that trumps the society guideline, whether it's restrictive or not.
- Kevin Walsh: OK.
- Craig Blackmore: OK. Are there any other potential conditions that we need to talk about? OK. So, then procedurally, we are going to go through a series of votes. What we're going to do is vote on each of these separate conditions and then the conditions that are carried will stay in the final condition set. Then, we will have our official vote, which will be cover, no cover, or cover with the conditions set that the group has agreed on. So, these first votes will not be binding in the sense that we haven't agreed we're going to do conditions yet. So, we'll just simply hold up our hands and we'll explicitly and transparently count the number of hands, but these are not votes with cards.

So, we will start with the first condition under acute otitis media and that is to cover with complications or individuals who are immunocompromised or otherwise at risk for complications of an infection. So, as a perspective condition, who would favor that? And Josh has a procedural question, I think.

Josh Morse: I do. It's eleven.

Craig Blackmore: So, what... what is your concern?

Josh Morse: So, back to bilateral/unilateral. So, again, the preface of this is this is covered for children 16 or younger for uni or bilateral?

Chris Standaert: This is... this is effusion.

Craig Blackmore: Yeah. We have... we haven't specified.

Josh Morse: That was number one. That was with acute otitis media, sorry.

Craig Blackmore: Yes. So, then the second condition under which we could cover... yep, good. The second condition under which we would allow coverage for tubes, the second possible condition where we would allow coverage for tubes is in individuals with acute otitis media who have had three episodes in the last six months, or four in the last twelve months, with one occurring in the last six months in the presence of effusion at the time of assessment for surgical candidacy. So, I'd like a show of hands on if we vote for coverage with conditions, the individuals on the committee who believed this would be an appropriate condition for coverage.

Josh Morse: Ten vote, no? Sorry. Is your hand up? No?

Craig Blackmore: The third potential condition would be that we would allow coverage in individuals who have otitis media with effusion of a duration of three months or greater and with documented hearing loss. So, I'd like a show of hands whether we should cover for that condition if we cover with conditions.

Josh Morse: So, that is nine.

Craig Blackmore: And then the final prospective condition is, we will cover for otitis media with effusion in children who are at risk, meaning at risk for persistent infection based on anatomic abnormalities or at risk... at disproportionate risk from hearing loss, such as speech delay, underlying sensorineural hearing loss, or cognitive disorders. So, who would favor that as a prospective condition?

Josh Morse: Everybody, eleven.

Craig Blackmore: Eleven. OK. Having gone through that process, now we have the opportunity to do our final binding vote. Does anybody wish to comment or have further discussion before we do that? That's a good idea. Do you, do the agency

directors have any concern about the implementability of these particular conditions?

Gary Franklin: No.

Craig Blackmore: Thank you. And any other issues from the committee? OK. Then, we will proceed and so you now have... this is a binding vote, and you now have ... I'm still going to do this twice. So, we're going to do it twice. We're going to first vote on acute otitis media with the two conditions we've agreed on, cover, no cover, and then I'm going to do a separate vote for otitis media with effusion with those other two conditions that we decided on. So, you will vote cover, no cover, or cover with conditions as defined.

Josh Morse: There's eleven cover with conditions.

Craig Blackmore: And then the second vote will... and can I get you to just scroll up a little bit there, just so we can see the others. This will be coverage for otitis media with effusion with the conditions as defined.

Josh Morse: Eleven cover with conditions.

Craig Blackmore: OK. So, reconciling with Medicare National Coverage decisions, there are none, so we do not have any concern. Reconciling with other guidelines that exist, we... we were in agreement to some extent with the guidelines that are out there. The guidelines are not in perfect agreement themselves. We differed a little bit because we were relying on the evidence from the randomized trials for the times, etc., and I think we recognize the absence of data for some conditions, but the potential risk or harm being greater, and that affected our decision making. OK.

Joann Elmore: Can I make a comment on this one?

Craig Blackmore: Yes.

Joann Elmore: He says that hesitantly.

Craig Blackmore: Well, we decided, so (inaudible).

Joann Elmore: No, we decided. We decided, but I had a hard time with the effectiveness voting and I was frowning afterwards, but I didn't want to slow down the process, but this is what I was worried about. People are going to look at our vote and they're going to say, oh, you know, two-thirds of the committee voted that it was more effective, and that's because there was, like, two or three studies with only one of them multiple outcomes, and it was only of a short duration. So, I almost wanted to raise my hand and say, can we vote on this, like, four times instead of two times?

Kevin Walsh: You're presuming that anybody but us looks at the votes.

- Joann Elmore: They do, as Craig knows, they're starting to, and the fact that we... we just voted, and people might look at this to say, well, you know, this whole committee voted that it's more effective. Than one kind of bothered me.
- Craig Blackmore: Well, I mean, we try to make it explicit. This is if you believe there is any circumstance under which it is more effective, then you would... and that's why...
- Michael Souter: (inaudible) discussion.
- Craig Blackmore: ...that's why I try to make that clear.
- Joann Elmore: But they're just going to look at the numbers and say, oh, you know, ten of the twelve said it was more.
- Michael Souter: Then you refer them to the... to.
- Craig Blackmore: OK, Josh. Do you have any updates on Health Technology Assessment reviews in progress?
- Josh Morse: Yes. In the back of your binders, we have a submarine (inaudible). By the way, I've got a few slides. I'm not sure we have them (inaudible). So, just going over today's reviews. In January, the next meeting is January 15<sup>th</sup>. Draft reports for that meeting, the two topics are cardiac stents and Novocure (inaudible). So, for cardiac stents, the draft... comment period of the draft report has closed, and the final report will be published here in a couple of weeks. The draft report is out there for cardiac stents. The same for Novocure. The comment period is closed, and the draft report is available, and the final report will be available soon. Again, the meeting is January 15<sup>th</sup>. The meeting following that is March 18<sup>th</sup>, and the two topics, again, one is a re-review, the spinal injections topic, and the draft report will become available on December 14<sup>th</sup> for a month for review, and the same Accupril membrane oxygenation. That report will be available on or about December 14<sup>th</sup> for 30 days. Then, scheduled for May, at this point, bronchial thermoplasty. We just wrapped up the draft key question period for that topic. We have yet to initiate the draft key question comment period for platelet rich plasma. I apologize I didn't have that for you today. That will be out, I believe, early next week. We'll have those questions out for review for that report. We don't have it out in public comment right now. So, but that... that's out. So, you know, the rest of this just shows timelines and the concerns. If you have any questions about any of these topics right now, we can talk about them. (inaudible)
- Craig Blackmore: Does anybody have any concerns or issues?
- Michael Souter: I'm curious on the scope for the ECMO discussion, given there's, you know, so many different indications for that at present, just what populations are we talking about? If we're talking about everybody, including the kind of pediatric populations (inaudible).
- Craig Blackmore: Is it wound healing?

- Josh Morse: For ECMO?
- Michael Souter: Yeah.
- Josh Morse: The population does not include the pediatric populations. It includes, I think, everything beyond that, everything else.
- Michael Souter: Alright. That would be...
- David McCulloch: Well, you do the math for me.
- Michael Souter: ...that... that may... that may prove an interesting discussion. I think there's... there's obviously ECMO for the critically ill population, you know, that require oxygenation in the ICU, but there is also ECMO as a bridging therapy for those patients who are acquiring active, ongoing cardiac support, whilst they're... sometimes needing both, valvulars and inotropic support, but needing oxygenation, as well. And then there's ECMO as part of acute resuscitation ongoing, as well. So, there's... I'm... I'm just saying that there may be a larger topic than we think on first look, and if you want to talk, you look at where there's going to be a well-developed... or the best developed evidence pool, which will probably be within the critically ill population or supporting, you know, or treatment of hypoxemia.
- Josh Morse: OK. The scope is available. It is published, and we will have a draft report in a couple weeks, but I believe it includes those... both those populations, the critically ill and the bridging, if that's not the same.
- Michael Souter: OK. Alright. I'll be interested to see that.
- Craig Blackmore: Other concerns, questions? Alright, the final item is the Chair closing remarks. I don't usually say anything at these meetings, but this is my last chance. So, I'm... I'm going to. You know, I think we're... we're all involved in this group for maybe different reasons, but fundamentally the same reason, and that is that we are all practicing clinicians in our specific areas, and we have the ability to affect the care of the people that we care for, but this gives us also an opportunity to affect the care for the people throughout the State of Washington, and really beyond that, and it still remains a... a pioneering program and a novel program in many ways, and I think a program that has a lot of influence, even beyond the... the bounds of our state. It's... it's hard. It is hard for us to get together and make these decisions. There is also a lot of process, and I want to take the opportunity to thank Josh and his team. Most of you don't realize, but behind the scenes, Josh is navigating all three branches of government, because all three branches of government are actually intimately involved in what we are doing, not just the governor and not just the legislature, but also through the judicial works. So, thank you, Josh, and thank you, Christina and Kris, for... for helping me in my time here. I think what we do is hard. I think it takes all of our skill and all of our intelligence, and a lot of our time to come up with these decisions to distill through this huge bout of often conflicting and always inadequate data, and... and then we have to do it in the

public forum, not usually with the television cameras and the newspaper reporters, but sometimes. So, maybe there's a little bit of courage involved, as well, and courage, in particular, because we are not always supporting the guidelines from the societies and not always supporting the approach of our peers and our colleagues, and we are trying to maybe raise that bar a little bit and alter how care is going and... and rock the boat a little bit. It's... it's good work, and it's important work, and I have learned from all of you, and I have deep respect for all of you who are willing to do this, and admiration, and I won't say it has always been pretty, but I have always enjoyed it, and I have always left this room feeling like we... we made a good decision, even if it wasn't the decision that I thought we would make when I came into this room. Term limits are generally a good thing, and eight years is a long time. So, it's time for me to move on, as well as several of you who will be following me off into the abyss here.

Chris Standaert: The sunset.

Craig Blackmore: The sunset. I... I...

Chris Standaert: Into the pit of hell.

Craig Blackmore: I wouldn't go that far. The committee will continue to face challenging decisions going forward. And the one thing I can say is that I'm sure the committee will make the right decision going forward, because the reality is, you are all very good at this job. So, I want to thank you for giving me the opportunity to participate with all of you, and that's all I will say. So, we are adjourned, thank you.