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**Health Technology Clinical Committee Public Meeting**  
May 15, 2015

Craig Blackmore: Well, good morning everyone. I'd like to call the meeting to order if I could have the committee members please take their seats.

Welcome to the Health Technology Clinical Committee meeting. I'm Craig Blackmore, the committee chair, and we have a quorum of committee members. So, I'll call the meeting to session. The first item on the agenda is program updates, Josh.

Josh Morse: Thanks, Craig. So, I'll give a brief presentation for those who are new to the program. Let's start with... here we go. So, the topics for today include imaging for rhinosinusitis first this morning, and then in the afternoon bariatric surgery. The next meeting with a decision agenda is in November of this year, so some months away, and the topics we're working on for that meeting are tympanostomy tubes and the re-review of the lumbar fusion topic.

So, some background about the Health Technology Assessment Program, the Health Technology Assessment program is located in the Health Care Authority, an agency in Olympia. The 2006 legislation created this program to use evidence reports and a panel of clinicians to make coverage decisions for selected medical procedures and tests based on the evidence of their safety, efficacy, and cost-effectiveness.

Multiple state agencies participate to identify topics and implement the policy decisions that come from this program, and they include the Health Care Authority programs for the Uniform Medical Plan and Medicaid, the Department of Labor and Industries, which operates the Worker's Compensation program, and the Department of Corrections. The agencies implement these determinations within their existing statutory frameworks.

So, the purpose of the program is to pay for what works, to ensure that medical treatments, devices, and services that are paid for with state healthcare dollars are safe and proven to work. The program provides resources for these agencies that purchase healthcare. We develop scientific evidence-based reports on the medical devices, procedures and tests that are selected, and we facilitate the work of this clinical committee to make these decisions.

Our objective include to be transparent, to minimize bias in the decision-making process, to be consistent with our methods, to be evolving and flexible, and to be cyclic in terms of keeping up with the evidence and processes. Ultimately, our goal is better health for the citizens' health insurance and healthcare to.

So, this is a high level view of the process that we use. The Health Care Authority director selects technologies for review. We contract for evidence reports and develop the...we develop these reports over the course of between two and eight months. We bring these reports...and this report will be presented today to the clinical committee here. They'll make a decision today, a draft decision, and then ultimately when this decision becomes final in a few months, the agencies will implement these decisions. So, the primary questions that drive the development of the evidence reports are, is it safe, is it effective, and does it provide value, and these are around the technologies that are selected.

So, again, more values. We value transparency. We publish all of the deliverables from the program, including the topics, the criteria used to identify those topics, the reports that are developed to answer the questions, and we conduct these decision-making meetings in public. We seek to identify the best available evidence through formal, systematic processes to review these healthcare technologies, and these decisions are from this independent committee. This is a committee of practicing clinicians. They make these decisions based on the science.

So, the decision basis includes the objective factors. For the evidence consideration this includes the nature and the source of the evidence, the characteristics of the studies that were used to understand these technologies, the consistency of the outcomes across the studies. Additional factors might include the recency of the information, the relevancy to the populations and the questions being asked, and the influence and bias in the process.

Technology topics for this year have included functional neuroimaging for primary dementia and mild cognitive impairment and appropriate imaging for breast cancer screening in certain populations. At last March's meeting, the previous meeting, was for testosterone testing. Again, today's topics are shown here, and the future topics of tympanostomy tubes and lumbar fusion in November.

There are multiple ways to participate with the Health Technology Assessment program. They include our website, which is our primary means of communicating deliverables and the drafts from the program. We encourage people who are interested to join our stakeholder list by emailing the email address shown here, and we can provide that to anyone who is interested. Anyone may comment on the topics that are proposed for review on the key questions that are developed on the draft reports... on the draft decisions, and make comments on the public meetings.

So, a couple of other updates for the committee this morning. We have released the recruitment announcement for new committee members. That went online earlier this week and is open for a month. If you know people who are interested in participating in the future, we will be seeking three new committee members in the next six months. The application period is open for 30 days, but the replacement process will probably take six months. We also have a new staff person to introduce, Kris Urv-Wong, who is seated over there. She is the new Health Technology Assessment program manager. She is a data and informatics person. She is rapidly coming up to speed with the program. This is the end of your second week?

Kris Urv-Wong: Yes, it is.

Josh Morse: You started May 1<sup>st</sup>? So, we welcome Kris to the process. So, this is her first meeting today. The final announcement is, Teri Rogstad, as you know, who will present to you today on the rhinosinusitis topic, this is her last day in her current role. So, we will be wishing her well in her new prospects. So, thanks very much.

Craig Blackmore: Thank you, Josh. I just want to, sort of, echo or amplify the point you made about recruitment. Serving on this committee has its own set of skills and requirements that may or may not be common in the medical community. So, I would encourage the committee members to think about if they know of other individuals who might be good candidates that could be encouraged to participate.

Alright. Next item is followup on business from the prior meeting, and the first piece of that is approval of the minutes. So, the minutes have been distributed to the committee members and are available in your packets, and I would accept any comments or concerns about the minutes or else a motion to approve.

Seth Schwartz: I move to approve.

Richard Phillips: I second.

Craig Blackmore: Thank you. So, just a show of hands, all in favor of approving the meeting minutes from last.

Josh Morse: It looks like nine approve, one abstain.

Craig Blackmore: OK. Alright. Next item on the agenda is approval of the decision we made at the prior meeting, the March 20 meeting on testosterone testing and the draft findings and decisions document is here and has been available for public comment. We did receive one comment from Dr. Steve Hammond from the Department of Corrections regarding some wording around clarification of the decision. So, if I could call that to the attention of the committee members. It is

in your packet, that first section just before the divider. There's a letter from Steve Hammond. The purpose... there are several purposes for us going through this additional step of looking at the decision we already made and making a final approval at a followup meeting. It allows us to do several things. One is just kind of as a safety check to make sure we didn't leave out something important that wasn't apparent. It gives us the opportunity for feedback from the greater community, and again, as kind of a safety check. Another reason to do this is, if there's questions of clarity, particularly from those who would be in charge of implementing the decision. So, in this case, Dr. Hammond has asked us to make some changes in the wording, which he believes will help with clarity. So, our job will be whether to consider whether we agree with that and it's important that if we're making a change here that it be only for clarity and reflect the intent of our decision in the previous meeting, that it not be a change. If we're going to make a change in the decision, we need to do that with the full body of evidence before us, and that's not where we are. So, I would ask that the committee members, particularly those that were here last time, look at the concerns Dr. Hammond has raised and see if either our original wording or the suggested modifications fit with the intent of what we have decided. So, thoughts on that.

Chris Standaert: It looks like the only real change is the word "suspected" goes away from the first one, because the second change suggests that this divides one thing we put into two separate issues. He changed signs of hypogonadism to physical examination signs of hypogonadism, which I would think would be the same thing, myself. Signs, I would think of, as physical finding, and I think our intent was...I remember we talked about suspected or known. We talked about do we do that, and the issue was if you don't know somebody has it, how do you go looking for it if you can't do this. So, I guess my only question would be, are there reasons to suspect hypogonadism that wouldn't be identified or characterized with physical examination signs or symptoms of sexual dysfunction. If there are other reasons to suspect hypogonadism beyond that, then we should leave it as suspected.

Craig Blackmore: Other comments?

Richard Phillips: I don't see any reason to change it, personally. I agree with what Chris said. I think if the nature of the way we discussed it was that suspected was part of the perspective we were approaching the patients at the time and while obviously Dr. Hammond, this is his specialty. He knows a lot about this sort of thing, and maybe he has more information than I do, but based on our discussion I don't see any reason to change it.

Craig Blackmore: So, his concern was, he says listed suspected primary hypogonadism without qualifications, too vague to allow adequate implementation. Instead, list physical examination, signs, and sexual dysfunction symptoms as the clinical findings that would raise clinical suspicion of hypogonadism.

- David McCulloch: I think what Steve Hammond is trying to get at is that suspected hypogonadism you say well yeah, this guy just feels kind of tired and, you know, it could be hypogonadism. Whereas, this is trying to get a little more specific saying, no. You can't just test in an older guy who's tired. You need some more objective findings that would indicate...and that's the intent of what he's trying to clarify, which I think is reasonable.
- Chris Standaert: I guess, I don't know. Are there reasons to suspect hypogonadism other than things you find on exam or sexual dysfunction? Are there other medical conditions? Is osteoporosis in a young male...are there other reasons to go looking. That's my only... I don't know. I don't know the answer and if some doctor's always looking for a reason to track it down based on some other suspicion, I don't want to say you can't do it. I just don't know enough to know whether that's the case or not. So, I defer to people who do. That person would know enough to take out that word.
- Michelle Simon: I think...Chris, I think you bring up a good point, and if we want to go that direction, we probably do need to re-review some evidence and have another clinical expert sitting with us if this is opening something up that we don't have the resources to answer, but I do agree with Dr. Hammond putting the reference in for the male aging study. I think that was an important thing to add, and we did omit that, and I would like to propose that we do add that reference.
- Craig Blackmore: Yeah, we...we included...so, he wants two things. He wants known primary hypogonadism the first bullet point, and then the second bullet point, he simply wants us to split...on our fourth bullet point, we have signs of hypogonadism or...and he wants that split and clarification of what we mean by signs as being physical examination sign. Then, we already say all three criteria from the European Male Aging Study. So, I don't know what...
- Michelle Simon: But the study's not included. So, the criteria are not listed in our...
- Craig Blackmore: Oh. So, he wants us...so, we would add the reference. Well, we can certainly add the reference, I think. That would be...
- Marie Brown: Or list the criteria.
- Craig Blackmore: Right. OK. So, I'm getting conflicting...when we're talking about primary hypogonadism, my memory, in the context of this discussion, is that it was really the secondary...concerns of secondary hypogonadism that was more the area that we were concerned about the over-utilization. Does that resonate? No, it doesn't. That's not right.
- Kevin Walsh: That resonates. There are other tests one can do to evaluate suspicion for primary hypogonadism, but your point is well taken, because it is one of the primary tests that one would do.

- Craig Blackmore: Right.
- Seth Schwartz: I don't really understand why it's less operational for primary but it's OK for the secondary to have suspected.
- Kevin Walsh: I think it's the point David made is the issue. I think the implication is that the, the barn door is too wide open and that anybody with fatigue can be suspected of having hypogonadism and would qualify for a test.
- Seth Schwartz: But I thought our concern was more with the secondary hypogonadism, whereas primary hypogonadism is not, wasn't really our, we weren't worried about overuse in that circumstance. So, I think limiting it more in the circumstance that we weren't concerned about it being too accessible anyway doesn't make sense, particularly since we have that issue, which you're concerned about it, which is it's not terribly clear what we might be excluding by changing this. So, I would also be in favor of leaving it as is.
- Richard Phillips: Craig, can we...might I suggest that we break it up into the two sections, vote on the first one and then on the second section, in other words, the two divisions?
- Craig Blackmore: Yeah.
- Richard Phillips: There might be two different feelings about that.
- Craig Blackmore: I mean, I think we can...we can only vote once, but we can have a show of hands and take an informal assessment.
- Richard Phillips: Yeah.
- Craig Blackmore: So, why don't we start with this first bullet point? Do we want to keep our bullet point of suspected or known primary hypogonadism or do we want to change it to simply known primary hypogonadism? Should we suggest hypogonadism with elevated gonadotropins? So, keeping that original bullet point, can I get a show of hands? Changing... how many is that? One, two, three, OK. So, we're going to keep that one and then in the second part, his suggestion is that we divide our number four bullet point into two. The first would be signs of hypogonadism and he lists examples. I'm not sure we need to list examples, because we don't need to list examples. He says physical signs...physical examination signs of hypogonadism instead of simply signs of hypogonadism. Are we happy with that?
- Group: Yes.
- Craig Blackmore: Alright. So, we like physical examination, signs of hypogonadism. We don't like the example piece, and then symptoms of sexual dysfunction would be the following bullet point, as Dr. Hammond has suggested. We already say all three criteria from the European Male Aging Study present, and the only change there would be adding a reference. So, the users, presumably, know what we mean

by the European Male Aging Study, though I haven't actually checked that reference.

Chris Standaert: Was our intent to actually have the symptoms put there instead of just saying...I think we're using shorthand for saying put these in, like, actually listing the symptoms, not saying...making somebody go find the reference to find out what they are.

Joann Elmore: Yes. I would like to put in the actual criteria that (inaudible).

Chris Standaert: Still reference it but actually (inaudible).

Craig Blackmore: For the Male...European Male...

Chris Standaert: Find this article and find out what they are before you do anything, which I think is...yeah, I agree.

Craig Blackmore: OK. OK. Then, I'm going to...do we...do we have that handy? Do we have the European Male Aging Study handy?

Christine Masters: No.

Craig Blackmore: OK. I'm going to table this, and we're going to bring it back after lunch, and that'll give us time to get the exact wording of the European Male Aging Study criteria so we can avoid having to dance around how we did it.

Josh Morse: OK.

Craig Blackmore: So, that is our plan. We're going to divide the bullet point out. That will give us time to get it in writing on the board, as...we'll have time to get it in writing on the board, and then we'll have a final vote again. This is not about changing our decision. It's about making sure our decision is clear. OK. So, we'll move on.

OK. The next item on the agenda is imaging for rhinosinusitis. The first presentation comes from the Washington State Agency representative. Before I do that, I want to introduce our clinical expert. So, we...at each of these meetings we have a clinical expert on each of the topics that is under discussion, and that is because the members of the committee may or may not have specific clinical expertise in that area. So, the job of the technology review is to look at the evidence and then the role of the clinical expert is to make sure we understand what's going on clinically so that our decision fits appropriately into context. So, the clinical expert for this meeting is Dr. Amy Anstead from Virginia Mason. So, thank you for joining us. We have not asked you to prepare a specific presentation. We will have questions, as the discussion goes on, particularly around the clinical aspects because most of us are not experts in this field. So, thank you for being here and we will... we will be calling on you.

Charissa Fotinos: Good morning, everybody. This is the agency medical director's report on imaging for rhinosinusitis, and we as a group got some feedback that what we were doing a little bit too much of was reiterating what the report was actually gonna be about in the presentation. So, this is a little bit different in terms of just regurgitating what the report says. We tried to look at this from a practical and clinical standpoint.

So, in terms of why this topic, medium concerns about safety, efficacy concerns in terms of the ability of the test to provide useful clinical information were high, and the costs were medium. This is just a picture of plain sinus x-rays on your left. You can see no handy-dandy clues, but on the right you can see in the right maxillary sinus the air fluid level that's pointed out, and that would be a sinus infection would appear on a plain x-ray. Clearly, the imaging obtained from either a CT or an MRI is much better. On the left you can see the right maxillary sinus opacified, excuse me on the left, and then on the right you can see both the maxillary and ethmoid sinuses involved.

So, in terms of background, again, I thought about approaching this from a clinical perspective and why we do diagnostic tests in the first place. We're usually presented with signs and symptoms, and then we have to think about giving those signs and symptoms...how likely we're thinking a diagnosis we're thinking about is present. Is it really present or is it not, and that sort of leads us to our next sort of critical thinking. We do all this in seconds, but as I was doing this I realized, gosh. We actually do think and we actually do have to put stuff together, even though it happens in milliseconds. So, we sort of get our initial thought about whether or not we have a high or low probability of the condition we're thinking about, and then we sort of say, is that enough to test or not? If someone comes in to me with a bone sticking out of their skin, I don't need an x-ray. The orthopedist might to figure out how to approach treatment for that, but I don't need it, and if someone comes in and they say they think their arm is broken. There's not a scrape, there's not a scrap, there's nothing, they probably don't need an x-ray. So, in that middle ground is where we have to figure out what we need to do next, and in the case of sinusitis, we have to decide, do we want imaging whether that's x-ray, CT, MRI, or ultrasound. Part of the discussion, then is, well, if I get those results what am I going to do with them? If I'm going to treat based on those results, then I need to get that test. If I'm not going to treat or I'm worried that the treatment is worse than the condition, then I'm probably not going to bother with that test. So, that sort of takes up next to the next diagnostic...or to the next clinical piece of thinking, and that's does this test that we got the results from change what we're going to do, in which case it makes sense to do that test. Or, if it doesn't change what we're going to do, why are we bothering to get that test. That's sort of the treatment threshold.

Added into all this, and I just put sort of the definitions that you'll hear again in terms of what kind of sinusitis we're talking about, whether it's acute, subacute, or chronic. The other piece to keep in mind in the background of all of this is, what's the natural history of the condition? We can see something at a point in

time, and we can jump all over it and intervene, but if it's something that's going to resolve on its own or not cause any problems, then maybe we need to take a step back and say, is this really important enough to do.

So, these are just some considerations about that sort of first step. Should we test or should we not test? And in terms of whether or not we do that, we'll consider safety, cost of the test, is the test burdensome or not, for instance pulmonary angiogram. We don't want to do that unless you absolutely have to. What's the prognosis? Is the treatment effective, and do we have ready access to the treatment. Then, if we think about treatment, if we don't get the information we need from this test, how safe is the next thing that we have to do? How costly is the next test if this doesn't give us all the information. Again, what's the prognosis, the effectiveness, safety of treatment, and is it available. So, these are just some of the things that we, in milliseconds, kind of get together in our head and make a decision quickly, but we actually go through a ton of work in doing that.

So, just to take another step and remind folks, what's the utility of a diagnostic test? Usually, you have to compare it to some gold standard. You need to understand the performance of the test, and we'll hear a lot about the sensitivity, specificity, positive and negative predictive values. I focused a little bit on likelihood ratios in terms of looking at the tests we're going to be hearing about, and really, I think a key point is understanding the situation in which that test was applied. In this case, you'll hear that some of these studies, most of these studies were actually done in specialty settings either in ENT offices or radiology, and only one was done in an Emergency Room, which might better represent what you'd see in a primary care setting. So, when you think about the situation, who are our patients? Are they more likely to be sick, less likely, what are the settings, and how likely is it that they have the condition that we're looking for?

So, in terms of a refresher, I always have to remind myself of these, even though I use them all the time. So, sensitivity is the proportion of people with the condition who have a positive result. Specificity is the portion of people without the condition who have a negative result. Positive predictive value is the proportion of people who have a positive test that actually have the condition, and then the negative predictive value is the proportion of people who test negative that did not have the condition. I think important things to remember in this discussion is that sensitivity and specificity are fixed test characteristics. They do not change. They are fixed with the test. On the other hand, the positive and negative predictive values, those results will vary with the prevalence of the condition. So, just keeping that in mind, as we think about it.

I think that in terms of diagnostic tests, likelihood ratios can be more useful, in that a positive likelihood ratio tells you the probability that a person who has the disease will test positive over the probability that the person without the disease will test positive. So, it gives you a ratio, how much more likely is this person with the disease to test positive than not, and similarly the negative

likelihood ratio is if a person doesn't have the disease, how likely are they to have a negative test over someone that... a person who does test... a person with the disease who tests negative over the person who doesn't have the disease. So, these are a little bit more useful, in that they don't change with the prevalence.

So, what I did was, I took some of the information from the studies that were presented, and I converted the sensitivity and specificities to positive and negative likelihood ratios, and I assumed...I just used the prevalence in the report as the pre-test probability. I sort of said, what if we think this condition is less likely or more likely, and then if there were two radiologists who gave information, I used the better test characteristics of that test. So, basically if you look at this broken down into the top part, acute rhinosinusitis, chronic, and fungal, the green bolded are the prevalence in the studies. So, if you take the Berg, for instance, x-ray versus CT, 72% was the pre-test probability, because that was prevalence, and looking at the likelihood ratio of that test, the positive likelihood ratio of five, you can use a nomogram or you can stick it into a computer, but what that says is, if I have a positive test, that takes me from a pre-test probability of 70%, because I'm in a specialist office and that's what I would think to have, to 90%. So, let's step back and say, is that enough to make me do the test. If I already think someone is more likely than not to have the condition, is that additional information going to help me based on that likelihood ratio. When you're talking about likelihood ratios, likelihood ratios of ten or higher are usually pretty good in terms of saying, yeah, this is a good test. Less than that, two to five, not so bad, five to ten, pretty strong, but ten you can pretty much say, yes. This is a good test. In terms of negative likelihood ratios, the lower they are from one the better. So, you can see that again, looking at these, the likelihood ratios, overall, are not that stellar. Take, for instance, the same test for acute Berg. If you thought...let's say in your normal practice...your primary care practice one in five people that you see you think really have acute rhinosinusitis, well if I got that test, in this case the x-ray, that would increase my post-test probability to 50%. Is that enough to treat? Again, these are all decisions that we make all the time, but again, the power of the test is in your ability to move from that pre-test sense you have, or if you know the prevalence of the condition to that sort of post-test probability. What I would add...actually, before I go to this, I would add a couple of comments about acute rhinosinusitis. About 80% of people who have it in this Cochran Study, and this was referenced in the report, will resolve without intervention or with placebo in two weeks. So, the natural history of this disease is, more often than not it goes away without intervention. So, I think that's an important thing to realize. Another thing that was mentioned, and I apologize, it's actually in this reference at the bottom of the test here, is that in one study folks did a retrospective look at people who had head CT's done for different reasons that was not sinusitis, and they found about 40% of those people had findings in their sinuses, but you could say, gosh, maybe they had sinusitis, but that's not what they were being seen for. Then, another study looked at a bunch of folks with acute upper respiratory illnesses and found that about 20% of those folks had changes that

you could, again, diagnose as sinusitis without really having any symptoms, and those are found in that resource at the bottom.

I show this slide to show you that in terms of making a diagnosis of acute rhinosinusitis, physical exam, if you look at these likelihood ratios or signs and symptoms, are as good if not better than most of those tests that we saw. So, these are just different signs and symptoms. When you have, to the left, more than four, you have a likelihood ratio of six, which is a pretty good predictor that that's going to move my initial thought to a more positive diagnosis, and the same thing on the right. So, these are just stronger clues that you might have an acute sinusitis than actually the tests in the previous slide.

Let's talk about harms for a second, really pretty minimal. These are just different millisievert doses compared to what the imaging study is. If you look at the arrow, point one is with the new cone CT's that can give a much more directed sense of radiation, so much lower, point one, and then the one millisievert is from a traditional CT, which I don't think are used as much for this imaging, though I'm not a radiologist. So, in terms of harms, not hugely problematic, but still some radiation.

I focused on this particular set of recommendations for acute uncomplicated rhinosinusitis, in part because it's from the American College of Radiology, and if you look, they rate things on a scale from one to ten, and if they rate something, seven, eight, or nine, it's usually an appropriate test to use, and if it's four, five, or six maybe it's appropriate. So, if you look at CT paranasal sinuses without contrast, you can see in their comments that most episodes are managed without imaging. It's primarily a clinical diagnosis, maybe imaging is indicated if you suspect acute sphenoid sinusitis, or if there are atypical signs or symptoms or the diagnosis is uncertain. So, if that's maybe a test, and they say radiologists who actually would want to have x-rays, that it's not really a good idea, then that's a pretty compelling thing to me to say, gosh, maybe we need to rethink how often we do this, and then the RRL on the right is the relative radiation level that people are exposed to with a CT without contrast. The more dots, the higher the exposure. If you look in terms of an x-ray of the paranasal sinuses, they say usually not appropriate, and that's their lowest rating, and again, this is for acute uncomplicated rhinosinusitis.

Is it any different for, um, chronic sinusitis? Their contention is that if you are considering surgical planning, as far as managing someone who has chronic sinusitis then yes. CT of the paranasal sinuses without contrast is a very appropriate test for presurgical planning, but other than that, there is really no indication in the absence of presurgical planning they say may be appropriate. So, again, not particularly compelling from the group of folks who do the test and interpret it.

Choosing wisely, treatment for sinusitis, and this is just a partial part of this sentence, don't rush to antibiotics. The American Academy of Family Physicians and American Academy of Allergy Asthma and Immunology, antibiotics usually

do not help sinus problems, costs money, and have risks. They go on to say that if people have persistent symptoms for a week, they get sick, they get better, they get sick again or have signs of severe infection, then antibiotics may be appropriate. In terms of their recommendations, CT is only appropriate if sinus problems are often or you're considering surgery. So, again, pretty consistent messaging.

Is it a test that's done a lot in terms of Health Care Authority? This is Public Employed Benefit UMP utilization rates, and comparing the blue 2012 to red 2013, you can see that the use of CT went up a little bit from 2012 to 2013. MRI usage was about 400, pretty stable. Ultrasound, and most recommendations around ultrasound were linked to women who might be pregnant, not a great diagnostic utility so pretty low utilization. Then, x-ray there was a slight decrease around 373 down to 340.

This is just costs. Not an unreasonable amount of money spent on sinus CT's over those two years, about \$388,000 in 2013 versus \$340,000 in 2012, and again not insignificant amounts for MRI but not nearly as much. X-rays and ultrasounds are not nearly as expensive.

Looking at the Medicaid population again, this is just fee-for-service. I was reviewing this last night, and I was tired flying back from...I was in Nashville, and I thought, oh look at these. Look at these docs. Look how good they're doing from 2011 to 2012 to 2013 in their utilization of CT's, and then I realized that was when we switched all of our population to managed care. So, our (inaudible) shrunk a ton. So, that's just a reflection of many fewer people in fee for service, but still you can still a fair number of CT's done and x-rays. Not so much in the way of MRIs.

Then fee-for-service costs, you can see that looking at the most expensive CT from a peak of 94,000 in 2010 down to 25,000, but again, a large percentage of the population switched to managed care plans, and we don't have that data to compare. So, it's not clear what utilization in those different plans is.

So, in terms of what we cover now, Medicaid fee-for-service covers without conditions. Managed care plans, I am not certain what they do. I didn't request that information for this. Public Employee Benefit covers x-ray and ultrasound. CT and MRI require a prior authorization, which is similar to Labor and Industries, and the Department of Corrections covers x-rays but any other test, CT/MRI/ultrasound, do require prior authorization.

So, putting all this together, our summary for acute sinusitis...I didn't mention this, but as you'll hear in the report, it's challenging to distinguish between viral and bacterial sinusitis clinically and even with imaging. Sometimes, people have findings when they're not symptomatic. Most cases resolve without intervention. X-ray will identify and rule out fewer cases than CT. So, the point to make about CT is often used as the reference standard in these studies. CT changes can occur in asymptomatic patients who just have colds, and even

though CT was used because it's sort of the gold standard, there's not been a gold standard test against which CT has been compared, and then the favorable positive predictive values that we saw were, in part, due to the high prevalence and the settings in which these studies were done, and when you look at the likelihood ratios, they're a little bit less compelling in terms of making you switch from whether you're going to treat or not treat.

Chronic sinusitis, the likelihood ratios for both x-ray and ultrasound are low and not particularly helpful, especially when you're in a setting where you don't have a high prevalence. CT may be useful if there's surgical planning, but otherwise, its routine use may or not be of added clinical value. Chronic fungal sinusitis, CT is better at picking this up and is probably more useful in this setting, and they are both sort of aggressive and nonaggressive and I'm sure our expert can explain what to look for and what the difference is. So, this is a little bit different, perhaps, clinical entity. And then the cost-effectiveness, the studies that were done were for chronic rhinosinusitis and suggested that it might be cost-effectiveness if you don't do nasopharyngoscopy first. Again, as a primary care provider, I'm going to refer someone if I'm not sure of the diagnosis, and then that diagnostic piece will continue from there. So, the cost-effectiveness, I think, due to some of the caveats and limitations, may or may not be that solid in terms of recommendations here.

So, what do we recommend? For acute and chronic sinusitis, x-ray do not cover. CT scan, we recommend covering with conditions. If a person's acutely ill or red flags, and the next slide will suggest the red flags that were suggested in the different articles reviewed, if there's a concern for complications, and it's not just a straightforward sinusitis, or for surgical planning CT makes sense. Ultrasound, perhaps there is some utility to cover it in pregnancy, though that wasn't really clear from any of the information that the evidence report presented. An MRI, really, the utility probably is best left with a specialist in terms of if they're not able to see a tumor or something else. So, that again, could be covered with prior authorization.

Red flags, we sorted through this whole contention of how useful is imaging with a disease or condition that goes away on its own more often than not and that antibiotics can cause adverse side effects. Red flag symptoms that would change this would be altered mental status, someone with a severe headache, obviously swelling of the orbit or visual changes, any neurological findings, signs of meningeal irritation, or signs of intracranial complications whether that be meningitis, an intracerebral abscess, cavernous sinus thrombosis, or involvement of nearby structures, i.e. a periorbital cellulitis. These conditions presenting with signs and symptoms of acute rhinosinusitis would obviously elevate your pre-test concern to a whole lot higher, more serious problem that would warrant more active intervention than watching and waiting.

Craig Blackmore: Questions?

Richard Phillips: Could you go to slide 18?

- Charissa Fotinos: Sure.
- Richard Phillips: Up to this time in your discussion, you were talking about acute sinusitis. You then presented utilization rates. Are those utilization rates indicative of both chronic and acute?
- Charissa Fotinos: They're both. Yeah, we weren't able to separate those out, unfortunately. We had some data limitations. Is that correct, Suzanne? We were hoping to sort them out, but we couldn't.
- Richard Phillips: Is it fair to say that those data would also include patients who have no sinusitis at all, who undergo diagnostic studies for...
- Charissa Fotinos: We...well, no. We used...we used the diagnosis of sinusitis, whether it be acute or chronic. We weren't able to separate them out. So, anybody who had a diagnosis of sinusitis across that spectrum were reflected in these tests. So, it wasn't just a sinus CT because they had a headache. Is that correct? Yeah, but we couldn't parse them out as finely as we wanted to.
- Richard Phillips: OK.
- Craig Blackmore: So, I'm sorry. So, this is not the total number of sinus CTs, this is the number of sinus CTs in people diagnosed with sinusitis?
- Charissa Fotinos: Yes, that is correct.
- Craig Blackmore: Do we know the total number of sinus CTs?
- Charissa Fotinos: I didn't. I can look in the report and ask.
- Craig Blackmore: So, one interpretation of this would be these are the ones that were positive, but we don't know how many of them were negative.
- Charissa Fotinos: Well, but you can make your diagnosis before you did the test, right? You... presumptive diagnosis, so I'm not sure...
- Craig Blackmore: Presumptive diagnosis.
- Teresa Rogstad: ...if we can parse it out. I mean...
- Craig Blackmore: ...so it may or may not be.
- Charissa Fotinos: Right. I mean, our...yeah, again, this is a really rough and not particularly helpful demonstration of what tests are being ordered for and again, it's just a limitation of our ability right now to full information. Yes?

- Chris Standaert: This is a radiology question. So, are there people who order something not called a head CT for sinusitis? Do they order...do people only order sinus CTs?
- Craig Blackmore: They order a sinus CT.
- Charissa Fotinos: Oh, our expert wants to say something here. Yes, sir.
- Richard Phillips: I have another question about your...as I understand it, your current coverage decision basically has one decision for all of sinusitis, and what you're now suggesting is that we divide it into acute sinusitis and chronic sinusitis. Is that fair enough?
- Charissa Fotinos: I think so. I mean, but again, if you look at the recommendations, I mean, I think you could...you could probably combine them and say that we'll only cover CT if someone is acutely...I mean, I think you can combine the two. I don't think you have to make separate recommendations. I broke them out just to fit more with the way the evidence was reported.
- Richard Phillips: Your current recommendations...your current coverage decision basically globs them all together, though, does it not?
- Charissa Fotinos: Correct. It just says, order what you want right now for fee-for-service, correct. Yes?
- Amy Anstead: First, I was going to compliment you on a very good presentation, but yes. People do order head CTs to rule out chronic sinus disease. I'll just talk loud. So, people order CTs, they'll order head CTs, they'll order just a plain x-ray (inaudible) who have had imaging for a variety of reasons. People have had an MRI for a headache. So, imaging of the head looking for sinus disease. You know, people think that they have sinus disease. Everybody has sinuses. Everybody has from time to time a nasal complaint. Everybody from time to time gets a headache, and then eventually they end up in their doctor's office. So, the doctor has, you know...doesn't have an endoscope on hand. So, what happens is, some type of imaging gets ordered.
- Chris Standaert: Right.
- Craig Blackmore: Well, a couple things. We need you to actually have a microphone, because the meeting is recorded.
- Amy Anstead: Oh.
- Craig Blackmore: So, if that one's not working, we need to...
- Amy Anstead: I can turn it down.
- Craig Blackmore: OK.

- Amy Anstead: We had a little adjustment with the volume this morning.
- Craig Blackmore: Yeah. And so, and then sort of...the flip side of that is, you know, you're a specialist who gets referral and our challenge is that, there may be a lot of reasons to order a head CT. They may not all be appropriate, but one of them is headache, and that head CT might show sinus disease. Then, they get sent to you, but that's a different question from what we're facing today, which is what is the use of the sinus CT. So, sinus disease will show up on a lot of other imaging, but we're not here to look at indications for head CT, one of which may be headaches that might or might not be due to sinus disease.
- Chris Standaert: I guess, my question then, one, I suspect this grossly underestimates this, because I suspect a lot of people do order a head CT when they think somebody has sinusitis and they don't order a sinus CT, you know? Unless they have a radiology group that is particularly sensitive to readjusting their order, they're going to get a head CT. So, I suspect that underestimates it, and if we're only talking about...our ruling only applies to the sinus CTs, somebody will just turn around and order a head CT if we're not adjust...if we're not talking about...are we talking about only sinus CTs or are we talking about CTs for sinusitis? So, I just...I'm...I...the terminology...ordering the codes I'm not totally clear on. So, I just want to be clear on what we're discussing.
- Craig Blackmore: Well, that's a good question. So, the key questions for evaluation of rhinosinusitis or related complications.
- Michelle Simon: So, it depends on how the data was pulled. It sounds like if they used the ICD-9 codes for sinusitis and then pulled all imaging studies for the head CT related, then it would have rounded up both of those. I don't know how the data was pulled, so.
- Josh Morse: I believe that's how the data was pulled.
- Charissa Fotinos: Yeah. We have both of our data pools.
- Craig Blackmore: Yeah, I mean, I'm not sure we can get at head CT, but...so that I...well, let me make sure I understand. So, this data is all CT scans with the diagnosis of sinusitis or CT scans of the sinuses?
- Charissa Fotinos: All CT scans with the diagnosis range for sinusitis.
- Craig Blackmore: So, all CT scans. OK. OK. I have another question, and that is how, on slide 18, there's 2000 odd CT scans performed. How many surgeries were there? If we're going to discuss this potential one indication that's been discussed, this preoperative planning, so how does this number relate to the number of procedures that are performed?

Charissa Fotinos: That is information we'd have to ask to be pulled, but that's a good question. We'd have to look. We'd have to figure out the timeframe after this was ordered, in which it would count toward...

Craig Blackmore: I mean, how many sinus CT...how many sinus procedures are done a year in any timeframe? Do we know... we don't know that, yeah?

Charissa Fotinos: No. I do not.

Craig Blackmore: Any other questions?

Seth Schwartz: I'm just struggling with how important this data actually really is pertaining to our question, because there's two...there's very distinct indications for sinus surgery...or sinus imaging that we're talking about, which is...there's... a patient comes into their primary care clinic with some symptoms of sinusitis, and either they get treated, they get treated, or they get imaged, and I think that's sort of the circumstance where there's...there should be scrutiny on this, because there's a real question of whether a sinus CT is indicated in that situation. The second situation is, somebody has sinusitis and has not responded to therapy or it becomes chronic and you're considering something else like surgery or out to a specialist or something, and in that situation, the CT is being used to sort of say, either is surgery appropriate or is there something going on, or is it not sinusitis at all that's causing their symptoms, which is...which I think is probably less controversial or is less questioned as an indication. So...and I don't think this data separates those scenarios out at all. So, I don't think we really have any meaningful idea on whether CTs are used appropriately, inappropriately, too much, not enough. I think this, I mean, we just have a number that probably doesn't mean very much to us right now.

Craig Blackmore: OK. So, let's move on. We're at...the next item on the agenda is the scheduling of open comment period. So, these are open public meetings. Anyone is allowed to participate, and we also have the opportunity for anyone, either here physically present or on the phone, to provide input to the committee. So, this is that designated time period. I don't know. Did we receive any advance?

Josh Morse: No, Craig. There's nobody signed up in advance.

Craig Blackmore: OK. So, nobody has signed up in advance, and we've put a clipboard out front to see if anybody wanted to sign up to address the committee, and nobody has. I'll ask if there's anyone here in the room who wishes to address the committee and seeing no volunteers, we will check the phone. This is the Health Technology Clinical Committee meeting on the topic of imaging for rhinosinusitis, and this is the open public comment period. So, if there's anybody who has called in to the meeting that would like to address the committee, this would be your opportunity. So, please let us know now. Hearing no one, we will close the public comment period and move on.

So, the next item on our agenda is the evidence report.

- Seth Schwartz: Craig, can I ask one further question for the presenter? I guess I don't...I'm sorry. After that presentation, I still don't really understand why we're asking this question. So, can you maybe summarize for us what...really why this topic came up?
- Charissa Fotinos: I think Josh (inaudible) it as well. I mean, I think the topic came in just because I think that there was a sense that there was a reasonably high utilization and questioning the utility of imaging in most circumstances. So, I think it was sort of a...I don't know if there was a particular instance that prompted it, but it was a topic that just folks noticed a sense of, gosh, they seem to be ordering a lot of these, and it's not probably how good is this test to use. It's a common condition. I think it was more the sense of...Josh, would you add to that in terms of the discussion?
- Josh Morse: Sure. So, when the agencies selected this topic, they were looking at some utilization data from an earlier data pool, which goes back further, and I believe the numbers in the older data show higher utilization around x-rays. In particular, I recall a conversation around that, and the... I think choosing wisely, the recommendation in there was a trigger to put this on the priority for consideration.
- Kevin Walsh: One of the, one pieces of information that would have been helpful to see was the...the number of diagnoses that were made for these different payer groups, because if the...if the utilization of CT scan now is 0.05% of all diagnoses, do we really think we're going to improve that a lot by clamping down on the test. I mean, so this is a little bit of a...it's difficult to wrap your arms around.
- Amy Anstead: Fair question. I can see if anyone can pull that data this morning. I doubt it, but I can see. If you're...if you're trying to clamp down on the number of CT scans, maybe you can clamp down on the number that are done on a single patient. One thing that I often see is, patients will come in and they'll have eight CT scans of the sinuses in a year and so, you know, really a patient...maybe they need one and then they need one more before they have surgery. So, they have one to diagnose what they have, another one to prove that they didn't respond to your treatment and that they're going to have surgery. So, I would say a maximum, really, of two per year unless they have some type of complication or immunosuppression.
- Craig Blackmore: Dr. Rogstad?
- Joann Elmore: If we're moving to the evidence review, I'd like to make a request. In thinking through measures of accuracy of the imaging, we need to know what the gold standard reference is and how it's being defined. This can be defined based upon, according to these papers, many different ways. They can define the presence of this clinical entity by clinical history and exam findings, or they can define it based upon CT scan, or they can define it based upon histopathology and cultures. So, as you're going through, it would help me to understand, you

know...giving us sensitivity and specificity without knowing how is that defined, what is the gold standard, is not helpful. So, that would help me as you're going through this, please.

Teresa Rogstad:

Absolutely. Good morning. I'm Teresa Rogstad. I go by Teri. My colleague, Natalie Slezak, is also here. We are both senior medical research analysts with Hayes. Natalie was the primary writer of the report. So, we'll be working together to answer your questions during the discussion. There are two binders on the committee's table with all of the studies...hard copies of the studies that we selected for the key questions. We've got a slide with some abbreviations that you might need to refer to. The presentation will follow the usual format starting with background, describing the report and the findings, summarizing guidelines and payer policies, and then a wrap-up.

Rhinosinusitis refers to inflammation of the lining of the paranasal sinuses that may or may not be due to an infection. A prevalence estimate suggests that 35 million Americans in a given year might have chronic rhinosinusitis. The diagnosis, as has already been stated, is a presumptive diagnosis based on symptoms. The case definition for acute bacterial rhinosinusitis are upper respiratory infection symptoms lasting more than ten days or symptoms that worsen after an initial improvement or are especially severe or accompanied with a high fever, and those typical symptoms include things like nasal congestion but also facial-dental pain or headache. Several factors can make individuals more likely to develop rhinosinusitis. That includes allergies, systemic disease like cystic fibrosis, immunosuppression, anatomic abnormalities, and recent dental work or trauma.

Rhinosinusitis can be classified according to duration. The definitions that you see there are pretty widely recognized. These are just conventional definitions. The disease can also be characterized as recurrent if there have been at least three episodes in the past year with the patient being asymptomatic between episodes. The reason for symptoms, or the reason for inflammation can be varied. The vast majority of cases of rhinosinusitis are the result of a viral upper respiratory infection, and most of those spontaneously resolve. A small percentage of cases are bacterial. Other causes include fungal infection or an allergic condition.

Because the symptoms are so nonspecific, clinicians sometimes turn to a more objective means of confirming a diagnosis. The gold standard is considered aspiration with culture or histopathology using a biopsy specimen, usually obtained during surgery. The aspiration procedure is very painful, so it's not used in every day practice, and of course surgery is reserved for more refractory cases. The practice guidelines advise that when patients don't respond to an empiric trial of antibiotics, that an imaging and typically CT and/or nasal endoscopy be performed, but the relationship between CT and rhinosinusitis is not straightforward. Only about 20 to 36% of patients with symptoms of chronic rhinosinusitis have CT-confirmed disease, and it's widely recognized that

there is no correlation between symptoms and severity according to CT findings. MRI, x-ray and ultrasound are also sometimes used.

There are several scales for radiographic staging for assigning a score to the severity of radiographic disease. The most common one is called the Lund Mackay score, and it's based on the degree of opacity across all of the sinuses. It appears, from what we saw in the literature that this is used primarily in research. The Lund Mackay score was used in some of the studies that we selected, but not most of them, and these radiographic scoring systems are not mentioned in the practice guidelines. When a scoring system is not used, then the most common features that we saw being looked at were mucosal thickening, opacification, and the presence of an air-fluid level.

If symptoms have persisted for more than ten days, or they're severe, then patients are typically offered antibiotics. Three systematic reviews have demonstrated a modest effect of antibiotic treatment for acute rhinosinusitis, but one of those reviews found that 80% of the adults in placebo groups improved within two weeks. There's an increased risk of adverse events with antibiotics, but they are minor. We didn't find any systematic reviews of antibiotic x for chronic rhinosinusitis. Other treatment includes steroids and immunotherapy or over-the-medications or nasal irrigation to relieve symptoms.

Refractory cases sometimes undergo surgery. The current technique is functional endoscopic sinus surgery, and the purpose of that procedure would be to remove infected mucosal material or correct a complication. Immunosuppressed patients are at a greater risk of invasive infection. So, they are especially likely to be considered for surgery. We identified four systematic reviews comparing endoscopic sinus surgery with medical treatment and none of them demonstrated a clear advantage for adults or children, but unfortunately, the systematic reviews did not analyze results according to patient factors or clinical history, and one of the reviews mentioned that most of the included studies didn't report that kind of information either. The practice guidelines consider imaging to be mandatory for surgical planning.

As has been noted, the policy context for this report had to do with observed utilization rates and the fact that imaging is not sufficiently accurate to serve as a gold standard for a diagnosis. The American Academy of Allergy Asthma and Immunology submitted its list of things that physicians and patients should question as part of the Choosing Wisely program, and number two on their list said don't order a sinus CT for uncomplicated acute rhinosinusitis. So, the evidence-based assessment was requested to look at the accuracy of imaging and its impact on outcomes and cost.

The PICO statement specified four imaging modalities, CT, MRI, x-ray, and ultrasound, and the key questions related to PICO. The main questions had to do with the clinical performance of imaging. Clinical performance is another way of saying accuracy, and clinical utility looking at not only the impact on

management decisions but also health outcomes, and there were subquestions asking whether or not clinical performance or outcomes varied by the type of imaging or patient characteristics.

Our search ended on March 20<sup>th</sup>. We excluded studies conducted in inpatient settings at the program's request, and we restricted our selection to English language publications. Our final selection included 21 studies. Fourteen of these looked at accuracy. There were three clinical utility studies and four cost comparisons. We did not find any studies directly assessing safety outcomes, or the differential effect or accuracy.

Before I go into the findings, I would like to remind the committee that the slides present a limited amount of detail. There are more quantitative details in the summary of findings tables and also in the full evidence tables, which are at Appendix IV of the report.

I would also like to give just a little bit of a refresher on how to evaluate the meaning of sensitivity and specificity results. If you take a hypothetical situation where a test is, say, 100% sensitive but only 65% specific, the clinician can have a high degree of confidence in negative test results, because you're not going to have any false-negatives, but confidence in a positive test result would be relatively low, because there's a good chance for false-positives, and there's a helpful mnemonic for remembering that. It is called...huh, it didn't come up. It's in your slide handout, and it is SnNout, which reminds us that a highly-sensitive test is a good test for ruling out disease if the results are negative. Then, the correlator to that is SpPin. A test that is highly specific is a good test for ruling in disease if the results are positive. So, that might be helpful to think about, as we go through the discussion.

For key question number one, I'm first going to give you the preview and show you the volume of evidence that we found by imaging modality, and then I'm going to reorganize that information and discuss it by disease classification. For CT, we did not find any studies looking at accuracy for diagnosis of acute or chronic rhinosinusitis, but we did find several studies looking at the accuracy of CT for detecting fungal rhinosinusitis. One study looked at the ability of a preoperative CT scan to predict adverse events associated with surgery.

For x-ray and ultrasound, we did find several studies looking at accuracy for acute and/or chronic rhinosinusitis, but they all used CT, as the reference standard. A single study looked at the ability of MRI to detect fungal rhinosinusitis using histopathology as a reference standard.

So, this is the same information organized a little differently. In the middle column, we present the results of the studies, and we used red font to highlight the problems with each body of evidence. The use of the terms low, moderate, and high might be a little bit confusing, because we're using them in two ways. In the right hand column, low refers to the quality of the evidence and the degree of confidence that we can have in the study findings. In that middle

column, we're talking about whether a sensitivity and specificity were low or high. So, that's the actual results of the studies.

So, for acute rhinosinusitis, we just found three studies evaluating x-ray and using CT as the reference standard. We downgraded the quality of that evidence not only because of inconsistency in findings and the quantity of data but also because CT was actually...we considered that an imperfect reference standard, because we don't know how accurate CT is. That was all we found for acute rhinosinusitis.

For chronic rhinosinusitis, a single study looked at CT as a prognostic tool prior to surgery. Again, a few studies looking at x-ray and a single study looking at ultrasound to diagnose chronic rhinosinusitis, and then, several studies looking at CT and/or MRI.

So, I'll go through the quantitative data now starting first with acute rhinosinusitis. The three studies all demonstrated pretty good sensitivity but there was a lot of inconsistency in how specific x-ray would be for detecting acute rhinosinusitis using CT as the reference standard.

Craig Blackmore: 70 is pretty good? 70% is pretty good for sensitivity?

Teresa Rogstad: That would be considered moderate. The cutoffs we used are 70 to 80 for moderate, 80 to 90 for moderately high, and above 90 would be high. Anything below 70 would be considered low.

Craig Blackmore: OK.

Teresa Rogstad: 50% is, of course, random chance.

Craig Blackmore: Yeah.

Teresa Rogstad: So, then for chronic rhinosinusitis, we had another three studies. Well, let's see, I guess I'll look at preoperative prediction first. A large observational study showed a statistically-significant association between the Lund-Mackay score and the occurrence of intraoperative complications, as well as revision surgery at 36 months, but the authors did not consider these findings to be particularly useful, because they couldn't identify a meaningful cutoff score on the Lund-Mackay scale. So, they weren't sure how the score would be used to choose patients for surgery.

Another three studies looked at the accuracy of x-ray, again, using CT as the reference standard. Although the overall accuracy calculations were not too bad, the results, specifically for sensitivity and specificity, were pretty inconsistent, and the pattern of the relative value of those varied across studies. In one study, sensitivity was high, and specificity was low. It was the other way around in another study, and in the third study, both values were pretty good.

A single, very small study calculated very low accuracy rates for using ultrasound to diagnose chronic rhinosinusitis.

I will pause a minute. Dr. Fotinos made a very good point that almost all of these studies seemed to take place in otolaryngology settings. So, that would mean the spectrum of disease would be somewhat more narrow than in a primary care practice, which could mean that the accuracy estimates are higher than they would be in a broader spectrum of patients that you might see in primary care practice.

For diagnosing fungal rhinosinusitis, there were six studies looking at CT. In all of these studies, the patients underwent surgery because of refractory symptoms of chronic rhinosinusitis. Sensitivity findings were inconsistent, but all of the studies showed moderately-high to high specificity. Positive predictive value was variable, but there was a clear reason for that, and it had to do with the true prevalence of disease in the various study populations. So, let's look at that.

Four of the six studies were cohort or cross-sectional designs, which meant that we could calculate prevalence and positive predictive value. In the two studies on the left, prevalence was high, over 70%, and by prevalence I mean prevalence according to the histopathologic findings. So, positive predictive value was also high in those two studies, and in both study populations, the patients were selected because they had particular risk for fungal infection. In one case, there had been recent endodontic work, and in the other case all of the patients were immunocompromised. In the two studies on the right, the true prevalence was less than 10% and correspondingly, the positive predictive value was low. So what these data tell us is that even though specificity was really good across all of the studies, and that means that you could have high confidence in a positive test result and a decision to proceed with surgery, the efficiency of this...of using CT scanning for this indication would be a lot greater if the patients were at high risk for a fungal infection. The two other of the six studies were case controlled studies, which don't allow us to calculate prevalence or positive predictive value, but they both reported 100% specificity and one of them was conducted in patients who had hematologic malignancies. So, presumably, they were also immunocompromised.

A single study had imaged patients by MRI and CT, and MRI was found to be somewhat more sensitive than CT, but because of the small quantity of evidence, we considered it to be of very low quality.

Because we found so little regarding the accuracy of CT for diagnosing chronic rhinosinusitis, which is the main way that it is used, we looked at correlation studies. Two studies demonstrated a statistically-significant correlation between CT scores measured by the Lund-Mackay scale and either a culture rate or severity according to the presence of inflammatory markers, and what this relationship...what these findings tell us is that there is a relationship

between CT results and infection/inflammation, but it doesn't tell us what the sensitivity and specificity of the test would be in quantitative terms.

So, to recap, we found some evidence on the ability of CT to detect fungal rhinosinusitis and to make preoperative predictions of adverse events, and we found several studies of x-ray, one study of ultrasound looking at accuracy compared against CT. None of that evidence made a real compelling accuracy case, and then one study looking at MRI, and it did suggest superior sensitivity to CT for detecting fungal rhinosinusitis.

There were three clinical utility studies. They all were done in patients with symptoms of chronic rhinosinusitis. They provided very low quality evidence that a CT scan may alter clinical decision making. So, we will go into that in a little more detail.

In one study, three surgeons changed their minds about the appropriateness of surgery in 26 to 37% of cases, after they looked at the CT scan. In the other two studies, the CT scan seemed to be...seemed to result in reduced use of antibiotics. In the Conley and Tan studies, they were looking at the use of up-front CT, and that refers to a strategy where the CT scan is the first step in evaluating chronic rhinosinusitis, as opposed to offering an empiric trial of antibiotics and reserving the imaging for the nonresponders to medical treatment. So, in those two studies, the individuals who had the up-front CT had a lower use of antibiotics, zero versus 12% in one study and 40% versus 100% in the other study. We don't know the statistical significance of those comparisons, and both those studies are applicable only to patients who had a negative endoscopy before they were considered for the CT scan. We didn't find any clinical utility studies looking at the impact on actual health outcomes.

This was mentioned in Dr. Fotinos' presentation, I think. There is indirect evidence from two meta-analyses suggesting that there is no relationship between the use of imaging and the diagnostic workup of acute rhinosinusitis and the effectiveness of antibiotic treatment. So, you can draw an inference from that, that there might not be any clinical utility to doing the imaging in terms of impact on health outcomes. We didn't find any corresponding evidence applicable to chronic rhinosinusitis populations.

No studies directly looked at safety. These are well-established technologies that have been used for a long time. The primary safety concern would probably be repeated use of CT or x-ray because of the radiation exposure.

No studies evaluated whether the clinical performance or the impact on outcomes varied according to patient characteristics. Most of the studies didn't provide much detail about clinical history or patient risk factors. Several of the accuracy studies involved both children and adults but did not report results separately.

We found four cost comparisons, and these also looked at that strategy of up-front CT where the CT is done initially, and that's compared with the strategy of empiric medical treatment and reserving the imaging for the non-responders. Those studies suggested that overall costs were at a minimum. Medication costs would be reduced with the up-front CT strategy, and those results apply only to patients with a negative endoscopy result or no endoscopy before being considered for the up-front CT.

There are a lot of problems with those studies. Three of them were modeling studies. So, of course, they drew data for their assumptions from multiple different sources. They used Medicare rates for non-medication costs, even though there was no age assumption. The treatment response rates were not based on systematic review evidence, and the one trial based study computed only medication costs, not total costs. None of the studies looked at outcomes data. They all happen to be performed at the same institution, and the other thing that is unusual about this comparison is the up-front CT strategy is not actually recommended in the guidelines that we found.

I will very quickly run through these slides. Two studies suggested that in a tertiary care, either overall costs or medication costs, would be reduced with the use of up-front CT scanning. This would be for patients with negative endoscopy. A third study suggested that in a tertiary care setting, costs would be reduced regardless of the prior endoscopy results, but in their subgroup analysis, they found that if patients had a positive endoscopy, costs would be increased by doing the up-front CT scanning, and in the last study assumed a primary care setting, and estimated substantial cost savings if the primary care physician ordered an upfront CT before trying the antibiotic therapy or referring.

The only payer policy we found was with AETNA, and it applied just to paranasal sinus ultrasound, which is not covered for sinusitis or any other indication.

The practice guidelines were really quite consistent. I'll just focus on the recommendations regarding imaging. They all agree that imaging cannot be used to distinguish between bacterial and viral infection. CT is recommended when complications are suspected or symptoms do not improve, or there is a need for surgical preplanning. MRI was mentioned by some of the guidelines as a complement to, or an alternative to, CT in special situations. For instance, when there's a suspicion of central nervous system involvement. One guideline suggested ultrasound for pregnant women. Some of the guidelines mentioned x-ray as an option, but they characterized CT as the preferred imaging modality, and only one guideline said anything about repeated imaging. They made the comment that CT findings provide an objective method for monitoring recurrent or chronic rhinosinusitis.

So, to wrap up, this slide pulls together all the evidence we found for CT and the guideline recommendations. Perhaps, the most meaningful set of evidence had to do with the use of CT to screen for possible fungal rhinosinusitis, and we

found that CT has good specificity for that indication. The evidence, or the lack thereof, does seem to be fairly consistent with the restrictions implied by the guideline recommendations, which were in the right hand lower corner.

Then, this slide wraps things up for the other imaging modalities. There were several studies evaluating the accuracy of x-ray and ultrasound, but they used an imperfect reference standard, and the only consistent evidence from those two bodies was that x-ray seemed to be consistently fairly sensitive to acute rhinosinusitis. A single study suggested that MRI might be more sensitive for CT for detecting fungal rhinosinusitis. We don't know anything about the clinical utility of these three imaging modalities and their routine use is not supported by the guidelines. Additional research is really needed for all of the key questions, and I'll take my seat, and we'll answer your questions.

Craig Blackmore: Thank you.

Chris Standaert: I have some questions about sort of background. So, Dr. Fotinos mentioned some studies on people who had CTs for reasons other than sinusitis pointing out the frequency of sinus abnormalities on imaging in an essentially an asymptomatic or unsuspected population, and my background comes from the spine world where we have gazillions of studies on MRIs of asymptomatic people. We have studies where they took MRIs of asymptomatics and symptomatics and gave them to radiologists and said, can you tell which one's hurt. We have all these different studies. We have MRIs of people with a disk herniation and six or twelve months later we have MRIs. So, we understand the natural history of a disk finding. We understand time over population. We understand...we understand that we don't understand how to tell who hurts by looking at imaging, and your...you didn't get any of this if it even exists. So, I don't know if you were looking for it (inaudible) go looking, but I would love to know, you know...the data on CT...you look at this and go why do you CT anybody if you're not worried about something horrible is what I sort of come away with, because there's no data to say that it really helps you diagnose this...sinusitis. And things like CTs in symptomatic versus asymptomatic people would help. Radiologists looking at CTs trying to figure out who has symptoms and who doesn't. Can you do this by looking at CT.? Natural history data. So, if you CT somebody and then you CT them a year later, do they look the same? Are they better, are they worse? Have they changed? What happens? I mean, all that stuff would really help in terms of trying to figure out how you use this clinically. So, I'm just wondering if it exists or if you went looking, or you don't any of this because you didn't go looking?

Teresa Rogstad: We didn't go looking, but a lot of the review articles and the practice guidelines did cite studies showing a lack of correlation between symptoms and the severity of radiographic disease. So, we didn't pull those studies and analyze them, because there seemed to be a consensus that there isn't any correlation, and I think it is very analogous to back pain and spine imaging.

- Richard Phillips: I had a further question about the symptoms, and I'm having a big difficulty in trying to define what group of patients we're talking about, in particular, you know, you mentioned just a minute ago about the lack of correlation between the clinical symptoms and pathology, and the...Charissa's presentation she talked about red flag symptoms and her...I think it was in slide 16 of the...of her presentation where there's a whole list of things that are symptoms, and I'm not even sure how those relate to the symptoms that were considered for chronic sinusitis, things like headache, altered mental status, etc. In other words, I'm wondering if we're talking about two different groups of patients, you know, that we're going to be making a decision on. I'm wondering if you can really address the issue and perhaps our clinical expert can address the situation, too, of are we...are these red flag symptoms part of the complex that these patients present with that...in these studies that you have, or not, I guess?
- Teresa Rogstad: Well, Dr. Anstead should probably comment on this, too, that we didn't find an authoritative list of symptoms. Different specialty societies have slightly different lists. So, the symptoms that we put on our slides were the ones that seemed to be mentioned most frequently, but they overlap with symptoms for headache and for allergy, too. So, maybe you want to comment on that.
- Amy Anstead: So, I think your question's a valid one, because chronic sinus disease, or chronic sinus disease of a variety of different diseases. So, when she's pointing out some red flags, this is probably in a more acute setting where she's talking about complicated sinus disease, which is something different than just chronic sinus disease, which is different than fungal sinus disease, which is different from invasive fungal sinus disease, which is...so, I mean, there are a lot of different types of sinus disease. I think when she was talking about with the symptomatology that she was going through with the purulent rhinorrhea and the nasal congestion, headache, etc., etc., that's more for your acute...you know, your viral versus bacterial sinus disease. So, that's a different clinical entity than in somebody who has chronic sinus disease, because they're going to clear. So, getting a CT scan on a patient like that who has acute either viral or bacterial sinus disease is worthless, because they're sick and their sinus scan is going to look back, and then in the vast majority of cases no matter what you do to them, they're going to get better. Then, their CT scan will clear in the future. That's different than somebody who has chronic sinus disease where either they have allergy or they have allergic fungal sinus disease or some other type of chronic sinus disease, and you get a scan and there will be some disease, and then you'll treat them, or you won't, and their scan will look different in the future, and whether or not that person is symptomatic or not, bringing you to the other question about whether or not you can say does the...do the symptoms correlate with their scan. There are a lot of great studies that show symptoms have no correlation with what the scan looks like. So, some people can think...can walk around and think that they have horrible chronic sinus disease and you get a scan...and I've had patients break down in clinic crying because they've been told their whole life that they have chronic sinus disease, and they have a beautiful, clean, clear CT scan. Then you have the reverse of this, as people come in and their eyes are literally bulging out of their head

because they have such severe allergic fungal sinus disease. Their sinuses are eroded and encroaching upon their orbital walls and their eyes are literally being pushed out of their head by this severe chronic sinus disease, and those patients have no symptoms. So, does that answer your question?

Richard Phillips: Thank you. That's good.

Marie Brown: Could you help me understand slide 46 where it showed cost savings to do same-day CT along with endoscopy?

Teresa Rogstad: Is this the slide that you want, or one of the slides with the actual study detail?

Marie Brown: 46.

Teresa Rogstad: The next one, right. Is that the one you're referring to? That one and the previous one?

Marie Brown: Uh-huh.

Teresa Rogstad: So, you're wanting to know how they did those analyses?

Marie Brown: The cost savings. Can you help me understand the cost savings in doing same-day CT, what that would be due to?

Teresa Rogstad: OK. They looked at the cost of...all of the direct medical costs. That included the office visits, the cost of endoscopy, the cost of CT scanning, the cost of antibiotics, the cost of other medications, the cost of the followup appointment, and they found that total costs were less in the group that had...and this is the Modelling Study. So, they predicted that total costs were less if patients had up-front CT scanning compared with empiric medical treatment, and then they did kind of a subgroup analysis, and the subgroups were whether or not the same-day CT was available. If the patient can go directly from the initial office visit to get a CT instead of coming for an extra appointment, that's going to reduce costs. So, that's why there was more of a cost savings where the same -day CT was available.

Marie Brown: So, they were assuming cost savings if they had a positive CT prior to having the endoscopy?

Teresa Rogstad: No. The endoscopy was done first.

Marie Brown: OK.

Teresa Rogstad: And then regardless of the endoscopy results, this particular study predicted these cost savings, but then if they assumed a positive endoscopy result, it actually added costs to do that up-front with CT.

- Amy Anstead: By ruling out the disease so that they don't get treatment. Is that what the cost savings is from?
- Teresa Rogstad: Yes. Good point. Right. The reason you would expect it to save cost is they avoid treating disease is the theory.
- Chris Standaert: So, that's confusing to me, though, because there's very little correlation...there's no correlation between what you see on the scan and symptoms.
- Marie Brown: Right.
- Chris Standaert: So, how can get a scan really change your clinical behavior unless it's utterly normal, and you say I'm not going to give somebody who has an utterly normal CT antibiotics, but then that's where these questions about studies in the general population become quite relevant, right? So, if you have a 40% prevalence in the general population of sinus disease, asymptotically, you get lots of CTs in your...I mean, frankly you're...
- Amy Anstead: Well, it's not quite that high. It's somewhere between 10 and 20%. So, 10 and 20% of the people are walking around with some kind of finding, some type of sinus disease. Whether or not it...
- Chris Standaert: So, again, that...we...that's from...
- Amy Anstead: And so there's...there's various studies looking at just...
- Chris Standaert: Right.
- Amy Anstead: ...CT scans for whatever reason.
- Chris Standaert: Right.
- Amy Anstead: So, if somebody comes in and they get a...they think they have an aneurysm and they get an MRI and then they look and they see, oh they have a cyst in their maxillary sinus. Well, a third of the people can have some type of little cyst in their maxillary sinus. So, it just depends on how their data...how they're defining chronic sinus disease on the scan. So, whether or not that's clinically relevant, and usually it's not clinically relevant.
- Chris Standaert: Right.
- Amy Anstead: So, what...I think what this study is trying to say is that many, many, many people come in and they think that they have a sinus problem, and I'm sure it's often in headache or allergy or these types of settings. So, what they do is, they go ahead and get a CT scan and probably in most cases, they're ruling it out. So, they're not starting them on antibiotics and prednisone and nasal steroids.

They're not starting them on medical regimens. At least, that's what I would gather from this study.

Marie Brown: Because they had normal scans?

Amy Anstead: Because they had normal scans.

Chris Standaert: But this study...

Amy Anstead: Or they have something that...

Chris Standaert: ...is just a Modelling study. This isn't actually...

Craig Blackmore: And this is only dealing with people that are being...

Amy Anstead: The same day.

Craig Blackmore: ...referred for endoscopy. This isn't the primary care population.

Amy Anstead: No. It's not.

Chris Standaert: Right.

Amy Anstead: (inaudible)...

Craig Blackmore: And this is...

Amy Anstead: ...other study.

Craig Blackmore: You know, this...what's the relevance of this? The people that are already being sent to the otolaryngologist or from...

Amy Anstead: Right.

Craig Blackmore: ...this, they've already gotten an endoscopy.

Joann Elmore: This is a Modelling study based on 80 patients. It is not...

Craig Blackmore: We're not a primary care population.

Joann Elmore: ...relevant. It's classification regression 3 analysis.

Craig Blackmore: I mean, I don't...

Michelle Simon: Well, the second one is in a primary care setting, or so it says.

Craig Blackmore: But they are people that already got endoscopy?

- Michelle Simon: It doesn't say that.
- Teresa Rogstad: In that last one...this also was a Modelling study. So, based on a lots of assumptions. For the up-front CT strategy, it was assumed that the primary care physician would order the CT. If it was interpreted as positive, the patient would get sent to an otolaryngologist or the primary care physician would do the treating. There are two scenarios there. For the empirical medical treatment comparator, it was assumed that either the primary care physician or the otolaryngologist that the patient was referred to would try the medical treatment first, and then would do an endoscopy first, right, and do the empirical medical treatment if the endoscopy was positive, and then do a CT scan if the medical treatment didn't work.
- Craig Blackmore: But, this is not the reality of clinical care. I mean, you don't refer every patient with sinusitis to an otolaryngologist, right? It's a primary care condition in the vast majority of...
- Teresa Rogstad: Well, that's...that's why they did look at two scenarios, one...
- Craig Blackmore: Well, no, they looked...you told me they looked at the CT scan people, and they compared that with referring them to the otolaryngologist. I mean, that's not...
- Teresa Rogstad: No. They looked at...they compared up-front CT scanning with empiric medical treatment under two scenarios. In the first scenario, treatment was carried out by the primary care physician. In the second scenario, the primary care physician referred to the otolaryngologist.
- Chris Standaert: Yeah, but they're...
- Teresa Rogstad: And this was all Modelling decision based...
- Craig Blackmore: But how can a...
- Teresa Rogstad: ...on a...based upon ENT data for their probabilities.
- Craig Blackmore: ...I just don't understand how it can be cheaper to give somebody antibiotics that cost \$30, how that can cost more than a CT scan that costs hundreds.
- Chris Standaert: In a disease that has a pretty benign natural...
- Craig Blackmore: Treated as a benign...
- Teresa Rogstad: Right.
- Chris Standaert: ...history, and it's also confusing to me, because that includes two assumptions. There's the CT assumption and a treatment assumption, and we're not addressing treatment. We're not addressing should you treat acute

rhinosinusitis, and maybe in their model they're treating something they shouldn't be treating, but then there is debate, but...

Kevin Walsh: Well, we can ask a specific question about the study, which is what was the prevalence of sinusitis based on imaging in that study? Can you...that's a number you should be able to pull out for us, because if it's 5% and they didn't treat 95% of the people, you can understand why it would be cost saving, right? If they, if it was 50% then the data doesn't make sense. So, can you find that number for us, or do you know that number off hand?

Teresa Rogstad: Uh, I'll look for it.

Craig Blackmore: Actually, that doesn't...that doesn't make sense. You're still doing CT scans on 100 people whether you're treating 50 of them or 5 of them.

Chris Standaert: The question is maybe you shouldn't be treating them at all, frankly.

Seth Schwartz: There's that, yeah.

Craig Blackmore: The screening costs more than the treatment. How can screening save money?

Marie Brown: Right, yeah.

Michelle Simon: Is the cost of the screening included, or are they referring...are they taking this out of this amount?

Chris Standaert: Because they give them C. diff and they went up to the hospital and then they...I don't know.

Marie Brown: Maybe we can just conclude this is not a helpful study.

Joann Elmore: That's what I'm concluding.

Craig Blackmore: Richard, what's...

Marie Brown: And, I mean, because it was showing cost savings, that's why I wanted to bring it up, because I thought this could be a little problematic, but it doesn't look like it really applies to...

Seth Schwartz: OK, it does make sense, because what you're modelling is if you do CTs versus not do CTs.

Craig Blackmore: And they're saying doing CTs saves money?

Teresa Rogstad: The assumed prevalence of chronic rhinosinusitis in that Leung study was 12%.

Joann Elmore: Because it was based upon reference 14 in that paper, which was an ENT referral.

- Craig Blackmore: I still don't...
- Seth Schwartz: And also, are we talking about chronic sinusitis, or are we talking about acute sinusitis here?
- Teresa Rogstad: Chronic.
- Seth Schwartz: Yeah. So, I mean, that's a different situation that we're talking about.
- Craig Blackmore: Richard, do you want to?
- Richard Phillips: I have a question about our...the imaging studies in general, in terms of their...how they relate to the diagnoses. It seems, as an example, fungal sinusitis, that, say post-test diagnosis. Pre-test diagnosis, you're not going to have a clue, and most of our decisions have to be made on pre-test conditions, I think, and yet we're being given information that is based on post-test diagnoses. So, it's a basion, you know, conundrum for me. It's, you know, a conditional diagnosis, and I'm not sure we're saying...we're coming to the same conclusions. We're never going to come to the proper conclusion if we use this data as the basis for our answers. So what I'm wondering... I guess what I'm wondering is that so what... so what we have... and so what if the CT is better for picking up fungal sinusitis. It's almost irrelevant because it's a post-test diagnosis, and we want to look at it pre-test. We need that data at the time before.
- Teresa Rogstad: The way we interpreted those studies, and Dr. Anstead should probably speak to this, but it appeared that the CT scanning was done either to demonstrate the probability of a fungal infection, or the patients had such refractory symptoms that they were going to do surgery anyway, and then they used the post-surgical results to evaluate how accurate that pre-surgical assessment based on CT was. So, if you generalized those findings to other situations where you weren't going to get the postsurgical confirmation, you know, you would use those sensitivity and specificity estimates to decide whether you believed the results of the CT scan. Does that sound about right?
- Amy Anstead: So, can you repeat the question?
- Richard Phillips: Well, I think the real issue is that so much of the testing, which has been provided to us is based on a diagnosis decided after this test has been done when in reality, what we're really asking to do is to look at people before when they present. So, I'm just trying to figure out if this is the same group of people, and I suspect it's not.
- Amy Anstead: Yeah, and I think that it's the conundrum of the primary care physicians. You have a patient who comes in, and I think the majority of patients that they're presented with are the patient who claims that they have chronic sinus disease. So, the patient comes in and tells them, I have chronic sinus disease. I have had

sinus problems for five years, and I have tried this, that, or, you know, the other thing. So, the primary care physician is then, you know, what do I do? Do I go by the patient's symptoms and continue to treat the patient, even though they're not, you know, wait and see if they get better, or do I do a CT scan to see if they actually do have some type of finding that I should treat. So, I think that that, that's probably the more often case scenario.

Chris Standaert: I think there's some more blurring here, which goes back to one of the questions I brought up earlier that some of these people who are refractory, and you start talking about people with erosion into bone and orbital changes and neurological, I mean, you're looking for osteomyelitis. You're looking for all sorts of horrible stuff. This is not sinusitis, as I think of it, right?

Craig Blackmore: Right.

Chris Standaert: So, you're in a whole different category by the time you're talking about these people, and you look...if somebody was, you know, gross immunosuppression who's ill with fevers and horrible headache, yeah. You're worried about a fungal infection. So, you might go looking, but again, you're almost...these different categories, and we sort of, even when we get to some of the, like, the first presentation when we heard about these thromboses and other sorts of things, you're after different diagnoses. I mean, if it's a severe crushing headache, you may be having sinusitis somewhere in your differential, but you may also have all sorts of other things, too. You're looking for osteo-... you're looking for bleed. You're looking for all sorts of stuff. You're looking for a tumor. You're going to...

Richard Phillips: See, I totally agree with you. That's what I'm concerned about is...

Chris Standaert: CT, they make this leap...

Richard Phillips: ...that we're...

Chris Standaert: ...into other medical conditions or overall. You're not just looking for sinusitis. That may be all you find and you say, oh, OK. This is what I got, and they have horrible headaches, and I'll send them to the ENT and see what they think of this, but they didn't get the CT necessarily looking to make that diagnosis, you know? So, it's...it definitely morphs as we go...as you go further into this sick, bizarre, chronic, you know, more complicated presentation.

Seth Schwartz: I think that makes a lot of sense, and I think that's what we're going to be struggling with is that there's really different populations where you're using the imaging for very different reasons, and I'm thinking more and more about this study and realizing that they're using it for chronic rhinosinusitis. I think the question, probably, that they were addressing has to do with, if you have a patient with chronic rhinosinusitis, and you're trying...or at least with symptoms that could be consistent with chronic rhinosinusitis, and you're trying to decide what do I do with this patient, and the question is, do I send all of those patients

to the ENT doctor, or do I get an imaging first, and if the imaging is negative, I don't have to send them to the otolaryngologist. So, if only 12% of them have a positive CT, then only those 12% are going to be referred to an otolaryngologist for further management whereas 88% are not going to get that. So, you can see how it would be actually cost savings in that situation, because 88% of the people did not need to get referred for further treatment. Whether they got antibiotics or not is irrelevant. It was the referral for more advanced care. So, that's a situation where I don't know what the clinical data really is, but you can see how it would be useful.

The other scenario is the primary...is a patient presenting with symptoms consistent with acute sinusitis, do those patients need imaging or do they simply need to be treated or not treated based on what you want to do. I think we're having a hard time because the data that we got presented is fairly muddled about what's talking about chronic sinusitis and what's talking about acute sinusitis. In the setting of acute sinusitis, we've seen basically no data to say that it is useful other than this presumed situation, but if you got someone who has symptoms of acute sinusitis and their eyes bulging out of their head, that's a situation where yes, you're looking for something else. You think maybe they have...not only do they have sinusitis, but maybe it's causing this acute complication that you have to manage differently than a standard patient with acute sinusitis. So, I think we're kind of struggling because everything is kind of muddled together, and then you have these other questions of fungal and acute...invasive fungal which is really a totally different disease, which we really have no business talking about today, because those are very, very different patients. I think when you look at what the Choose Wisely campaign had, that data was pulled from the guidelines, which were really looking at the situation of what do you with a patient presenting to a primary care situation or presenting...initially presenting with signs and symptoms of acute rhinosinusitis. Should you image? Virtually all of the guidelines say, no, you should not. The data is not good, but there was no data to support it. So, multiple different specialties said, don't image in that situation, and that's what kind of brought this topic to us today, and I think that's really what we should be trying to pull out of this and figure out. OK, can we either say yes, don't image in that situation or come up with circumstance under which it's useful or not useful in that primary environment. I think the rest of it is going to be very, very hard for us to make any useful statements about, and the data is a morass, because there is no data that's...it's...I mean, I'm sure we can ask Dr. Anstead to come up with a million clinical scenarios where there's no question. We would have no question. You're going to order a CT, and whether you want a CT or an MRI, that's a different story, but I don't think that's really where we need to focus our attention today, and if there's any questions of the data, we should really try and pull out the data about that primary acute sinusitis as a question.

Amy Anstead:

Yeah, and I agree completely with Seth in that at least we can pull out the uncomplicated acute and you have in your...in both presentations you've pulled this out and mentioned it, that in uncomplicated acute sinusitis, there's no...there's...there's good evidence to tell you to say do not image, so.

Craig Blackmore: Other comments?

Teresa Rogstad: I just wanted to get back with some information from the question earlier. We were able to look at the Public Employees Benefit population and see how many people had a primary diagnosis of sinusitis in 2012 and 2013. In 2013, it was 17,600, so about a 15% ordering of scans with that as a diagnosis, which is what I saw reflected in some of the literature that was presented, so.

Craig Blackmore: Thank you. OK. So, Seth has given a framework that we might use to get started, which would sort of push us into the next item on the agenda, which is for us to get moving on a decision. It's 10:00. So, why don't we use this opportunity to take a quick break and come back here at 10:15, and we'll resume.

So, I'm calling the meeting back to order. The next step in the process is for the committee to begin their deliberation with a view towards heading towards a decision. Before we do that, are there any questions committee members still have for any of our presenters? It's all crystal clear. OK. So, as we move towards a decision, we like to narrow the options a little bit, and we have three options and that's to cover, not cover, or cover with conditions and it looks to me, as is often the case, like we're probably going to be converging on a cover with conditions, and the challenge is going to be deciding what those conditions are, and I'm saying that based on what I think I've heard. That there are some situations, immunocompromised, concerns about complications, where we would be covering this study but that it doesn't sound...and I may be jumping ahead, but it doesn't sound like the unlimited coverage under all circumstances is where we're headed either. So, if I could just get some nods of heads to confirm, and we'll focus in on what conditions might look like. Good? So, who wants to take a first stab at how we might break down this problem from broad to narrow, and I think we've already heard from Seth. I think it's a good starting point, but does somebody want to frame that, in terms of conditions? I'm looking for a volunteer.

Kevin Walsh: Well, the red flag symptoms that Dr. Fotinos presented, which is on page nine of the handout are a reasonable place to start looking.

Craig Blackmore: OK. Page nine?

Richard Phillips: It's slide 16.

Craig Blackmore: I think we even need to...maybe we do. Well, go ahead Chris. What were you saying?

Chris Standaert: I mean, we can separate out uncomplicated, acute rhinosinusitis, as a diagnosis, I assume. That would resonate with people. That's a diagnosis. Chronic rhinosinusitis gets a lot trickier, and I think, although I'd like to list those reasons the head CT...these are really, I mean...if you have neurologic findings in

somebody with headache, and you're thinking sinusitis, you're cutting for more than just sinusitis. You're CT'ing because you have neurologic findings, and you're aware that there's something in their brain, or their peripheral nervous system in their head. So, I think you can go to acute and chronic, and I wonder, though, if you can do it by modality. Like, for ultrasound, frankly, I didn't see anything that suggests why you would do an ultrasound, and even in pregnancy, I don't know. I mean, it doesn't penetrate the skull. I don't know what you're getting from that. You can go by modality, and somebody might say there's no indication at all to do this ever, or certainly not under specific conditions, but we could do it by acute and chronic and then chronic we could break down, are there things in chronic that tip you off that you should be doing this. It seems like...

Craig Blackmore: OK.

Chris Standaert: ...in acute, we have a...

Kevin Walsh: Those were actually...those were actually acute. Those were actually proposed as symptoms that would lead one to...

Chris Standaert: ...that's what I...

Kevin Walsh: ...get a study in an acute situation.

Chris Standaert: ...but can you use the phrase uncomplicated? I mean, again, these are...

Kevin Walsh: Well, I would prefer acute and chronic, because that's what the literature...

Chris Standaert: No, I agree with for acute...so, as opposed to saying uncomplicated you say acute and then acute with...

Craig Blackmore: Well...

Chris Standaert: ...one of these things as a reason, too.

Kevin Walsh: Well, that's a proposal.

Craig Blackmore: Well, I mean, I think acute and uncomplicated are not the same thing, right? Uncomplicated means absence of the red flags, in essence. Then, there's acute, there's recurrent, and there's chronic, right? So, we can start with those three, and we can talk about defining complicated and uncomplicated based on the red flags or based on whatever. Does the acute, recurrent, and chronic resonate, or are recurrent and chronic kind of the same? I'm just looking for a way to divide and conquer.

Seth Schwartz: Yeah. I don't think recurrent and chronic are the same, but I think...I don't think we've seen any data on recurrent.

- Kevin Walsh: No. We haven't.
- Seth Schwartz: So, it's going to be hard for us to talk about that situation. I think it's going to get lumped under chronic based on what's...
- Kevin Walsh: Lack of...
- Seth Schwartz: ...kind of the way we're thinking about these conditions.
- Kevin Walsh: Yeah.
- Michelle Simon: Right.
- Seth Schwartz: So, I might just talk about acute and chronic and then let people figure out what chronic means.
- Craig Blackmore: Acute and non-acute. OK. So, OK, any other thoughts on that? So, can you show the slide before this one, please? So, we might, as a suggestion, start with both defining and providing a recommendation for acute uncomplicated rhinosinusitis. I think this is the area...this is an area that has been identified as a potential for overuse, right? This is the target of the Choosing Wisely. So, can we operationalize what this is? So the ACR has a definition. There's probably other definitions. I know there are other definitions in the literature. So, I guess this is complicated. Can we define a set of conditions where we're going to not allow imaging?
- Kevin Walsh: Yeah. I think when someone presents with symptoms suggestive of rhinosinusitis in the face of not having received a course of antibiotics already for that diagnosis, that's...we're calling that...that becomes acute. That's the acute field, and we all pretty much agree that the literature says there's no value in imaging those people unless they have these red flag symptoms.
- Craig Blackmore: OK. So, do we want to define acute, or do we want to say acute?
- Joann Elmore: Well, acute is four weeks or less.
- Marie Brown: Four weeks or less.
- Craig Blackmore: OK. So, four weeks or less?
- Chris Standaert: Well, these apply to...so, well we can call it...chronic is not defined as four weeks. They're saying subacute and these other things define chronic as invariably eight to twelve weeks.
- Michelle Simon: Right.
- Chris Standaert: So, if we don't...we need a dividing line. So, is 12 weeks acute and greater than 12 weeks chronic, eight weeks? So if there is...

- Michelle Simon: I think acute is four weeks or less. That's...
- Chris Standaert: But we only have two categories. So, chronic would be more than four weeks.
- Craig Blackmore: Let's start with acute.
- Chris Standaert: We only have two.
- Craig Blackmore: Let's start with acute. Let's get this...this...
- Michelle Simon: Yeah, I...
- Chris Standaert: OK.
- Craig Blackmore: Let's... let's...
- Chris Standaert: I just want to define it.
- Craig Blackmore: I know, but let's move forward on acute.
- Marie Brown: Well, if we only define it as four weeks, then we're going to have to do something between four and eight, and we're going to have to pull in sub-acute.
- Michelle Simon: The literature did define it as four weeks or less. So, if we make a different definition, then we're not using the literature's definition. So, we're not using the literature.
- Joann Elmore: The literature was subpar to say the least.
- Michelle Simon: But it's what we have.
- Craig Blackmore: It is what we have. So, I, what I'm trying to do is, I'm trying to look for the low hanging fruit here, right? There's going to be a big area where we're going to be scratching our heads, but I think there's some low hanging fruit. So, I think if we start with acute as less than four weeks, that's low hanging fruit and then maybe we can expand or not. So, do we want to provide coverage in acute as defined as less than four weeks, uncomplicated rhinosinusitis, and we can define uncomplicated. We have red flags to do that. What is the...what's...I'm looking for discussion. I'm not looking for a decision. Is that a starting point for a reverse of the condition?
- Richard Phillips: Yes.
- Marie Brown: Yes. Then we just have to have some support for the red flags.
- Chris Standaert: Other than time, do we have to define the phrase uncomplicated? So, we can define acute, or we could subacute and match the guideline up there and say

acute or subacute, but do we have to define the word uncomplicated or can we leave that to clinical discretion where somebody's worried about more than just...

Kevin Walsh: It can be the absence of red flags.

Craig Blackmore: I think it's the absence of red flags, right?

Joann Elmore: Is it defined by the ACR?

Craig Blackmore: Probably not. They have a few criteria.

Joann Elmore: Because I'm just...

Chris Standaert: And are there...

Joann Elmore: ...wondering where they came up with the definition.

Seth Schwartz: The radiologists.

Chris Standaert: Yeah, but are they standardly accepted red flags? I don't...I don't know that, so.

Craig Blackmore: I know there is an algorithm published in the literature on defining when to use CT.

Marie Brown: It seems like...

Chris Standaert: I just worry. When we each had to go make exhaustive lists of...

Marie Brown: ...right.

Chris Standaert: ...complicated, we get in trouble, because...

Marie Brown: Right.

Chris Standaert: ...it's really hard to do that. So, if we make that...you have to meet our list to be included, we get in trouble.

Marie Brown: Right.

Chris Standaert: Because it's just so hard to do.

Marie Brown: So, let's do, you know, uncomplicated, or in the absence of complicated...uncomplicated acute.

Seth Schwartz: I think some of the guidelines may tackle that for us. I'm just looking at the AO guideline, which actually has a paragraph that specifies what complications...they define what the complications are and which imaging is OK.

So, they talk about CT imaging of the sinuses is appropriate when a complication of sinusitis is suspected based on severe headache, facial swelling, cranial nerve palsies, forehead displacement, or bulging of the eye. That's what's in that guideline. There may be other characteristics. I mean, we talked about...

Craig Blackmore: Immunocompromise.

Seth Schwartz: ...immunosuppression and other things. So, there may be other things, but.

Richard Phillips: I'd really like to, you know, sort of emphasize with Seth said, because I, my...my real fear here is that we're going to come up with some kind of things that tell ENT physicians and other specialists how to do a practice, when I'm not sure there is a problem with the current practice, and yet, we're trying to depend on this literature that really has obfuscated the issue for me more than it has clarified, and it's probably more my limitations than anything else, but I really would like to make sure we follow guidelines. They seem very reasonable to me. At least the organizational guidelines seem to be very reasonable in terms of the imaging, and they tend to follow acute and chronic, as I recall.

Marie Brown: What if we said acute and subacute to... no?

Craig Blackmore: So, let me ask the agencies, do you not have an existing set of criteria that you already use for preauthorization on sinus CT?

Group: No.

Craig Blackmore: No?

Charissa Fotinos: QUALUS does our radiographic reviews, and I can pull those...I can try to find those. I don't know what they are off the top of my head.

Craig Blackmore: When we went through this with the advanced imaging management group several years back, and you guys started implementing pre-authorization for advanced imaging, I thought there were some criteria that were discussed at that time about sinus CT. Is that not true?

Charissa Fotinos: I wasn't here at that time. Do you know?

Craig Blackmore: Gary, do you know?

Charissa Fotinos: I can find out if QUALUS has criteria now, or what they had the criteria based on CT imaging. That I can do while we're talking.

Seth Schwartz: Just to go back to the acute and subacute, I'm just thinking about this clinically. I think, you know, when we talked about what is the low hanging fruit, and we think about that acute scenario, pretty much within that first month of decision making about what's happening in treatment is really...we've seen no evidence to say the CT is going to change management, but I mean, using a scenario

where you've had someone who's had symptoms for six or seven weeks, and they've been on three courses of antibiotics already, and they're still not better, that might be a scenario where you might question your diagnosis or have other concerns. So, I can see how a CT might actually alter management at that point. So, I think the subacute setting, in many instances, may be the same as acute. I think there are scenarios in that category that are going to be different; whereas, I think within the acute category, it's really hard to come up with a condition where it would be useful.

Chris Standaert: So, could you...could you say and uncomplicated untreated? So, if somebody came in with six weeks of what sounds like a sinus infection, would you really CT them or would you just give them antibiotics if you're worried about it?

Seth Schwartz: You'd give them an antibiotic.

Chris Standaert: Yeah, you'd give them...so, if they've never been treated, even in subacute, if they've never been treated, you're still probably just going to give them antibiotics before you CT them. So, I agree with that, but that's not a...but I wouldn't think of that as uncommon. When they have three courses of antibiotics still with persisting symptoms of headache and malaise and all this, you're not uncomplicated anymore.

Seth Schwartz: Well, you may be uncomplicated. You just may not be sure of the diagnosis.

Chris Standaert: Right.

Seth Schwartz: You may, you know, I mean...

Chris Standaert: Right.

Seth Schwartz: ...you may be treating depression with antibiotics, and it's not going to be...

Chris Standaert: Yeah, right, maybe.

Seth Schwartz: ...effective, but, you know, but you're not necessarily worried that they have a brain abscess. So, I think, you know, when I think about complicated, it's your worried that something...something bad is going to happen, and that's really the way that the guidelines have been written is that, we don't want to miss something bad happening.

Marie Brown: Right.

Seth Schwartz: Whereas, in the subacute phase, you're still not really worried about, I mean, the complications would be defined in the same way. Failure to respond to therapy is not really a complication. So, I think...but that's a...but that may be something that's a realistic indication. We don't have any data to say it's an indication.

- Chris Standaert: So, how would...does it help me, though? How would...so, somebody comes in at seven weeks. They've run two courses...two Z-Paks, and they still have headaches. Somebody just CTs them looking at their sinuses. I can see you CT'ing them to say the sinuses are normal. We don't send you to ENT, but they CT them, and the sinuses aren't normal. What do they do? Do they send them to you guys, or to primary care? What do they do?
- Seth Schwartz: They...
- Chris Standaert: How does that change decision making? How does that help you?
- Seth Schwartz: Well, it may, I mean, again, this is a specific situation. So, who knows exactly what's going on. If they, if their exam is consistent with it, I mean, if they've got purulent rhinorrhea at the same time as that and they're not responding to any therapy. That patient is probably going to get referred for...referred for a consultation.
- Chris Standaert: Right.
- Seth Schwartz: With a negative scan, they may not. Whether you do a scan first, I think there's a lot of questions about that. I think most ENTs would prefer to have a patient already have a scan before they arrive in their office, but whether that's indicated or not is...we don't have any data on that...on that scenario, but it's still not complicated. It's just a different clinical scenario, but I don't think...I would...it's not clear to me that we should say no, you shouldn't have a sinus CT in that situation or yes, it's fine to do it if you've had...if you've been treated a few times and it's failed. I mean, I think that's reasonable, but I just, again, there's no data to say.
- Chris Standaert: Yeah. There's no data saying you should.
- Michelle Simon: Right.
- Seth Schwartz: There's no data to say either way, and that's...so, my point being, I don't know what the right answer is in subacute, but there's...but you can make arguments either way. So, it's muddier water, whereas in acute, in the shorter timeframes, it's more clearcut.
- Marie Brown: Right. And in primary care, we may do at least two, sometimes three, sometimes four courses of antibiotics, um, trying different ones, before we refer.
- Chris Standaert: So, there is a paper in the literature from, I think, 2010, that described implementing a set of criteria to limit the use of sinus CT that successfully decreased the number of sinus CTs that were performed and without any identifiable complications. I won't say it was a great study, because I wrote it, but it did have criteria that we could think about, and it is published, and the criteria were sinus symptoms with acute onset of double vision, preorbital

swelling, redness, or severe facial pain, findings of meningitis, or immunocompromised host. Also defined as criteria were symptoms lasting more than four weeks and despite two courses of antibiotics, four episodes of acute sinusitis within twelve months, or persistent asthma symptoms despite maximal medical therapy, and then there were some other conditions, which were occult fever and hospitalized patients in preparation for sinus surgery or the presence of an intranasal mass.

Kevin Walsh: So, that was more than the acute situation.

Craig Blackmore: Those were the indications for sinus CT.

Kevin Walsh: Right.

Craig Blackmore: So, again, I mean, it's in the literature. We can... we can say it's published. Again, I'm not going to claim it's a great study that had longterm followup on a huge cohort, because it didn't, but I'm looking for something to start with. So, I'm throwing it out there. I thought that went into the Aim group, and that's why I brought it up. I thought it was incorporated in some similar form into the QUALUS criteria.

Charissa Fotinos: The QUALUS recommendations speak just to head CT. The Aim recommendations do state for acute sinusitis basically, where was it, no radiographic...they define it less than four weeks, and they define common symptoms. No imaging is necessary for immunocompromised patients with acute rhinosinusitis unless a complication or an alternative diagnosis is suspected that requires imaging. Then they say, yeah.

Craig Blackmore: Well, I think maybe we could get a blank sheet and start capturing. So, can you read that again? OK.

Charissa Fotinos: (Inaudible-Not at Microphone) No radiographic images usually necessary for immunocompromised patients with acute rhinosinusitis unless that complication or alternative diagnosis is suspected that requires imaging. CT may be performed if symptoms persist beyond three to four weeks of adequate treatment, which may include antibiotics, nasal steroids, and/or decongestants. Under these circumstances, a complication of acute sinusitis, rhinosinusitis, or an alternate diagnosis may warrant CT imaging of the paranasal sinuses. Then, it goes into acute recurrent sinusitis, chronic sinusitis, as well. Would you like those three? You know what'd be useful? If we could just pop, no. Just pop this up right now. Here, just pop that up real quick. We're just going to pop that up on the screen.

Craig Blackmore: OK. So, I'm just, again, trying to figure out how we can get some traction. So, I think we all agree there are certain sort of red flags that we're going to need to image, and I think we all agree that in the absence of red flags for some time period, we're probably not going to support imaging, and we can start with that, and then we can also start to talk about imaging...well, we can start with that.

- So, again, if we say less than four weeks and the absence of red flags, is that sufficient, or do we want to also say it's OK within four weeks to image if you fail antibiotics?
- Group: No.
- Chris Standaert: I don't think...there's no reason to image unless you have something to worry about...something horrible going on.
- Marie Brown: Right.
- Craig Blackmore: OK. So, no imaging less than four weeks and the absence of red flags.
- Group: Mm-hmm.
- Craig Blackmore: OK. How about four...how is subacute defined in one of these? Four to eight weeks, four to twelve weeks?
- Seth Schwartz: We didn't...that's a definition in some societies, but there's no...there's no data about subacute.
- Craig Blackmore: I know there's...I know there's no data, but we still have to...
- Seth Schwartz: So, let's not...no we don't. We can say this is acute. This is chronic. That's it.
- Marie Brown: So, everything over four weeks, you would consider chronic?
- Seth Schwartz: I'm not, no. I'm not...I'm not suggesting that. I'm just saying, we don't have to parse it out the way they do, because we don't have any evidence to parse it out the way they do.
- Craig Blackmore: So, you're saying just use the word acute and don't define it.
- Seth Schwartz: No. I'm saying, separate it into two categories, acute and chronic. That's what the literature gives us.
- Richard Phillips: Yeah.
- Seth Schwartz: So, otherwise, we're just kind of hypothesizing.
- Craig Blackmore: OK. So, but we got to figure out where the cutoff is, or else we have to leave it vague. So...
- Richard Phillips: Make it eight weeks.
- Male: Four weeks.

- Craig Blackmore: So, four weeks, I think, is easy, and so now I want to walk people... I want to walk people back and see if we can come up with a number to divide acute or chronic, or be vague if you think we have to be that vague. Does that make sense? So, I'm...I'm...and maybe this isn't the right approach. Let me know, but I'm thinking if we're good on four weeks, OK, let's think about four to eight weeks and see where we stand on four to eight weeks...where the committee rests, and then at some point, we're going to reach...
- Chris Standaert: I guess, is...is there a difference between four to eight weeks and then chronic in more than eight weeks...than what you would do. It seems to me if your primary concern is sinusitis, and that's all you're trying to figure out how to treat, you're going to CT when you think you have to do something else, and you think you might have to operate and when you think you need an alternative diagnosis. To just treat sinusitis, I don't know that CT...you're ever going to CT if you can treat it medically and manage it, right? And it seems like you CT when you want to operate, when you need another diagnosis, when you're worried about something, or when you're...
- Kevin Walsh: So, you're saying don't parse it out by time, parse it out by...
- Chris Standaert: I'm saying what you're saying. Separating out subacute and chronic doesn't make any sense to me, because I think you're going to deal with them the same way. I think in four weeks, there's no reason to do it, unless somebody's really ill, or...
- Marie Brown: Right.
- Chris Standaert: ...you're worried about something. I think once you get past that, this...I agree with you. The literature doesn't separate out subacute for us at all. It talks about chronic, but I'm not sure the approach in four to eight weeks or four to twelve weeks is different than sixteen weeks or twenty weeks, because you have the same issues. You're going to...I would think you're going to want to image...that doesn't support your imaging when you do something else or you're worried about something else other than medically manage it.
- Marie Brown: So, if we just put acute and then everything else is chronic, and then people know, I mean, they deal with acute in a certain way and then the shades of grey play out in chronic.
- Michael Souter: So, then the only other question I have is...and I support that kind of acute/chronic position. I'm not trying to mess with it in the interim, but the only question still in my mind is four weeks from the onset of symptoms or four weeks with treatment, because it's not possible that people might be put off...
- Craig Blackmore: I mean, I'll...
- Michael Souter: ...medicate for some time.
-

- Craig Blackmore: ...I mean, I would say, if we're going to use four weeks as a cutoff, and you want to get imaging after that, it should be after failure of, you know, two courses of antibiotics or...
- Michael Souter: (inaudible)
- Craig Blackmore: ...we don't have to be that specific if we don't want. We can say failure of conservative treatment or whatever.
- Seth Schwartz: I think it gets muddy. I mean, I think you should...if you're going to talk about defining a timeframe, it should be from diagnosis of sinusitis. I think there's a little challenge there, because, you know, often these people get diagnosed as having sinusitis when they've had, you know, a stuffy nose with, you know, facial pain for two days, and that's not acute sinusitis, and all of the guidelines specify that's not acute sinusitis. There is an operationalized definition, which is symptoms for greater than ten days or, you know, or recurrence after improvement. I mean, there's...there's...so it should be four weeks from the diagnosis of...which is what we're really talking about, but that's the window that we're talking about where it's not...it's not useful, as far as the acute is concerned.
- Marie Brown: Right.
- Seth Schwartz: So, in that subacute state if you're thinking about failure of therapy and other things, those all come, but it's not really defined on a timeframe.
- Craig Blackmore: So, then we have...so, to operationalize that, we would have to say four weeks from the time of diagnosis, as defined by the following criteria.
- Seth Schwartz: Yeah, which is, I mean, and there's well-specified criteria. That's not hard to do. I mean, I think all of the guidelines have very similar criteria.
- Marie Brown: I can't hear you.
- Chris Standaert: Before we get there, we still get into a situation sort of...if you look...if you make chronic all one thing, which is what they...I agree with Kevin totally. The evidence talks about chronic. So, there's the acute, simple presentation where there are no red flags. They're not worried about something, and then there's other stuff, and other stuff where they've had it for six weeks or twelve weeks, or sixteen weeks, you have the same, almost clinical algorithm where you're going, I'm going to treat this like sinusitis medically, or I'm not. I'm worried about something else. I need diagnostic clarity before I do that, or you're going to treat it, and then it's going to work or it's not going to work. If it doesn't work, then you'll say I need something else, and that's when the imaging comes into play. It helps you with alternative diagnoses. It helps you with surgical planning to a degree. It helps you with clarity on is this his sinuses or not that I'm dealing with even to a degree. So, that doesn't come until you've made that medical decision of I have sinusitis and I'm going to treat it medically and it

failed, or I'm not sure what I have and I need imaging. Since they all kind of tumble in the same basket, it almost doesn't matter to me when the clock starts. If it's acute, simple stuff you're going to treat them, and then if they fail, then you earn a different category already, because then you have to sort of sort this out medically.

Seth Schwartz: I think we should get Dr. Anstead's opinion on this, but I think some of this has to do with the definitions of time are a little bit arbitrary, but we're just trying to really think is that acute sinusitis is a different disease than chronic sinusitis.

Chris Standaert: Right.

Seth Schwartz: So, the treatments that you have for acute disease are different than the treatments that you have for chronic disease, and surgery being one of the treatments for chronic disease. When people are in that in between window, there really...it's not clear what's going on. They may be having an evolving chronic sinusitis, or they may just have a more prolonged course of acute sinusitis, but the treatment in that phase is going to be, you know, the graduation from treatment from acute disease all the way up to whatever, because other things haven't worked. You're generally not thinking about surgery yet. So, I tend to agree with you that in that in between window, you know, when would CT sinus be indicated? Really, it would only be if you're uncertain...if you're questioning your diagnosis, because you're not going to operate based on that...at that time unless they have some complication. You're not going to change your therapy based on the CT scan, because you're going to change your therapy based on what's working or what's not working. It's not until you get into that chronic window when you're really thinking about different treatment algorithms that are going to involve surgery as a realistic measure. So, then the imaging becomes very valuable. So, if we're going to try to operationalize that in between period, I think you could say something like, you know, to exclude alternative diagnoses, but when you get into the chronic window, that's not the case anymore, because that's not the only reason.

Marie Brown: Mm-hmm.

Seth Schwartz: There...it's...you're trying to really figure something else out.

Marie Brown: Mm-hmm.

Seth Schwartz: But I mean, Dr. Anstead, do you want to comment about that...that transition period at all?

Amy Anstead: About the subacute or recurrent acute, and there's another entity of recurrent acute. So, I can't think of a reason why in the subacute period you would image if it was uncomplicated, even if they weren't responding to therapy at that time, you just change it.

Marie Brown: Mm-hmm.

- Craig Blackmore: So, do we try to define...again, we're happy with less than four weeks for this next kind of block. Do we try to come up with a time window, or do we say failure of two courses of antibiotics. I mean, does that...does that get us where we want to go, or not? I mean, that's...
- Amy Anstead: Failure of two course of antibiotics? What does that define?
- Craig Blackmore: Well, that would either define, I would think, recurrent acute or chronic and is that...
- Amy Anstead: Well, chronic is just based on time. So, somebody who's been sick for twelve weeks. It doesn't matter if you treat them or you don't treat them or you...it's twelve weeks of them being sick because...
- Craig Blackmore: So, I'm, I'm looking for...
- Amy Anstead: ...80, over 80...you know, 80...some people say 90% of acutes are going to resolve on their own by...by that time...in that timeframe. I mean, the literature will show you that whether you treat acute and subacutes with antibiotics or you don't, you can throw anything you want at them. It's not going to change their outcome very much. So, the chronics are really people who are just twelve weeks, they're sick. It doesn't matter what you do.
- Kevin Walsh: But I want to go back to Chris's point. I mean, while that...that's true in one perspective. In the office, if somebody comes in with twelve weeks of symptoms, and they haven't been treated yet, the first thing you're going to do is treat them. You're not going to...
- Amy Anstead: Sure.
- Kevin Walsh: ...send them off to the ENT because they've met the criteria for 12 weeks. So, you're not going to image them because they've met the criteria. You're going to treat them first. So, I don't know that parsing it out by time of duration of symptoms is necessarily...it doesn't help you operationalize.
- Amy Anstead: It doesn't help you with the...making a decision about whether or not you're going to do your CT scan. I agree.
- Michael Souter: I like the idea of having treatment failure being the (inaudible) indication to proceed to imaging. Plus, I think it's simple and would be easy to operationalize.
- Craig Blackmore: Is treatment failure a criterion that you guys use clinically when you're trying to decide what to do? Do you say, well, you know, we've tried antibiotics once, twice, three times, whatever it is, and it's not getting better. Now, I need to either reevaluate and figure out what's really wrong or think about something else.

- Seth Schwartz: That's exactly the scenario.
- Craig Blackmore: I mean, that's how we used it at VM. We said you had to fail two courses of antibiotics, and then we'd say, alright. It's time to reevaluate.
- Richard Phillips: Are you saying treatment failure in lieu of the concept of complication or as a subsection of complication?
- Craig Blackmore: It's in addition. Well, I mean, there's...there's the red flags, but then there's also...I don't have any red flags, but I'm not getting better.
- Richard Phillips: Right. Yeah.
- Joann Elmore: I'm not getting better despite treatment.
- Chris Standaert: And medical treatment is antibiotics and decon - ... and some combination of antibiotics and decongestants and steroids and all sorts of stuff. So, it's not just...
- Craig Blackmore: Right.
- Chris Standaert: ...antibiotics. There's a whole...
- Seth Schwartz: Yeah, but I think loosely we talked about failure of maximum medical...
- Chris Standaert: Yeah.
- Seth Schwartz: ...therapy. I think it's hard to define that, and we talk about courses of antibiotics. I think that gets a little challenging because for some people, that's ten days or a week. For other people that's a four-week course of antibiotics. So, I think...
- Chris Standaert: (inaudible) appropriate medical treatment.
- Seth Schwartz: ...right, and we don't have any data on what's right or what's wrong about that. So, I think it's hard to define a course...and some people might take six weeks of antibiotics. So, it's hard to define two courses of antibiotics. I wonder if we can just leave it more vague, which is failure of medical therapy or, you know...
- Amy Anstead: Yeah. I would leave it vague as failure of maximum medical management, and then maximum medical management is defined by the American Academy of Otolaryngology, and they, I mean, they just published this year their update to the guidelines on treatment of adult chronic and acute rhinosinusitis with, you know, with all of the data support, all the different treatment, including topical steroids and antibiotics, etc., etc. So, I would just leave it maximum medical management.

- Craig Blackmore: Can you guys operationalize maximal medical management?
- Amy Anstead: Or you could even say maximum medical management according to the, you know, the guidelines per the American Academy of Otolaryngology.
- Charissa Fotinos: This may be one of those things that we would not require...we'd go back and do an audit on or something, because I don't know how we would necessarily operationalize it.
- Gary Franklin: That'd be very hard to implement.
- Charissa Fotinos: It would be...we might just have to say we're not going to cover it and then go back periodically pick...see if folks are doing it and say, you know, you didn't meet the criteria or something to that effect. I don't know how we'd sort it out.
- Chris Standaert: What is, like, the maximum in referencing a specific guideline makes early check through a practitioner, because you're making them go find this guideline before they find it, as opposed to sort of saying appropriate medical management or something...you have a doctor who's treating somebody...
- Charissa Fotinos: Mm-hmm.
- Chris Standaert: ...they're trying to get them better and they think there's something else going on. They're not getting better, and they've got to do something else. Maybe they go to the guidelines and say I forgot to give them topical steroids, but maybe they don't. You're...you're making it challenging to follow one particular guideline.
- Seth Schwartz: I want to...can we go the reverse...the...the reverse way, which is, you know, I think there's a concern, if we think about what's going on, at least the reason we're looking at this topic is because of the concern about overuse in acute scenario. So, we put a negative statement on use of it in the negative...in that scenario. Can we think about it the same way...I don't think any of us feel that there's, like, overuse of sinus CT in patients who have had prolonged symptoms. Can we simply say, you know, that there's...try and come up with is there a reason why you wouldn't allow someone to image in that situation, and if there isn't, then only talk about acute and as otherwise indicated. You know, it's otherwise OK based on clinician judgment whatever that is.
- Michael Souter: Yeah. I don't like the fact that we're incorporating the criteria into the chronic timeframe. I mean, I thought we were actually talking about that in the subacute.
- Craig Blackmore: So, if I'm hearing, Seth, what you're...what you're saying is we would allow coverage beyond the four-week timeframe and before four weeks for the red flags.

- Seth Schwartz: I don't even know if we need to say that. Can we simply say we will allow coverage other than in the acute uncomplicated scenario?
- Craig Blackmore: Except in the...coverage except acute uncomplicated.
- Seth Schwartz: And we have...why do we need it, I mean, I guess I'm just trying to figure out why do we need it...struggle to define it beyond that. We're not worried about overuse in that scenario, and we think that...
- Michelle Simon: Right.
- Seth Schwartz: ...probably it's indicated.
- Craig Blackmore: I still think we need to define acute and uncomplicated.
- Seth Schwartz: I understand that, but I mean, I think we can...we can define acute and uncomplicated. I don't think that's that hard, because what we're struggling with is, when it gets beyond that, then we don't know what to say, and I don't think any of us really think it's being overused in that scenario. It's really more a question...
- Joann Elmore: Yeah, I don't think we need...
- Chris Standaert: Wait, wait, wait...
- Marie Brown: I thought (inaudible).
- Chris Standaert: ...hold on. Wait, that's an assumption. I don't know if it's not being overused or not overused. I have no freaking idea. So, don't say we assume it's not being overused. I mean, I...
- Seth Schwartz: OK.
- Chris Standaert: ...have been to an ENT clinic, and they use a CT scanner like an orthopedist uses an x-ray. Everybody who walks in the door gets a CT then sees a doc.
- Marie Brown: Right.
- Chris Standaert: I guar-...they probably are being overused.
- Seth Schwartz: Well...
- Chris Standaert: And so, this idea of...it all depends how you look at it. I don't know. I don't know, but I don't know that we have data to say that in chronic symptoms of uncomplicated sinusitis that CT really helps a whole hell of a lot. We don't have any data to say that. So, why do we let it go unfettered when our data doesn't say that everybody who has chronic symptoms of sinusitis should have a...could or should have a CT if there's no other...

- Amy Anstead: And I would say, in chronic sinus disease, you really...there's no indication for you to get a sinus CT unless you're planning on having surgery.
- Chris Standaert: ...unless you're going to do something.
- Kevin Walsh: Or...or you're questioning the diagnosis.
- Chris Standaert: Yeah, exactly. Those are the two reasons, but if you have chronic sinusitis you're managing, I don't know why we (inaudible).
- Kevin Walsh: I agree. We need to...I think, I think Seth opened the door a little too wide.
- Chris Standaert: Yeah.
- Kevin Walsh: I want to close it a little bit.
- Marie Brown: Yeah.
- Richard Phillips: Could you clarify that statement about surgery? Is it if you're...would you do the CT because you're maybe thinking of surgery, or only if you've made the decision for surgery?
- Amy Anstead: So, if somebody has chronic sinus disease and they're symptomatic, and they're...they want to have surgery, if they're thinking about having surgery, then that's an indication to do a CT, but if they have chronic sinus disease, I, you know, there are millions of people walking around with chronic sinus disease who don't want to have surgery who live with their chronic sinus disease, and maybe they respond to treatment or maybe they don't, but they're not interested in doing anything further. They don't need a CT scan.
- Richard Phillips: So, just to clarify, you would not use that as a criteria to decide on surgery?
- Amy Anstead: Chronic? If they're chronic or not?
- Richard Phillips: Yeah.
- Amy Anstead: No.
- Richard Phillips: You wouldn't use it for that?
- Amy Anstead: Yeah.
- Richard Phillips: It's only when you've made the decision for surgery that you would do the...
- Amy Anstead: So, but they're...they're (inaudible).
- Richard Phillips: To consider surgery.

- Chris Standaert: They can still...
- Amy Anstead: To consider surgery.
- Chris Standaert: ...can you...can surgery help me with this? If it would help me, I'd be willing to do it. Then, the CT may help make the decision, but for people, actually lots of people have chronic sinus symptoms who really have no interest in surgery. There's (inaudible) surgery is really going to help them with every mild ongoing chronic symptom, and there's no data that CT helps anything.
- Richard Phillips: Yeah.
- Chris Standaert: And those people don't need to be imaged, even though they have chronic symptoms, and they don't totally go away with antibiotics.
- Marie Brown: Right.
- Chris Standaert: And they don't totally, you know?
- Craig Blackmore: Unless you're not sure of the diagnosis.
- Chris Standaert: Yeah. Yeah. Unless the doctor (inaudible) clear.
- Craig Blackmore: Which...
- Chris Standaert: Yeah.
- Craig Blackmore: ...yeah.
- Seth Schwartz: I'm struggling with this a little bit, because I think, you know, when there...I agree with Dr. Anstead that there are a lot of patients who are walking around with chronic sinusitis that are not bothered enough by it that they go to the doctor or that they ever get referred to an otolaryngologist, but for patients who are symptomatic with disease who are going to get...who their primary doctor is going to figure out what's going on or is going to refer them on to further management, I can't think of an otolaryngologist who is not going to want to know what their sinus CT looks like before they make decisions about what to do, because ultimately, you're...as a subspecialist you're deciding, are you going to treat this patient further medically or are you going to offer them surgery, and the CT is, I think one of the big bonus of that. So, I'm finding it hard to limit that scenario. Maybe we can come up with ways, but I'm just finding it hard to limit that.
- Craig Blackmore: I think if you leave the option open to do a CT scan to confirm the diagnosis, then it's very hard to limit it, I mean.
- Marie Brown: Uh-huh.
-

- Amy Anstead: Well, I would just limit the number.
- Michael Souter: The scenario.
- Chris Standaert: (inaudible) one way or the other is the problem.
- Amy Anstead: I think where it gets abused is in the number of CT scans. So, in the patients who have chronic sinus disease and they're referred to the, you know, the ENT doctor, I don't think you're going to be able to tease out, you know...to have chronic sinus disease is it CT indicated? I don't think you're going to be able to tease out the ones that aren't. So, I think...I think what you can do is say in somebody who has, you know, stable chronic sinus disease, they don't need more than one CT scan in a year or, you know, or give a timeframe if it hasn't changed.
- Craig Blackmore: So, the challenge of this committee, and you're new to this, is that we have to act based on the best available evidence.
- Amy Anstead: Mm-hmm.
- Craig Blackmore: And so the problem you're presenting to us is something about which we really have no evidence...
- Amy Anstead: No control?
- Craig Blackmore: ...whatsoever. Which, I mean, the absence of evidence we can use as a reason to not cover something, but it makes it very hard for us to parse. You say...there's no evidence that CT is effective under any circumstance, we cannot cover it, but I don't think we're there. When we start talking about how many scans, I mean, we just have nothing to go on.
- Chris Standaert: I think if you follow the idea that you're doing this either to consider a planned potential surgery or confirm the diagnosis, you'll limit the number of tests you get, because you just don't need to keep doing it over and over and over again, and I think, you know, the idea that everybody who sees an ENT needs a head CT is sort of, like, does everybody who sees an orthopedic surgeon for back pain need an MRI? No, and is this policy of orthopedists who require MRIs before they see anybody, that's a bad idea. That's over-utilization. It leads to too much surgery. Clearly, the data show it leads to excessive bad things. So, I could see someone going to an ENT with symptoms of sinus stuff and the ENT saying, you know what, you're really not sick enough to have to go through the risks of surgery. Even if this is...your sinuses are the problem, I don't think this is your sinuses at all. You have something else, and they didn't need a CT before they got there, and the doctor is a doctor and tells them yes, the CT will help me help you, or no. You don't need this. You have a totally different problem. You need to go work on it. So, you know. So, I don't know. I kind of like the direction of this language. It's sort of...you're using it for a purpose to confirm a

diagnosis, a plan to make some decision as to how you can help somebody and sort out what their issue is. I think it's useful, but I think as a routine sort of just do it, I don't...I don't see the data that says that's really helpful.

Craig Blackmore: I mean, I agree with you Chris, but I don't know how to operationalize it.

Chris Standaert: No, that's what I, I mean, this sort of...this sort of language.

Craig Blackmore: So, I think our current language is not...would be, coverage would be allowed for patients who have red flags, and we'll define those, or for patients who have symptoms that last more than four weeks, and then with failure of medical conservative treatment.

Michelle Simon: I don't think we should just cover for anybody who has symptoms more than four weeks.

Joann Elmore: Yeah. I would add more to that second one.

Craig Blackmore: Well, I agree, but I don't know how to do it. I mean, that's...

Michelle Simon: Well, if they have a recurrence of disease or they have failure of medical treatment or something that's going to...

Joann Elmore: Well, actually...

Craig Blackmore: I think we can...

Joann Elmore: ...I think we're all in...are we all in agreement on the first part, which is, there's a complication, you're worried about it, it's a red flag or...

Craig Blackmore: They can get it.

Joann Elmore: ...acute or chronic, they can get it.

Chris Standaert: Mm-hmm.

Joann Elmore: That's...I think we're in agreement.

Craig Blackmore: Yes.

Joann Elmore: CT scan we're talking about.

Craig Blackmore: We'll...we'll define the red flags or whatever, but...

Joann Elmore: I actually think it's the second one that we need to discuss. I'm going to throw out a third one, which is, if somebody's already had one CT scan of the sinus, they need prior authorization before we start doing more to try and get at this issue of multiple per patient. We have not seen data that this is happening, but

clinically I know it is, and we've heard from our expert. So, I would throw that in as the third one. For the second one, it seems that if they're uncomplicated but continue to have symptoms despite maximum medical therapy, more than four weeks, I'm hearing two things. One is, if they're considering surgery. The second is a little bit looser, and I'm not certain how to operationalize it, but it's if you want to confirm the diagnosis, or if you're worried about something else. To me, that...you would almost have to have, like, red flags to sort of be thinking that it's something else. So, I'm not certain how to operationalize the second part of that.

- Chris Standaert: Well, your...your red flag would be persisting headache, persisting...that's...
- Joann Elmore: And that's a red flag, though.
- Chris Standaert: ...but that becomes your...well, I don't know if that's a red flag, but it becomes...
- Joann Elmore: Well, those are the...
- Chris Standaert: ...your...
- Joann Elmore: ...complications.
- Chris Standaert: ...yeah. That becomes you're...you're wondering something else. You have some other disorder. You...
- Seth Schwartz: Can we go back...
- Craig Blackmore: (inaudible) because they don't get...
- Seth Schwartz: ...can we pull up, can we pull up the slide of the agency's recommendations and look at that?
- Craig Blackmore: Can you guys hear that? Can we...
- Marie Brown: Agency recommendations.
- Joann Elmore: And those were kind of interesting because they start with just x-ray saying no.
- Richard Phillips: Two level recommendation...they have one by technology and the other one by diagnosis. So, you want the one by diagnosis? In other words, the next to last slide really is the one by technology. The others are by diagnosis.
- Joann Elmore: Right, yeah. I was assuming our discussion was all about CT scans.
- Craig Blackmore: Well, we...
- Kevin Walsh: Yeah. We're talking about CT...yeah, we're talking about the technology.

- Richard Phillips: Yeah.
- Kevin Walsh: It's this slide. So, I'm proposing this is another way to come at a lot of the issues that we were...we've been wrestling with. That simplifies it.
- Michelle Simon: That's in acutely ill.
- Richard Phillips: I thought we were going to do both? Isn't that what...what Craig was saying is that we...you were going to go to the technology after we did this, correct? Am I...did I misunderstand?
- Craig Blackmore: Yeah. I...I think we haven't gotten to the other. Right now, we're just on CT scan, which I'd like to tie that up before we...there's going to be another mess, but can we tie up the CT scan?
- Richard Phillips: Yeah. I like what they have there, but...
- Craig Blackmore: So, acutely ill I don't like, because that means anything.
- Group: Yeah.
- Craig Blackmore: But red flags we...and again, we'll...we'll talk about that, which is kind of the same as concerns for complication.
- Joann Elmore: Yeah.
- Michael Souter: Well, concern for complications come...you have to factor in the time scale element to this again, as well.
- Craig Blackmore: I think you have to.
- Michael Souter: I'm...I'm...I'm having trouble with, you know, us tying ourselves up in knots when there really isn't an evidence base, and we're kind of thinking, well, what's the problem we're trying to correct. I'm going to go back to what Seth is saying, and I actually agree with Seth's position on this. We're trying to circumvent our constraints around inappropriate use of CT scanning for acute care. I'd like to preserve the option of the position of seeing the patient in circumstances outside of the acute care scenario to display some judgment in what is a point of ambiguity there where we really don't know what's going on. We don't have data to guide instruction of those elements there. There's nothing in the literature, and I think at some stage we have to...while we understand the nature we have to kind of put constraints to support the public purse, we also have to realize that there's limitations to our judgment in these areas there, and I don't really see an indication for us to kind of tie ourselves in knots pursuing what is going to be a much smaller element of the population in the acute care scenario. I think we put constraints around acute care and be done with it.

- Craig Blackmore: So, what are you proposing?
- Michael Souter: I think that we don't cover...I'll go back to what we said before, which is we should not cover in the acute presentations of symptoms there from a diagnosis of acute sinusitis unless there are overt complications, red flags, call them what you will. Anything else outside of that, we're really kind of putting some very tenuous, to me, and somewhat artificial distinctions onto an area where there really is no foundation for that.
- Craig Blackmore: So, let me...I'm...I like what you're saying, but I want to push back a little bit. What about people who haven't been treated and the self-described symptoms as being more than in the acute frame.
- Michael Souter: Make it a diagnosis, a diagnosis. When they present and if they're really...if they haven't been treated, and if they don't actually have evidence or signs of acute complications, then that's a timeframe, which maybe argues that they fall into this came where people are wandering around with chronic conditions for ions and they don't actually have a problem, and then in other words, another four weeks isn't actually going to cause any problems in the absence of any overt signs of more red flags to raise, to say otherwise. Does that make sense?
- Craig Blackmore: I think so, but I'm not sure about one piece of what you said, and that's about treatment. I'm not sure I heard it. Did...did you mean that...so we allow...here we go. People who have red flags, other people who have had symptoms for more than four weeks...
- Michael Souter: A diagnosis for more than four weeks.
- Craig Blackmore: Diagnosis for more than four weeks, a diagnosis based on test criteria.
- Michael Souter: Yeah.
- Craig Blackmore: What about failure of treatment? Do they have to be treated or do they just have to be diagnosed? I think failure of treatment is more important than the diagnosis.
- Joann Elmore: I agree. What does the diagnosis state? (inaudible)
- Michael Souter: So, it should satisfy both, the diagnosis time and (inaudible).
- Craig Blackmore: You can't get a scan until somebody's tried to treat you unless you've got something dangerous going on.
- Chris Standaert: Right. So, you're sort of saying that, frankly, the definition of acute is almost arbitrary, because somebody could just come in after a long time. So, you're saying it doesn't...because if you come in with sinusitis of some version, and you've never been treated, you could med-...and you're not complicated. You're not worried about anything bad, you should have medical treatment, and

if you fail medical treatment, then the doctor has some discretion in I can do something if I want to. I can go look if I want to. That's what you get.

Michael Souter: Yeah.

Chris Standaert: So, this whole acute/chronic you're getting rid of? Yeah.

Michael Souter: Well, yeah.

Chris Standaert: You're saying...

Michael Souter: (inaudible) acute timeframe.

Chris Standaert: ...people need to be...

Michael Souter: Put some limits around it.

Chris Standaert: ...yeah. People need to be treated before...

Craig Blackmore: And that gets us back to where these guys don't think they can implement.

Michael Souter: What? Can't implement a four-week timeframe with a failure of treatment?

Craig Blackmore: I don't...I think it's the failure of treatment. OK. Let's put some words up. Can we have the piece of paper again, please? So, the conditions are for A, let's just make it red flags, and we'll define those later. B is failure of conservative treatment. I don't think maximum needs to be in there.

Seth Schwartz: This may...may sound challenging, but could you just say failure of medical therapy because, you know, they can say...because the question is, we don't really know what's right treatment. So, were you treated or were you not treated. Yeah, you may have been inappropriately treated. You only got three days of antibiotics, but, I mean, we can't make that definition.

Marie Brown: Right.

Craig Blackmore: Nobody knows what the right treatment is anyway.

Seth Schwartz: Right. But if you just say failure of medical therapy period, they can say, did the patient get...they can operationalize whether they were treated medically.

Michelle Simon: Right.

Craig Blackmore: I don't think they can, but that's alright. So, failure of medical therapy, and then...

Marie Brown: Maybe (inaudible).

- Craig Blackmore: And then get rid of C. Get rid of...no, no, no. Get rid of concern for complications. C becomes surgical planning.
- Seth Schwartz: But, I think for B, it would have to be failure of medical therapy with persistent symptoms greater than four weeks.
- Michelle Simon: Or recurrent. That's the other category.
- Marie Brown: Well, if they didn't have...
- Craig Blackmore: Because, we don't care if...
- Marie Brown: ...symptoms, you wouldn't be doing it.
- Seth Schwartz: Well, no, no, no. But the point is if...
- Joann Elmore: Medical therapy (inaudible).
- Seth Schwartz: ...right. If they're treated less than a month...
- Marie Brown: Oh.
- Seth Schwartz: ...less than a month (inaudible).
- Chris Standaert: (inaudible) anything, and they'll get better (inaudible).
- Seth Schwartz: So, there's still no reason to...even if they failed medical therapy within the first month, there's still no reason to image those patients.
- Craig Blackmore: Failure of medical therapy after four weeks.
- Seth Schwartz: Yeah, just, still probably too short, but.
- Joann Elmore: Well, do we need four weeks of treatment or do we need it to be multiple courses of treatment? I think we just want to know that...
- Craig Blackmore: Failure...
- Joann Elmore: ...somebody's been trying to treat them, and they've been having the symptoms for more than four weeks while somebody's been trying to treat them.
- Michelle Simon: And I would say failure of medical therapy for six weeks, because their...their scan is not going to clear for six weeks.
- Joann Elmore: Yeah. I'd like to say twelve.
- Chris Standaert: (inaudible) medical therapy, but (inaudible) after.

- Craig Blackmore: How about failure of six weeks of medical therapy.
- Joann Elmore: Why don't we?
- Craig Blackmore: What's that?
- Joann Elmore: Why don't we say twelve? There's no data. Even the APR is giving low ratings for this. There's no data. Patients are dying. If they have red flags they can jump to get it right away.
- Chris Standaert: Six weeks and one course of antibiotics, and you're six weeks in and you're not better, are you really going to go operate on that patient? You're going to watch them for six more weeks and see what (inaudible).
- Michelle Simon: And why would you get a CT scan? You know it's going to look bad.
- Seth Schwartz: But the problem would be...so that...so that middle one would be twelve weeks of symptoms and failure of medical therapy.
- Joann Elmore: Yeah.
- Chris Standaert: Can we say failure of twelve weeks of medical failure?
- Seth Schwartz: No, because I...it doesn't need to be twelve weeks of that. You don't need to be on antibiotics for twelve weeks to get a scan.
- Chris Standaert: Well, the symptoms...I mean, that means you only have to treat them...they can have twelve weeks, return for a week and they failed and then you do something.
- Seth Schwartz: Right, because that's reasonable, because the point is, we don't actually know if medical therapy is better than surgery or vice versa, if they've had...in the chronic sinusitis category. We...that data does not exist, or it's unclear. So, for us to say you have to have been treated at all is actually relatively controversial, but I don't think you're going to find any doctor who's going to operate on somebody who hasn't had any kind of treatment.
- Chris Standaert: Actually, they can operate...they can cover based on surgical planning anyways. Yeah. If they want to operate, they can scan to operate anyway.
- Craig Blackmore: It's very lenient.
- Chris Standaert: It's very lenient.
- Joann Elmore: Do we need to flip those two and say twelve weeks of symptoms despite medical treatment, because we don't want them to come in saying they've had twelve weeks of symptoms, see the doc, and the doctor gives them three days of antibiotics and then they fail.

Craig Blackmore: I like that.

Chris Standaert: Right.

Joann Elmore: So, flip the two. Say twelve weeks of symptoms despite medical treatment.

Craig Blackmore: Yeah. I want them treated for twelve weeks. I don't want them to say I've had...

Michael Souter: So, twelve weeks from diagnosis.

Joann Elmore: Not from diagnosis, because I'm worried...we docs...do we di...give them the diagnosis the day that we see them in clinic or they come in with three weeks of symptoms (inaudible).

Chris Standaert: Symptoms three weeks ago.

Craig Blackmore: This has been bugging me, since Christmas.

Joann Elmore: So, I want them to have been under a primary care doc's care for twelve weeks, on and off treatment, trying to maximize it before they jump in.

Michael Souter: But I think (inaudible)...

Joann Elmore: Twelve weeks of symptoms despite medical therapy.

Seth Schwartz: I think the despite is challenging. I think you, I mean...let's talk about operationalizing simply were they treated medically. You have twelve weeks of symptoms and they were...and they were...had been treated medically.

Craig Blackmore: I don't understand what you said.

Seth Schwartz: We've already said we can't define what's appropriate medical treatment, right? So, when you say treated for twelve weeks, that doesn't mean anything. Or, at least it doesn't mean anything meaningful, right, because then are we advocating that people get treated with antibiotics for three months? That's probably not appropriate either.

Craig Blackmore: Well, we didn't say...

Seth Schwartz: No, no, I understand, but I mean, but to say twelve weeks of medical therapy seems wrong.

Amy Anstead: You can just say persistence of symptoms at twelve weeks...

Joann Elmore: Despite...

Amy Anstead: ...despite medical therapy.

Joann Elmore: That's good. In other words, yeah. I don't want them to come in saying I've had this for twelve weeks, but (inaudible).

Seth Schwartz: But why can't you say...

Joann Elmore: ...antibiotics for three days and say it's been persistent for twelve weeks.

Seth Schwartz: Why can't you just say symptoms of sinusitis for greater than...greater than twelve weeks, and failed medical therapy.

Amy Anstead: Sure, perfect.

Seth Schwartz: So, it would be persistent symptoms for greater than twelve weeks and failed medical therapy. I mean, it's kind of inherent...

Joann Elmore: Then you have the...

Seth Schwartz: ...that there's still symptoms.

Joann Elmore: ...and, OK.

Seth Schwartz: But, at least...it seems more operational.

Joann Elmore: Capitalize the and.

Craig Blackmore: And you can get rid of the despite. That's OK.

Seth Schwartz: And failure of medical therapy.

Joann Elmore: Yeah, get rid of our despite.

Craig Blackmore: Alright, well this certainly gets at, I think, Michael's point about focusing our attention on the early phase and leaving the flexibility for the later. Further comments on this?

Richard Phillips: I noticed we have CT up there. Do we really need that if we have a separate statement on the technologies at the end? In other words, if we make a separate statement consistent with what the medical directors have in that last statement, the one that Kevin pointed out.

Craig Blackmore: Well, that...this is...yeah.

Kevin Walsh: This is what they have.

Craig Blackmore: We'll circle back after we talk about the other.

- Richard Phillips: Right, but what I'm...what I'm wondering is if we really need to even put CT up there. That's all.
- Kevin Walsh: Yeah, that's...that's what this...that's what the slide has.
- Craig Blackmore: We'll leave it there for now.
- Kevin Walsh: The slide has CT and then they have ultrasound and MRI at the bottom as separate categories. So, this is about CT scanning.
- Richard Phillips: I don't disagree, but I'm just trying to...and I'll drop it.
- Michelle Simon: My only question is about persistent symptoms. Do we all know what those are and as a point of discussion, I would look at the clinical practice guidelines from the American Academy of Otolaryngology, and what they say is twelve weeks or longer of two or more of the following signs and symptoms, and they list four there. I don't know if we need to be that specific or if we're OK being general about symptoms. So, they say mucopurulent discharge, nasal bone obstruction, facial pain, and decreased sense of smell. Those are their four signs and symptoms.
- Amy Anstead: The big thing that they've done with their recommendations is, they're trying to, they're trying to dissuade people from doing the CT scan for the headache and trying to dissuade people from relating headache to chronic sinus disease.
- David McCulloch: I like that. Being specific, facial pain and mucopurulent discharge.
- Craig Blackmore: Well, what do you guys think? Do you want to use...we could use these specific criteria that the guidelines recommend, or we could leave it as symptoms.
- David McCulloch: I...I like being a little...despite what Chris says, in this situation, being specific. I think having headache or severe headache as a red flag is just a huge loophole for people to go through because it's subjective. I think this is, you know, mucopurulent discharge, facial pain, yeah. So, I...I think being...there only are four. So, we may just specify, persistent symptoms – brackets – those four after twelve, then reasonable.
- Craig Blackmore: So, what do people think about specifying the symptoms?
- Michael Souter: Well, I don't know. I'm just looking at all the other guidelines put out by the American Academy of Oncology/Radiology, and the...
- Craig Blackmore: Yeah, I wouldn't...I wouldn't...
- Michael Souter: ...I mean...
- Craig Blackmore: ...for symptoms and stuff like that, I wouldn't...

- Chris Standaert: Not for symptoms.
- Craig Blackmore: ...rely on the radiologist.
- Michael Souter: Yeah, I know, but then, OK. So, with that...
- Kevin Walsh: There's a Canadian...
- Michael Souter: ...limitation in mind...
- Kevin Walsh: ...practice guideline...
- Michael Souter: ...then there's the allergists and the immunologists who would actually include. So, as far as I can see, there's...there's cohorts of other practitioners in the field who seem to include headache as part of the criteria. Now, at some point, headache would be important to assess, and I wouldn't want to preclude someone's ability to investigate.
- Joann Elmore: But then you pull a CT scan not a sinus (inaudible).
- Craig Blackmore: Do a head CT first for a headache.
- Marie Brown: You wouldn't just do (inaudible)...
- Craig Blackmore: That or a sinus CT?
- Marie Brown: ...for a headache.
- Kevin Walsh: So, the red flag symptoms slide that the agency presented came from an article, which was from the Canadian practice guidelines, and they've got definitions of chronic, symptoms of chronic, facial congestion, fullness, facial pain, pressure, fullness, nasal obstruction, purulent nasal dis-, nasal drainage, and anosmia/hyposmia.
- Craig Blackmore: They're basically the same.
- Kevin Walsh: So, those are basically the same that David had described, the same as Michelle.
- Seth Schwartz: I'm sort of circling around this, and I'm initially...my initial thought was I don't want to be too restrictive on it because you don't...you know, you want to leave a little room for judgment here, but I agree with David's concern that if the loophole's too big, you might as well not say anything, but then in thinking about this further, I think some of these symptoms make sense to pull out, because what we're talking about is sinus CT. So, if you have someone assessing somebody for a headache, it doesn't mean they can't scan them because they're worried about a tumor or aneurysm or whatever. We're not saying that. We're saying don't get a sinus CT, you know, if you're worried...

- Marie Brown: Exactly.
- Seth Schwartz: ...sinusitis. So, I think it's reasonable to have the symptoms be targeted more at sinus condition, that could be attributable to sinus condition.
- Marie Brown: Right.
- Joann Elmore: So, we need to, instead of just saying CT, we need to say sinus CT.
- Chris Standaert: No, but our data isn't necessarily all on sinus CTs.
- Craig Blackmore: This decision is only about sinus CT.
- Chris Standaert: For treatment of sinusitis or is it only about sinus CT? Because you only limit...if you only limit sinus CT, they're just going to order a head CT if they want it. I mean, if that's the only restriction that...
- Kevin Walsh: It's imaging for...
- Chris Standaert: ...doesn't make any sense.
- Kevin Walsh: ...rhinosinusitis.
- Chris Standaert: Yeah, it's just imaging. So, it's...they got...you can...people order a head CT.
- Michael Souter: Well, they may not get the sinuses then. The number of head CTs I look at, which actually have no sinus or (inaudible).
- Craig Blackmore: Yeah, I mean, we're going to...we're going to focus on sinus CT, because the indications for head CT are so far out of the scope for what our literature review included.
- Chris Standaert: I guess, you know, I look at that. That still is a pretty big door, and the only thing...I recognize there's no data of abuse, but I know there's no data of not abuse, and it still seems like you should get a CT...the data that CT really can confirm your diagnosis of chronic sinusitis isn't very good. So, really, the only reason for getting a CT is you're worried about something else. Like, you have to...either you're trying to diagnose something else, or you've got to think about operating, and that's not quite what that says. It somebody who has symptoms for twelve weeks, you've tried a couple antibiotics, you get the...I mean, CT their sinus. It almost has the implication you CT their sinuses at that point, and it's really not helpful unless you're worried about...you have reasonable clinical suspicion of some other diagnosis, or you're going to really think, should we...should they be going to a surgeon. Should the surgeon be doing something?
- David McCulloch: I don't think...

- Chris Standaert: And I don't know if the...
- David McCulloch: ...you've got an evidence base to say that.
- Chris Standaert: Well, you know, my problem is not having the evidence base to say that we should be CT'ing people with diagnosed chronic sinusitis.
- Kevin Walsh: I think you do have an evidence base to say that, because all the...the literature's not...nobody's impressed with the literature.
- Michael Souter: Well, no one's impressed with (inaudible) literature. OK. I get that, but I am, I'm still concerned as to us extrapolating beyond an adequate foundation of knowledge, and I don't think that we're there, because it's not as if there are not downsides to this. Yes, I'm sure. OK. The red flags are there, but we've heard from our clinical expert that people will come into the clinic and actually have significant disease without any symptoms. So, that...that concerns me, you know, the fact that we're...that there are downsides to leaving people uninvestigated chronically over time, and I...I become uncomfortable when we start making severely significant prescriptions where we just don't have a good foundation of knowledge.
- Seth Schwartz: The fungal example that she gave was a patient with exophthalmos who came in. I mean, it...that's...in my mind, that would be a red flag. So...
- Michael Souter: (inaudible)
- Chris Standaert: I think that one's tricky because you can go to your point earlier that we don't have data that you can use this as a screening test for fungal infections.
- Joann Elmore: Or even followup treatment.
- Chris Standaert: Right. So, it's a...it...so if you, yeah. I mean, the data we had is on people who had known fungal infection. How good at it was...how good was CT at finding it was the data we got.
- Craig Blackmore: So, just as a starting point, not everybody is comfortable with this, can I get a sense from the committee, are most people comfortable with this sort of place, or not? Do we need...give me some hands? Are we doing OK here, or do we need to...do we need to rethink? Are we doing OK?
- Richard Phillips: Yeah.
- Joann Elmore: We're doing great with your leadership and despite the lack of evidence.
- Kevin Walsh: What's the...help me...I need some clarification. I...I've got the cover with conditions A, B, and C. I got that, but then we skipped down to medical complications, and so the implication there is, if you have...

Craig Blackmore: Sorry, these...

Kevin Walsh: ...these were an add-on?

Marie Brown: These are red flags?

Kevin Walsh: That was an add-on to B?

Craig Blackmore: No, no, no. These are the symptoms that we're using to define persistent symptoms.

Kevin Walsh: Those are persistent...those are the persistent symptoms.

Craig Blackmore: So, we're limiting it to these...

Kevin Walsh: Got it.

Craig Blackmore: ...sinus...

Kevin Walsh: Got it.

Craig Blackmore: ...specific.

Kevin Walsh: We could star, star to refer the...

Craig Blackmore: Yeah.

Kevin Walsh: ...the poorly...

Craig Blackmore: Yeah.

Richard Phillips: And the guidelines suggest two of four of the...the recommendations?

Craig Blackmore: I was thinking it was any, but could be two or four or all. I don't know what the committee...

Amy Anstead: I think in chronic rhinosinusitis that it's twelve weeks or longer of two or more of those. That's what the Inter-Qual guidelines use.

Kevin Walsh: Radion does the same.

Amy Anstead: Two or more.

Craig Blackmore: Two or more?

Marie Brown: Uh-huh.

Craig Blackmore: So, which would?

Joann Elmore: Persistent symptoms defined as two or more of the following.

Marie Brown: Yeah. Persistent symptoms and.

Michelle Simon: And inflammation, yeah, but we're not defining it.

Marie Brown: So, there's actually a fifth, inflammation, and inflammation at the bottom.

Michelle Simon: No, we're talking...we're trying to define what symptoms we're...

Marie Brown: Right.

Michelle Simon: ...pulling out a definition for symptoms.

Marie Brown: Right.

Richard Phillips: Yeah. That'd be a clinical finding, so.

Joann Elmore: Can we add something for the repeat CT'ers who get six a year?

Craig Blackmore: OK, but let's...are...are we happy here with what we? OK.

Richard Phillips: I am, yes.

Marie Brown: It just feels a little open, still.

Craig Blackmore: It is open.

Joann Elmore: It is open.

Craig Blackmore: I don't know how to close it.

Joann Elmore: Well, that's why I'm wondering about closing at least, you know...

Craig Blackmore: Alright...

Joann Elmore: ...because B and C they could get six CTs a year in a patient. So, I'm wondering about adding a D, you know, more than one CT per patient.

Richard Phillips: Could that be part of the cover with conditions, to say...

Joann Elmore: Well, more than one CT per patient requires prior authorization and just leave it up to these guys.

Chris Standaert: So, we'll put a...what would be the reasons for reimaging? So, rather than trying to put a number, do we go back to why would you be imaged?

- Joann Elmore: Right, fungal infections, they want to look at therapy and immunocompromised...I mean...
- Craig Blackmore: So, I mean, I think if they have red flags, we probably don't want to limit the number of CTs, right?
- Chris Standaert: You have to track the osteo. You have to track the whatever.
- Craig Blackmore: I mean, this...that's real disease.
- Chris Standaert: Yeah.
- Craig Blackmore: So, we could say persistent symptoms and failure of medical therapy and no CT scan within the past six months, twelve months. We don't have any data to tell us to do that.
- Kevin Walsh: Well, we have data telling us that continuing to do it doesn't offer improved outcome. So, we do have data.
- Craig Blackmore: Well, we certainly don't have data that says it helps to do another CT scan.
- Chris Standaert: We don't have data on recurrent CT scans, right?
- Kevin Walsh: No. I'm saying if...if doing the scan in the first place is not that definitive, then how can you propose that doing more is more definitive.
- Craig Blackmore: I actually don't have a problem with saying you can't repeat the scan, because you've got a caveat for surgical planning. So, surgeons can take them to the OR and they need...
- Joann Elmore: And we have a caveat for red flags.
- Craig Blackmore: And we have a caveat for red flags. So, I mean, if somebody has chronic sinus disease, do you need repeat scans to see how they're doing, and the answer is, the correlation between what you find on those scans and how they're doing is poor enough that I don't know why...
- Kevin Walsh: Well, couldn't it be one...one of three...I mean, couldn't it be an or/or/or there?
- Craig Blackmore: It is an or/or/or yeah. So, the repeat only applies to the symptoms people.
- Joann Elmore: So, red flags.
- Craig Blackmore: It doesn't apply to the red flag or the surgery people.
- Chris Standaert: You could see no repeat scan in the absence of red flags or additional surgical considerations or something like that.

Craig Blackmore: I think it's OK. For B, have persistent symptoms and failure of medical therapy and no CT scan...no sinus CT scan in the past six months.

Seth Schwartz: I think you're making that up.

Joann Elmore: We are.

Chris Standaert: Yeah, we're making that up.

Craig Blackmore: Because we have seen no data to suggest repeat scan has value.

Joann Elmore: Well, I'm thinking you want to make that the past six months.

Marie Brown: Right.

Seth Schwartz: That's what I mean. I mean, I'm just not...I mean, again, as you said earlier, we have seen no data on repeat scans.

Craig Blackmore: Right.

Chris Standaert: Right.

Seth Schwartz: And so I think it's hard to...

Craig Blackmore: So, we can interpret that as an open door. We can interpret that as nobody has ever shown there's any value in doing this thing. So, why should we pay for it?

Seth Schwartz: So, if that's the case, so then why are you limiting it to six months.

Chris Standaert: I mean, the only reason we did...

Seth Schwartz: I mean, again, the six months is ar-...my point is, the six months is arbitrary. So, I don't...

Craig Blackmore: It is arbitrary.

Seth Schwartz: ...so I don't think that should be part of B I guess is my number one point, because I think...

Richard Phillips: Yeah. Did the state have any utilization data on multiple scans?

Chris Standaert: I mean the only...

Seth Schwartz: I mean, you could simply say...have a D which is repeat scanning is only indicated for red flags or surgical planning.

Craig Blackmore: That's fine.

- Chris Standaert: I mean, basically, there's no...
- Marie Brown: Yeah.
- Chris Standaert: ...the only reason we're doing a CT is to clarify a diagnosis or you're going to do something, or you have something. So, once you've clarified your diagnosis, that's all. You don't need another one.
- Craig Blackmore: What about five years later?
- Chris Standaert: We don't have any data to...
- Craig Blackmore: It's all new...it's a new disease, you know? I mean, it's...
- Chris Standaert: Right.
- Craig Blackmore: ...you have to have some timeframe because just because you had a scan at age 16 and now you got new symptoms at age 50.
- Seth Schwartz: Well, I mean, here's the devil's advocate. You get sinusitis in January. You go for three months. Your symptoms are still there. You get scanned and then you get treated medically. You get scanned in...in April, and your scan looks not bad. You decide not to operate. You get another episode in August and you're terrible in December and now you're...well, I guess...
- Craig Blackmore: Now, you get surgery.
- Seth Schwartz: ...now you're thinking about surgery.
- Marie Brown: Surgery.
- Chris Standaert: Well, because my problem is, you can't really diagnose sinusitis well by CT. So, what they do in two years or twenty years later, if that's still what you're trying to diagnose, it doesn't really help you. You're doing it because you're thinking about...there's some anatomic thing you want to go fix, you have something bad, or you don't know what you have.
- Joann Elmore: Right. That's why I tried to make a B with part A...
- Chris Standaert: That's all you're doing it for.
- Joann Elmore: ...and part B (inaudible).
- Chris Standaert: (inaudible) repeat scan...even if you had a scan three years ago and it showed nothing and you still think you have chronic sinusitis, it doesn't help you at all to be CT'd unless you have some new consideration. You now have a red flag. You now want to operate or you now.

Amy Anstead: I agree. It's almost like you need a once in a lifetime CT scan of your sinuses and then after that, unless you're going to do something about it or it changes...

Chris Standaert: Right.

Amy Anstead: ...you don't need another one.

Craig Blackmore: What do you mean by it changes?

Chris Standaert: Like, you get a red flag.

Amy Anstead: Your eye starts popping out of your head or a polyp starts popping out of your nose, things like that.

Chris Standaert: Yeah, yeah.

Marie Brown: So, then we would say repeat scanning is not indicated.

Chris Standaert: In the absence of...

Marie Brown: In the absence of...

Craig Blackmore: It's up...it's up to the committee. I would be a little more lenient and say maybe a year or two years. You guys are saying you never get another scan.

Chris Standaert: Unless they have a...

Craig Blackmore: So, it makes me a little uncomfortable.

Joann Elmore: If you have a red flag...

Craig Blackmore: Whatever the committee says.

Joann Elmore: ...you still have those two outs.

Amy Anstead: You have outs, yeah.

Marie Brown: If they're planning a surgery.

Craig Blackmore: Well, you can say D, repeat...whatever, what was it? Repeat scanning is not covered except for red flags or surgical planning? Is that? And then...

Amy Anstead: Yeah. Seth had a good one. What'd you say, Seth?

Seth Schwartz: (inaudible) A and C.

Amy Anstead: Yeah.

- Craig Blackmore: I think...I think on the operational side, I think...I think that would work. That's fine, if that's where the committee wants to go. No, or is fine. Alright. How do we feel about this?
- Chris Standaert: D shuts the door a little more for me. It's good.
- Marie Brown: Uh-huh.
- Seth Schwartz: So, would D...would D include new red flags? New red flag symptoms or any red flag symptoms?
- Craig Blackmore: So, I mean, I think in the language we, we shouldn't say A and C. We should say repeat scanning is not covered except for...you can copy and past...red flags or surgical planning. So, I mean, that implies when there is a red flag, you can scan.
- Amy Anstead: Just replace A with what it says.
- Chris Standaert: Except for red flags and surgical planning, or surgical planning.
- Craig Blackmore: Or surgical planning. Yeah.
- Michael Souter: Are we really going to say red flags?
- Craig Blackmore: No. We're going to define the red flags.
- Amy Anstead: You could bring up your list.
- Craig Blackmore: I just thought this would be easier before we define the red flags. I might be wrong.
- Richard Phillips: As before, we should also make sure that we...maybe this is your point...specify precisely what the red flag symptoms are.
- Craig Blackmore: I think we're going to have to.
- Richard Phillips: As listed in the slide 16 I think it is or whatever.
- Amy Anstead: Yeah, and there...there's a list on the AAO guidelines of red flags. She can list them off for you.
- Chris Standaert: Do all the guidelines have the exact same list of red flags?
- Amy Anstead: I think there's some...
- Teresa Rogstad: Well in...
- Amy Anstead: ...there's some overlap.

- Teresa Rogstad: ...yeah. In the two guidelines that we cited in the report, we didn't include the Canadian guidelines, but in AAO, HNS, it's severe headache, facial swelling, isn't there a red flag list up there already? Lower. If you want to pull that up then I can just read the ones that are missing. Those are symptoms. There's a...a different red flag. There was earlier?
- Richard Phillips: Yeah, there was a slide #17, I think, in the...from the...Charissa's presentation.
- Teresa Rogstad: Oh, OK. That's what it was, yeah. Let's see, keep going. It's in red. There you go. OK. So, the AAO, HNS list, I'll just read it, and you can add ones that are new, severe headache, that's up there already, facial swelling, I think that's there, yeah, cranial nerve palsies, that's not up there, oh, right, right, OK. Forehead displacement or bulging of the eye, and that's up there, and then the other major guideline, oh, that was just orbital involvement. So, I guess, I guess we're covered.
- Michael Souter: I guess I don't see a difference between swelling of the orbit and (inaudible).
- Joann Elmore: Yeah. There's a lot of overlap, like, altered mental status is the same as neurologic findings. I think we can still say...
- Michael Souter: (inaudible)
- Craig Blackmore: Not all. Not all.
- Chris Standaert: A finding is a finding.
- Joann Elmore: No? OK.
- Chris Standaert: And it...would exophthalmos fall under (inaudible) of the orbit?
- Richard Phillips: Yeah, well see, there's also a combination of symptoms and physical findings there, so.
- Joann Elmore: Right.
- Richard Phillips: So, they just need to be segregated.
- Seth Schwartz: Can I ask a semantic question?
- Craig Blackmore: Yeah.
- Seth Schwartz: We've had the term...you've been using the term surgical planning, which I think is probably right, but I'm wondering about...we're sort of using it interchangeably with the concept of surgical decision making, which is deciding whether you're going to operate or not.

- Amy Anstead: Yeah, I agree.
- Seth Schwartz: And, so I guess my question is, does surgical planning capture that adequately, or should we change it to surgical decision making?
- Amy Anstead: Yeah, or surgical consideration, or.
- Craig Blackmore: Yeah. I mean, I think that was our intent. Now, how do we make that clear? OK. So, let...let's go back to that. So, are we happy with this list?
- Marie Brown: Yes.
- Craig Blackmore: OK. So, we're going to...
- Kevin Walsh: Aren't we saying add...say red flag symptoms and findings, or findings?
- Richard Phillips: Yes, I think it should include findings.
- Chris Standaert: Red flags and get rid of the word symptoms.
- Craig Blackmore: So, I'm going to ask staff to copy this list and put it on our piece of paper that we had up before. Suspicion of.
- Chris Standaert: But that's a sign of...
- Craig Blackmore: No, I want...I want all those bullet points except the red flag symptoms. Copy all those bullet points and past them onto the piece of paper we have. Yep, all those. Can we say surgical evaluation instead of surgical planning?
- Chris Standaert: Hmm-mm. No.
- Craig Blackmore: No.
- Chris Standaert: Because that means (inaudible).
- Craig Blackmore: That means the surgeon wants to evaluate. What can we say?
- Marie Brown: Surgical (inaudible).
- Craig Blackmore: How about surgical planning. We can say surgical decision making, whatever seems to be.
- Chris Standaert: Anything...unless they really think they're going to operate, they...they operate on (inaudible).
- Marie Brown: Right. That's why decision making, yeah.

- Chris Standaert: But if you've already made the decision, then surgical decision making means I want a CT of everybody who walks in my door.
- Seth Schwartz: No. Well, I guess the way I'm thinking, you know...
- Chris Standaert: Well, yeah.
- Craig Blackmore: But that's not the problem we're trying to address.
- Seth Schwartz: The way...the way I'm thinking about it is, you have a patient where everything lines up and, you know, sinuses...you scope him and his nose doesn't look good. He's got all the signs and symptoms that are consistent with it, failed medical therapy, but if you get a sinus CT in anticipation of surgery and his sinuses are totally clear, you may not operate on him. So...
- Chris Standaert: Right.
- Seth Schwartz: ...that is a decision point. So, the CT...
- Chris Standaert: Right.
- Seth Schwartz: ...is actually a decision point. I mean, in other words, we're not going to not operate on someone because their sinuses, you know...in other words, we might...if someone has sinus...doesn't have any abnormality on their sinus CT, you're not going to do sinus surgery.
- Amy Anstead: Right.
- Chris Standaert: Right, and you may not know that until you get the sinus CT.
- Seth Schwartz: Right, exactly. So, that's...so...
- Chris Standaert: You may not know what you're thinking is going to be a minimal (inaudible) until you get the sinus CT.
- Seth Schwartz: Exactly, so that's my point. So, maybe it doesn't matter from a semantic standpoint. I mean, if we say surgical planning is that OK, because you...but really, it's...you're not looking at a patient for surgical...when I think of surgical planning, it's I've decided to operate on you and now I need the scan to guide what I'm going to do surgically. That's different than, than making the decision as to whether or not you're going to operate.
- Amy Anstead: Right.
- Seth Schwartz: So, if...if the term surgical planning captures both of those, then that's fine, and the only other comment I would have...well, I guess it's not. I was going to say the only other comment I have about repeat scans is that you may have someone who has a diagnostic CT, because there's like...there are screening

sinus CTs, which may be enough to decide you're going to operate, but that may not be enough to operate on. So, you may need another sinus CT to actually do your surgery, but I think that's captured (inaudible). OK.

Chris Standaert: If you need another one to clarify your surgery, you'll be able to get it.

Craig Blackmore: OK. So are...so are you guys copying and pasting over there? Because we have a blue screen.

Marie Brown: I think planning is just too big.

Craig Blackmore: I don't actually.

Chris Standaert: Planning is (inaudible).

Michelle Simon: I think planning is better.

Marie Brown: Yeah, because decision making is...

Chris Standaert: Decision making really means (inaudible).

Marie Brown: Yeah.

Chris Standaert: You don't need surgery. I made a decision (inaudible).

Craig Blackmore: So, the guideline says surgical management. Do we like that better?

Chris Standaert: That's what it is.

Craig Blackmore: Surgical management? Does that resonate, surgical management? That's what one of the guidelines says. Alright.

Chris Standaert: It's better than decision making.

Craig Blackmore: OK. While they're doing that, let's talk ultrasound.

Group: No.

Craig Blackmore: About pregnant women.

Chris Standaert: Do we have any data on ultrasound in pregnant women?

Group: No.

Chris Standaert: We had none, and it...

Joann Elmore: And if somebody really wants one, they just call up and try to get it?

- Craig Blackmore: No.
- Chris Standaert: So, as a practical point. So, ultrasound looking for some...you're worried about something bad in the head of the woman's who's pregnant, right? You have exophthalmus, you have some infection, you have some something. Does ultrasound really help you, or are you going to be better off taking the risk and...an MRI seems like a much better bet...
- Joann Elmore: Yeah.
- Chris Standaert: ...than ultrasound, because ultrasound doesn't seem like it's going to do in the...it's not going to rule out the intracranial things you're worried. It's a very poor imaging choice for somebody who is acute ill, and that's all you're going to do.
- Joann Elmore: Right.
- Chris Standaert: It just seems odd, the data. We don't have any data...
- Richard Phillips: Based on the data...
- Chris Standaert: ...saying it's any good.
- Richard Phillips: ...we're not...wouldn't it be reasonable to say that ultrasound, MRI, and standard x-ray, except with prior authorization, would be prohibited?
- Craig Blackmore: Well, we can't say except with prior authorization without defining what the criteria are. We can't just throw it back at the agencies. So, ultrasound, so I'm not hearing any enthusiasm for covering ultrasound.
- Group: No.
- Craig Blackmore: OK. What about MRI? I think having an option in pregnancy is a good idea, and I don't want the committee to be having CT as the...it's my opinion, but I worry about having CT as the only option in pregnant women. MRI is more expensive than CT, but it provides basically the same anatomical information. So, I'm arguing that if we're going to allow CT under some limited cases, it makes sense, I think, to allow the more expensive test in pregnant women.
- Joann Elmore: Yes, with the same criteria.
- Craig Blackmore: With the same criteria, yes. Because, I think otherwise, you know, we're...we're...
- Chris Standaert: Are there times...
- Craig Blackmore: ...we look like we're forcing women to get radiated when they're pregnant, which...

- Chris Standaert: ...so, but are there times other than red flags when you would want to get an MRI?
- Michelle Simon: The evidence said it was better at distinguishing fungal issues.
- Chris Standaert: Right, but you're in the red flag...
- Craig Blackmore: You're in the red flag category, I think.
- Chris Standaert: Yeah, so could you say MRI for red flags, whether they're pregnant women or not. I mean, you may have other reasons why you want an MRI instead.
- Craig Blackmore: Oh, actually there were...actually, yeah, for some of the soft tissue abscess and orbital cellulitis. You'd want an MR.
- Chris Standaert: Yeah, you want an MR, so...
- Michael Souter: What about craniofacial abnormalities in children.
- Craig Blackmore: We haven't gotten to children yet, in my mind (inaudible).
- Michael Souter: Yeah, but if we're worried about pregnant women and radiation doses.
- Craig Blackmore: We need...we need to get into children, as well.
- Chris Standaert: You could just say MRI for red flags, and it'll cover anybody with a red flag, and that's the only reason for scanning a pregnant woman, I would imagine. (inaudible) say I want to know if you have sinusitis, if you have chronic sinusitis in somebody who's 20 weeks pregnant, you know?
- Craig Blackmore: I don't know.
- Chris Standaert: That's an odd decision to make.
- Craig Blackmore: I don't know.
- Chris Standaert: You'd have to have a (inaudible).
- Craig Blackmore: I think it...my own perspective is that it would be wise to allow a nonradiation choice in pregnant women if we're allowing...if we're...if we think this is important to cover it, in pregnant women if there's a nonradiation option, we should allow it. That's my opinion.
- Group: I agree, yeah.
- Chris Standaert: So, MRI in pregnant...

- Seth Schwartz: Same criteria.
- Chris Standaert: ...women or for red flags.
- Craig Blackmore: Pregnant women or red...pregnant women for the same criteria listed or one of the red flags. Otherwise, you get the CT. It's cheaper.
- Richard Phillips: But that's not based on anything in the literature, though. It's just a...
- Craig Blackmore: It's based on the same evidence we used for CT. If we're CT is appropriate, an MR gives you basically the same information. It gives you some more information about soft tissues, but it gives you basically the same information. We're saying it's OK to do the CT, I think in pregnant women we have to say it's OK to do the MR. Otherwise, we're saying...callously saying that we should radiate pregnant women because we don't want to pay for this other test.
- Chris Standaert: So, if we leave it as-is we're also mandating that we treat pregnant women, which may not be...
- Craig Blackmore: We're not mandating...
- Chris Standaert: ...the wise thing...
- Craig Blackmore: ...well, and we're saying...
- Chris Standaert: ...no, I think we're (inaudible).
- Craig Blackmore: ...medical treatment. We're not saying what it is. I mean, medical therapy might be different...
- Teresa Rogstad: Can I interject something as someone who did OB care. This is Teresa over here, for a long time. I would be surprised if a provider who is caring for a woman who is pregnant would refer her for treatment of chronic sinusitis. We don't treat early stage cervical cancer. So, I mean, I think your...your point is well taken of an MRI if appropriate, but I wouldn't...
- Craig Blackmore: I think this is an incredibly small issue.
- Teresa Rogstad: I think you're right. I don't...
- Craig Blackmore: But I don't want us to say we're not...
- Kevin Walsh: So, so small.
- Craig Blackmore: ...covering a...a test...
- Teresa Rogstad: I would agree.

Craig Blackmore: ...in women, in pregnant women, just because it's a little more expensive. I'm just...that's my...

Seth Schwartz: Craig, I appreciate your sensitivity. Should we talk about transgender people, as well. We're talking about very small segments of population.

Craig Blackmore: Alright. X-ray?

Michael Souter: Well, if we're still in CT, I thought we were going to talk about kids.

Craig Blackmore: Alright, kids.

Michael Souter: I think we should have MRI for kids, as well.

Craig Blackmore: OK.

Michael Souter: Satisfying the same criteria.

Craig Blackmore: I think it's a valid point.

Michelle Simon: Kids are 18 or younger, you're suggesting, or?

Chris Standaert: Does your PICO have an age on it, or no?

Teresa Rogstad: No.

Craig Blackmore: It's covering all...all...

Teresa Rogstad: Adults (inaudible).

Chris Standaert: We didn't...you didn't present us anything on children.

Teresa Rogstad: No. Some of the accuracy studies included mixed populations of children and adults, but there was no analysis by age.

Chris Standaert: By age? OK.

Craig Blackmore: So...

Kevin Walsh: And what's the basis, Michael, of your proposal?

Michael Souter: Just the sensitivity.

Craig Blackmore: Radiation.

Michael Souter: The effects in children.

Kevin Walsh: Uh-huh.

- Michael Souter: They have a much lower threshold.
- Craig Blackmore: So, some, some pediatricians use x-ray in children, because it is lower dose than CT. A single modified Waters view of the paranasal sinuses is still done in children for this reason, for...just to confirm the diagnosis of sinusitis. I would propose allowing that. X-ray is much...it's much lower radiation. Actually, it's not much. It's lower radiation than CT and...
- Chris Standaert: So, x-ray is covered for the same indications but in children?
- Craig Blackmore: The...the data is weak, and I don't feel strongly about it, but I'm trying to be sensitive to, you know, I don't want to be CT scanning children.
- Chris Standaert: Right.
- Craig Blackmore: And to do an MR on a lot of these kids, you've got to sedate them, so it's not...
- Chris Standaert: Right.
- Joann Elmore: So, x-ray cover with conditions, like (inaudible)...
- Chris Standaert: The same thing as above in children.
- Joann Elmore: ...criteria.
- Marie Brown: Yes. Cover with conditions in less than 18 years with the above criteria.
- Craig Blackmore: I don't know if the guidelines speak to that.
- Joann Elmore: And less than 18 years (inaudible).
- Craig Blackmore: What do they say? American Academy of Pediatrics.
- Chris Standaert: So, MRI has been...
- Craig Blackmore: These guide...actually the American Academy of Pediatrics recommends not doing imaging, not doing x-ray.
- Amy Anstead: Yeah, I would say I would never...I would really never get just an x-ray, and I think that that's the recommendation of the American Academy of Pediatrics, as well.
- Craig Blackmore: Yeah. The American Academy of Pediatrics...
- Amy Anstead: It's a waste of radiation.

- Chris Standaert: I mean, how...by the time you're messing with this in kids, you're worried about something, like, they're not doing well. I mean, you're really messing...I mean, the kids are not doing well, which is...
- Amy Anstead: There's cystic fibrosis. They have a complication.
- Chris Standaert: Yeah.
- Amy Anstead: They might have to go to surgery.
- Chris Standaert: Right. So, you're going to get the MRI.
- Amy Anstead: You're going to...you're either going to get the MRI or you're going to get a low-dose CT scan...
- Chris Standaert: Yeah.
- Amy Anstead: ...for your surgical planning.
- Chris Standaert: Because you're not just treating...
- Amy Anstead: Yeah, I mean...
- Chris Standaert: ...a nose in kids by imaging.
- Amy Anstead: ...by only getting an x-ray.
- Chris Standaert: No, you're worried about something.
- Michael Souter: It's probably going to be craniofacial conditions more than anything else.
- Amy Anstead: Mm-hmm.
- Craig Blackmore: Craniofacial conditions is not in...
- Seth Schwartz: You still see it in...
- Amy Anstead: You still see it.
- Seth Schwartz: ...primary care doctors wanting to say is this sinusitis just to confirm their diagnosis, and it's not useful, or you have a...it's for the same reasons that you don't need to get a CT in adult patients. It's...it doesn't really...I mean, if they have all the symptoms and everything you should treat them anyway or not treat them, as the case may be, but it's not going to change things.
- Craig Blackmore: So, are we going to...the occasional one that's done now, is that going to be pushed into CT, and the answer is probably not, because we defined CT to prevent...we decided our indication to prevent that. So, if there are people that

still do this, we're saying it's probably not a good idea. So, they can end up doing CT scans, which would be worse, but the way we've defined it, they should...

Chris Standaert: We can let them do MRIs in kids. You can make MRI for red flags in everybody or for the conditions above in pregnant women or children...individuals under 18 years old.

Michael Souter: I just...just put pregnant women and children together.

Craig Blackmore: OK. That's fine with me.

Chris Standaert: Under MRI.

Craig Blackmore: Yeah.

Chris Standaert: MRI surveillance (inaudible) same thing as putting kids and pregnant women.

Craig Blackmore: Well, the assumption is they're not going to do it very much.

Marie Brown: Right.

Craig Blackmore: So, x-ray would be not covered.

Joann Elmore: X-ray not covered then.

Craig Blackmore: MRI of the sinus if you have red flags, for everybody (inaudible) reasons why they would want an MRI in people with chronic sinusitis if they have red flags.

Craig Blackmore: And ultrasound, we said not covered, as well.

Marie Brown: Ultrasound, not covered.

Craig Blackmore: OK.

Chris Standaert: Can you add red flags to MRI?

Michael Souter: With conditions, as above.

Chris Standaert: That's for kids and adults. So, it'd be covered...the same reasons you covered in adults, CT in adults, you'll cover MRI in kids and pregnant women, and then we'll cover...didn't we say we cover MRI in the setting of red flags?

Craig Blackmore: For anybody.

Chris Standaert: For anybody.

Michael Souter: Why would you do an MRI for anybody?

Chris Standaert: Because you're worried about a brain abscess, a soft tissue abscess, and something (inaudible).

Michael Souter: You should probably do a CT first, though.

Michelle Simon: Yeah, that's a different education.

Craig Blackmore: Well, maybe.

Chris Standaert: Yeah, but you still might want an MRI.

Michael Souter: MRI is more expensive.

Chris Standaert: I know, but you might want an MRI, too. You might want both.

Craig Blackmore: So, you do a CT and it's abnormal, and there's periorbital cellulitis. You might want to get an MR.

Michelle Simon: But that's...

Craig Blackmore: But then we're out of...

Michelle Simon: ...that's out of our...

Joann Elmore: Then, you're out of...

Michelle Simon: ...decision making.

Joann Elmore: ...sinusitis. You've got other (inaudible).

Michael Souter: Yeah.

Joann Elmore: I mean...

Craig Blackmore: Yeah. We're splitting hairs.

Joann Elmore: ...my whole sort of diagnostic criteria for the reason I ordered that wouldn't be sinusitis. It would be something else. So, I'm not...

Amy Anstead: Mm-hmm.

Chris Standaert: Yeah.

Joann Elmore: ...you know? They've got altered mental status.

Michael Souter: I wouldn't want...

- Joann Elmore: Or it's something, like, I'm not thinking about sinusitis, now.
- Chris Standaert: No.
- Joann Elmore: I'm thinking about other things. So, I'm not even certain why we're going there.
- Chris Standaert: The main things are CT.
- Seth Schwartz: Well, I mean, the circumstance...occasionally, there are circumstances where you use an MR in sinusitis so you can maybe try to differentiate if someone has a tumor or if someone...you can kind of differentiate whether, you know...what...whether it's just mucus in their nose, of whether they've got something else going on, because actually you can use it to differentiate the consistency of what's filling the sinuses. I mean, there are some indications where you would use it, but they're really, you know, small. It's not everyone with a red flag.
- Michael Souter: You get an MRI because it's a tumor or because...I mean, you'll have done the CT first.
- Amy Anstead: Yeah. You could come up with another diagnosis code.
- Craig Blackmore: So, this...our PICO is adults and children diagnosed with or suspected of having chronic, acute, or recurrent rhinosinusitis. So, if we're into suspected tumor, we're out of our population.
- Michael Souter: Yeah.
- Craig Blackmore: So, we're out of scope.
- Michael Souter: The same with...
- Craig Blackmore: The same with...
- Michael Souter: ...(inaudible). That's a different diagnosis code.
- Craig Blackmore: Right. Craniofacial abnormalities in a child is out of scope and...OK. So, we have a very long, complicated decision structure here.
- Marie Brown: We worked hard to get it.
- Craig Blackmore: Alright. So, can you just put the first page and let us look at it for a second?
- Seth Schwartz: And I have one...one point about the red flags. That last of the red flags, which is involvement of nearby structures, periorbital cellulitis, I wonder if you could state that better and just say extension outside of the sinuses or something like that?

- Craig Blackmore: I mean, these are indications for doing scanning, right? So, it's kind of like...
- Seth Schwartz: Yeah.
- Craig Blackmore: ...are we differentiating the information you get from the scan from the information that you have to order the scan, and I think we're...
- Seth Schwartz: Or you can have...I mean, you could have intraorbital abscess and not have periorbital cellulitis if it's really posterior. You could have vision loss in a patient with sinusitis and yet, you're not really worried about periorbital cellulitis. So, I think that comes out as being specific for periorbital cellulitis, but you could have involvement, so...
- Michael Souter: Aren't these merely examples?
- Seth Schwartz: I guess...so, I guess that was my point. I think periorbital cellulitis was an example, but here it's pulled out as the only one.
- Marie Brown: Oh, yeah.
- Michael Souter: You could get rid of those examples and just have signs of intracranial complications and involvement of nearby structures.
- Marie Brown: Nearby structures.
- Michael Souter: I can't actually see that. Can you make it larger?
- Chris Standaert: So, like, the signs of intracranial...I was going to say...suggest we add the word including (inaudible) meningitis, da da da. So, you could say (inaudible) exhaustive, but anyway, such as or including or something like that to modify, yeah. Add the word including right there or such as.
- Craig Blackmore: After the word complications, comma, including, colon, and then after the word structures, comma, including, colon.
- Seth Schwartz: But is including also...
- Amy Anstead: But not limited to.
- Seth Schwartz: ...yeah.
- Michael Souter: Yes.
- Seth Schwartz: I mean, we have to say, yeah.
- Michael Souter: So, we've got these specific here.

- Richard Phillips: Anybody else agree that the red flags should be red flag symptoms and findings?
- Teresa Rogstad: May I ask a question directed from our neurologist here at the table. Severe headache, do we want to add something with signs of sinusitis as opposed to, I mean, it's implied, but Gary's a little nervous about us just having severe headache sit up there by itself.
- Chris Standaert: Imaging in the setting of sinusitis.
- Teresa Rogstad: Right, right, yeah. I think it's implied there and I just want to make sure it's interpreted that way.
- Michelle Simon: Good point, because part of the reason we called out those symptoms specifically just above that was...
- Joann Elmore: Beyond sinusitis symptoms.
- Michelle Simon: ...yeah.
- Gary Franklin: The only reason I had a concern about headache as a standalone is that, as a neurologist, you see a lot of people with chronic, severe headaches and they've either been to an ENT or one of any number, dentist whatever, rule out sinusitis as a cause of their chronic tension headaches, and they're all going to get a CT if that headache is a standalone on that list.
- Richard Phillips: But, they're not going to get a CT of the sinuses. They're going to get a CT of the head.
- Amy Anstead: No. They're going to CT the sinus.
- Michelle Simon: Really?
- Chris Standaert: As far as I know, this ruling applies to people being evaluated for the treatment of chronic or acute sinusitis, and we're saying if they have a severe headache, which is what all the guidelines tell us, they should be able to CT them. Now, severe is a different word, right? I mean, if you have the worst headache of your life, then you go the Emergency Room. When do you scan somebody in the Emergency Room, if they're...same thing, but, this is just looking at their sinuses. I don't know. We're not saying just because you have a headache you get a sinus CT.
- Marie Brown: Right, no.
- Chris Standaert: You have to have other clinical signs that you have refractory sinusitis. Or something.

- Michelle Simon: No. We, actually are saying they can just have a severe headache, you can get a CT for...of your sinuses, because it's one of the callouts.
- Amy Anstead: It's a red flag in the setting of sinusitis.
- Michael Souter: Yeah, I think that's an important distinction, in the setting of sinusitis.
- Chris Standaert: (inaudible) could go altered mental status. You're not going to get a sinus CT for altered mental status if you're worried about sinusitis. (inaudible) sinus CT if these aren't (inaudible).
- Michelle Simon: And I think what we're talking about is right on sinusitis. Isn't that right? It's not just sinusitis.
- Amy Anstead: Sure, it's interchangeable. It's often used interchangeable, but sure, that's more correct.
- Michael Souter: In the setting of sinusitis imaging (inaudible).
- Craig Blackmore: Other thoughts? Any other comments?
- Joann Elmore: Maybe hide severe headache in the middle of the list.
- Amy Anstead: That's a good idea. Put it last, really small.
- Craig Blackmore: Alright. Turn to your decision-making too document thing, please. Alright. So, committee members, I will ask you to turn to the HTCC coverage and reimbursement determination analytic tool. Alright, can you save...can you save this please and not alter it anymore? So, we turn to the tool and this tool is designed to help us with the decision making process, and it lists some information that the committee is fully aware of. Our decisions are based on the three questions of is it safe, is it effective, and does it provide value to improve health outcomes, and staff have prepopulated the document with some of the outcomes that are relevant to the group, including safety, effectiveness, efficacy, outcomes, and special considerations. Are there other outcomes that the committee members would like to note as having been important in their decision making that are not already on here? So, we talked a lot about surgical planning, kind of as an outcome about how good the scan was. I guess clinical management decision is kind of the same thing.
- Chris Standaert: And wouldn't the safety concern be the...the overdiagnosis, right? Or if you don't know the real value of it, you just sort of find it, does it...if you used it willy nilly you would over diagnose the condition. You might be inclined to...
- Craig Blackmore: That's a good point.
- Joann Elmore: That's a good point.

- Craig Blackmore: That's a good point. OK. So, we'll add that, and then while we're working our way through here, we always want to be aware of whether there's CMS coverage decisions, and there's no local or national coverage decision, and we've had a lot of time to look at some of the practice guidelines from other organizations. So, I think, unless there's other comments, I want to move on to the first vote, which is nonbinding, and that's whether the committee members believe there is sufficient evidence under some or all situations that the technology is effective, safe, and cost-effective, and we'll start with effective. You are asked to determine if you think it is unproven, equivalent, less, or more effective than the alternative, which, in this case, would be no imaging, and we're going to just lump it as imaging in general. So, if you believe that imaging, in general, under any circumstance is more effective than no imaging, you should vote more. If you believe it's less effective under all circumstances, you vote less, equivalent, unproven, etc. So, if I could have the first please.
- Josh Morse: Ten more.
- Craig Blackmore: Ten more, and then is it safe, meaning it's more safe under any circumstance. It is less safe under all circumstances. It is always equivalent, or it is unproven, and if I could have your cards, please.
- Josh Morse: Seven unproven, one more, one equivalent.
- Craig Blackmore: You missed one.
- Josh Morse: Eight unproven.
- Craig Blackmore: OK.
- Josh Morse: One equivalent, one more.
- Craig Blackmore: And cost-effective, again, if it's more cost-effective under any circumstance, we vote yes, less if it's less under all circumstances.
- Josh Morse: Unproven ten.
- Craig Blackmore: Alright. So, based on what we now know, is there any further discussion that the committee members would like to advance at this point? Hearing nothing, we'll move on to the pink cards with a binding coverage decision, and we have three choices, cover meaning no restrictions, not cover meaning we will not pay for imaging-cover imaging under any circumstance in the context of people suspected of having rhinosinusitis, or cover with conditions, and the conditions we have populated on the sheet here, and you've all seen and we've discussed at length. If I could have a vote please.
- Josh Morse: Ten cover with conditions.

Craig Blackmore: Alright. And then again, reconciling that with what we know about other guidelines and other coverage policies and there is not uniformity among the other policies, our approach is generally consistent with what is out there, although we differed in a few areas based on where we felt there was evidence or lack of evidence and some ability...some challenge around getting granularity around dates and specific symptom complexes.

Josh Morse: And Medicare?

Craig Blackmore: And Medicare does not have a coverage decision, so we're in line with that, and I think that is it. That is it. OK, and lunch is not here. It is here. OK. Lunch is here, so we will adjourn and reconvene at 12:30. That gives you twenty minutes to eat so go to it.

I want to ask the committee members to take their seats, and we'll bring the meeting back to session. Alright. Well, we have a quorum, so we will resume. The second topic for the day is bariatric surgery, but before we do that, can we read this testosterone thing? Have your...have? So, we're going to...we're going to go back to the first item in the morning, which was our draft findings and decisions from last time on testosterone, and we had tabled that temporarily while we got the specifics of the European Male Aging Study, the specific criteria, and so on the board now we have the specific criteria from the European Male Aging Study and here they are. So, committee members, I want to make sure we agree on the wording before we have our final approval of the testosterone testing decision. So, the...these were the three questions, and the...I mean, you've got it hopefully in front of you, but what we had said is, signs of hypogonadism or symptoms of sexual dysfunction, and then in parenthesis all three criteria from the European Male Aging Study, and the suggestion was made that we specify exactly what those are. So, we have in yellow...those aren't the right...well, I guess they are. They're in a different order. So, in yellow we have some suggested wording on how we would summarize that. So, I guess I might, for number one...so the three criteria are one frequency of awakening with a full erection...I mean, we can just put this whole thing in here, awaken with a full erection less than or equal to one time in the past month. Number two, never or sometimes able to get and keep an erection sufficient for sexual intercourse, and number three, think about sex two to three times or less in the past month, or we can just use a quicker summary, as provided in yellow. So, I don't know what...what does the committee think? Quick summary or specific wording?

Michael Souter: So, probably drive is a better word than desire.

Josh Morse: I believe those three come right out of the author's...

Craig Blackmore: Is that from the abstract? So, these are the actual questions, and yellow is the words the authors used to describe those questions. You need a microphone. So, poor morning...symptoms of poor morning erection... I can't...there's glare, low sexual desire...

Teresa Rogstad: These came straight from the article, this quote, and this is from page 123.

Craig Blackmore: So, poor morning erection, low sexual desire, erectile dysfunction.

Teresa Rogstad: I can't get it big enough, sorry.

Craig Blackmore: OK. So, I guess it's the...if that's how they summarized it in the abstract, I would be happy with us defining it that way. Does that...does that resonate with the committee? OK. So...so, back to our decision. We...then, I'm going to take a vote on approval of the previous decision with the caveat that under limitations of coverage, bullet point number three, signs of hypogonadism or symptoms of sexual dysfunction, open parentheses, all three criteria from the European Male Aging Study, and we will add dash, and no, they're not in front of me anymore, but the wording that we had up before in yellow.

Teresa Rogstad: So, are we taking the (inaudible) or are we just taking the one, two, three (inaudible).

Michael Souter: What's in yellow.

Craig Blackmore: The yellow bit. If you could copy the yellow bit, please. Yep.

Teresa Rogstad: I might make it a little smaller.

Craig Blackmore: I would like to keep the bit about the European Male Aging Study. Yeah, and then after...after the word study. OK. Alright. So, since we're being very precise with wording, because this is the final document, after the word study there's a period and an end parentheses, which we should get rid of both and add a colon, and then go to that...make that a dash. OK. Does that work? Thoughts? That's fine. OK. So, I will accept the motion to approve.

David McCulloch: Motion to approve.

Craig Blackmore: Second.

Kevin Walsh: Second.

Craig Blackmore: Alright. So, now we're voting for finalization of the testosterone testing decision with these points for clarity, and I would like a show of hands, please.

Josh Morse: Nine approve, one abstain.

Craig Blackmore: Alright. We move on. Thank you for that.

Alright. So, the next topic on the agenda is bariatric surgery, and we will start off with the Washington State Agency Utilizations and Outcomes, Dan.

Daniel Lessler: Great. OK. So, well thank you. I'm Dan Lessler. I'm the chief medical officer at the Health Care Authority and wanted to provide a brief overview on bariatric surgery from the standpoint of the agency medical directors.

By way of background, the estimates are that somewhere around 14.5 or 15% of the U.S. population has a BMI of over 35, and this is a chronic disease that is associated with complications. Medical and behavioral management of obesity is often ineffective and over the last many years, given the lack of effective medical treatment, bariatric surgery has been commonly employed to treat morbid obesity.

There are...well, we're going to be discussing four general types of approaches to bariatric surgery. I know that Daniel Ollendorf from ICER, I think, has got some wonderful pictures and so forth. So, I just have what these are in terms of adjustable gastric banding, vertical sleeve gastrectomy, Roux-en-Y bypass, and biliopancreatic diversion with or without duodenal switch and personally, the way I like to think about these is sort of graded, going from restrictive to malabsorptive and...so, banding really being a restrictive approach. Vertical sleeve gastrectomy actually incorporating somewhat of both mechanisms of action, and then the latter two being more malabsorptive in terms of their...in terms of how they achieve their impact on obesity.

From the agency medical stand...medical directors' standpoint, this is an area that really is high in all the different categories of concern, safety, efficacy, and cost.

I know these will be reviewed again, but just to remind people briefly of the key questions. First, comparative effectiveness of bariatric surgery in adults and then in children. What correlates of success in terms of...with bariatric surgery? Short and long-term harms. The impact of different kinds of programs or systems on outcomes of bariatric surgery. Differential effectiveness with respect to the patient or clinical factors. Then, finally cost-effectiveness.

I did want to remind the HTCC, actually, that there is a decision, a more narrow decision, with respect to bariatric surgery that this committee made a number of years ago that is relative to pediatric bariatric surgery, and this is currently being followed by the agencies. The first point is that pediatric bariatric surgery for patients under the age of 18 is not a covered benefit due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective. Bariatric surgery in people between the ages of 20 is a covered benefit with certain conditions, and those conditions are noted here in terms of the laparoscopic adjustable gastric banding being covered and then such patients must meet other criteria that are set out by the agencies in terms of qualifying for bariatric surgery. So, it's not covered in people under the age of 18. It is covered just for lap-band for 18 to 20 and that is an existing policy.

So, with respect to current state agency policy, these differ from the Public Employee Benefits versus...or actually, this is Uniform Medical Plan versus

Medicaid. These are the current criteria for Uniform Medical Plan. Bariatric surgery is covered in people with a BMI of 40 or over, or in people with a BMI between 35 to 39 with a diagnosis of diabetes or at least two of the following comorbid conditions that have not responded to medical management, and these include hypertension, dyslipidemia, coronary artery disease, and sleep apnea. So, that sort of provides the state on UMP.

With respect to Medicaid, bariatric surgery is currently covered in people with a BMI of 35 or over, age 21 to 59 years, with one of the following conditions, type 2 diabetes or degenerative joint disease of a major weightbearing joint, and the person needs to be a candidate for joint replacement if weight loss is achieved. I'm sorry, I got my finger a little bit heavy there, and other rare comorbid conditions where there is medical evidence that bariatric surgery is medically necessary, and the benefits outweigh the risks. So, that is the current policy for Medicaid. This gives you some sense of the numbers, although they're hard to see, but over the last...between 2010 and 2013, the number of bariatric surgeries for the Apple Health population broken out by lap band and Roux-en-Y, there you can see sort of off to the right, and then redos and lap band removals or replacements, as well. What I would comment here that under the current Medicaid criteria, because this is for Apple Health, are quite strict. So, the numbers relative to the size of the population is pretty small.

This is the number of bariatric surgeries in the Uniform Medical Plan non-Medicare population, and you can see lap bands, Roux-en-Y on the left, and then some of the revision numbers there. Vertical sleeve gastrectomy, up to this point, has actually been relatively uncommon in that population. This is UMP non-Medicare just some cost information, and you know, it's interesting looking at this. This actually looks, you know, overall pretty similar to what ICER...the numbers ICER has quoted in its cost-effectiveness analysis, but you know...for example, looking at Roux-en-Y it's somewhere close to \$20,000 for the procedure.

So, you know, I...I know with ICER coming in a moment, Dan Ollendorf, to present in more detail, what I'm really going to do is just present the takeaways that the agency medical directors had reviewing the evidence based report, sort of just high level. This is what we see in this evidence and some other literature review that we did on our own. First, in terms of effectiveness, most observational studies suggest that bariatric surgery improves survival in severe obesity. Bariatric surgery is more effective than medical management in the short-term with respect to weight loss and resolution of comorbidities, but there is really with respect to comorbidities, there is very little long-term data.

As far as the comparative effectiveness of the different types of procedures, Roux-en-Y and vertical sleeve gastrectomy appear to have similar short-term outcomes with respect to weight loss and impact on comorbidities and Roux-en-Y and vertical sleeve gastrectomy appear to lead to greater weight loss than...and resolution of comorbidities compared to...compared to adjustable lap band. Biliopancreatic diversion results appears to result in somewhat greater

weight loss than Roux-en-Y, and Roux-en-Y has better long-term outcomes than lap band in terms of weight loss and improvement in comorbidities to the extent that data exists out that far.

With respect to safety, perioperative mortality associated with bariatric surgery appears to be on the range of 1% and really, it depends on the type of procedure and it also depends on site specific, surgeon specific, and so forth. This is certainly higher with the open procedures, Roux-en-Y for example, and lower with lap band, far less than 1%, but that gives you a sense of what we're talking about more generally in terms of order magnitude.

With result to safety, you know, here I actually did some additional reading and I think, again, when Daniel Ollendorf presents, he'll present a lot of data and actually has some pretty wide variation around different medians and so forth, but there was one very I thought well-done longitudinal assessment in the New England Journal just to help get some sense of a prospective cohort data and some sense of the frequency of complications, and you can see they used a composite endpoint for complications and across procedures, the rates were lowest for lap band and then higher for open surgery, Roux-en-Y and intermediate for laparoscopic, and I think these are fairly consistent with the point estimates, the rough point estimates in the ICER analysis, as well.

As far as comparative, effectiveness, and safety in children and in adolescents, you know, I think, as was noted in the current decision of this committee, there really is limited data, I mean, across the board, but that data suggests that lap band is effective in adolescents in achieving substantial weight loss and improving comorbidities. There's one retrospective study in which Roux-en-Y did not appear superior to lap band, and there is a real lack of short and long-term data evaluating safety in children and adolescents, and my sense of that is that really has not changed much since the last decision of this committee.

This, actually, are two slides that I borrowed from ICER just looking at components associated with treatment success, and these are, you know, I think first the people looked at a lot of different components, such as weight loss before surgery, whether or not somebody gets counseling before or after and so on and so forth, and the, you know, the conclusion there is that really you can't reach any good conclusions about a lot of those programmatic elements. I think the one...in this respect, the one thing that probably is most clear is that people who have significant comorbid mental illness are less able to follow through with recommendations either to have the surgery or after they have the surgery done to adhere to a program.

Then, some other program factors, surgical experience/volume. Again, here, similar to what we see with other surgical procedures, which is that practice makes somebody better. So, higher levels of...usually you're looking at a cutoff around 50 here of people. If you do more than 50 procedures, you tend to have better outcomes, both in terms of the hospital, as well as the surgeon, and there is mixed evidence in terms of accreditation or not accreditation. I would

mention there that at one point, Medicare was requiring that surgeries done under Medicare...bariatric surgeries be done at accredited facilities but with recent...relatively recent data that came out showing that there was no difference, they actually have removed that from their coverage decision. Some evidence suggests better outcomes with multidisciplinary care, and finally one thing I found interesting is that really, there's no good evidence that requiring a certain amount of weight loss before surgery impacts outcomes overall.

Cost-effectiveness, I think the bottom line here is that there...there's fairly robust data in this area that bariatric surgery is cost-effective using sort of the commonly used metrics, you know, for cost-effectiveness, \$40-50,000 per life year saved. So, I think pretty good evidence there.

With respect to Medicare and current coverage decisions, there is a coverage decision from 2009 for Medicare on Roux-en-Y, biliopancreatic diversion, and lap band are covered for beneficiaries who meet the following criteria. BMI over 35, one or more obesity-related comorbidities, failed prior medical treatment for obesity, and the NCD does not...specifically states that type 2 diabetes should be considered a comorbidity for purposes of coverage, but it makes no specific mention of other obesity-related comorbidities and open adjustable gastric banding and open vertical sleeve gastrectomy are not covered.

There is a local Medicare coverage decision from Noridian as well, for Washington, which covers vertical sleeve gastrectomy if the patients meet the Medicare NCD criteria and are younger than 65.

So, from the standpoint, as we look at this in terms of recommendations, we would recommend covering bariatric surgery for people with a BMI of 40 or over and then covering for people with a BMI between 35 and 40 with at least one obesity comorbid condition and failed medical management. Then, noncovered for BMI of between 30 and 35. I just wanted to comment on the second bullet there. Most of the studies that have been done in people between 35 and 40 have been in people who have a comorbidity and are looking at a specific comorbidity, diabetes, type 2 diabetes being the most common. As I'm sure people are aware, there are some studies now in people who have a BMI of less than 35, but that literature is relatively young, we would say, and so we're somewhat more apt to say we would wait to cover that, at this point.

Then, we would cover in a way that the current coverage decision is written for the pediatric population, which is that patients would abide by other surgery program criteria. I think, you know, looking at the different criteria that had been evaluated and the evidence and so forth, there's just really no way to say definitively one way or another that you have requirements of an interdisciplinary program or other requirements programmatically. So, we would leave it up to the respective agencies.

For pediatric bariatric surgery, we would recommend continuing with noncovered for patients under age 18. We sort of don't see really much in the way to change this committee's decision from previous decision, and continue to cover in those adolescents between 18 and 20 who meet the criteria for lap band and then abiding by other agency surgery criteria, and this is the same as the existing HTCC decision. So, with that, I'll conclude. If there are any questions, I think there's public comment, and then ICER will present.

Craig Blackmore: Questions for Dr. Lessler? Thank you. I'm sure things will come up. So, the next item on the agenda is the open public comment period, and our timing is just about right. So, did we have any?

Christine Masters: Yes, we do.

Craig Blackmore: Yes, we do. Alright.

Christine Masters: We have these scheduled, and then these three people have just signed up today.

Craig Blackmore: OK. So, first is...so we invite people to tell us in advance and we heard from Dr. Michaelson and so this would be your opportunity to address the committee if you could come up to the podium, and we have slides, is that right?

Robert Michaelson: I do have a more concise version of the one I submitted. It's the only thing on this.

Christine Masters: OK.

Craig Blackmore: So, anyone is welcome to address the committee. We ask that you identify yourself, tell us if you're speaking as an individual or if you're representing some other organization, and also tell us if you have any financial conflicts of interest or if anyone has paid to subsidize your travel here or anything of that nature, and we can allocate five minutes per presenter. Whenever we have your slides ready, we'll start at that time.

Robert Michaelson: I may have a couple more minutes, because I read that if I'm representing somebody that it may be at the discretion of the chair up to ten.

Craig Blackmore: Yeah, I mean, if there's a group of people here, and you're speaking for all of them, we can add on. If you're the only here, then you're...then we...

Robert Michaelson: OK. Well, I'll start while you're waiting for the slides.

Craig Blackmore: That would be great.

Robert Michaelson: My name is Robert Michaelson. I am the current president of the Washington State Chapter for the American Society for Metabolic and Bariatric Surgery, and I'm privileged to represent the body...the largest body of physicians in the state

of Washington that are most knowledgeable in the treatment of this disease, obesity. I want to start with a criticism, because time is limited. The ICER report was excellent. You guys did a very nice job putting it together. However, I do think that there's a glaring omission that is the Swedish Obesity Subject Study. It is expressly in the language of the document, excluded because over two-thirds of the patients received gastroplasty, a procedure no longer being performed in the United States, and I would just like to clarify this procedure a little bit, because it impresses me that it appears to be the logic similar to saying that we can't use documents that were created on XP because we're using Windows 8.1 right now.

The vertical banded gastroplasty is a procedure that reduces the size...the functional size of the stomach in a non-adjustable way. There's a staple line that comes down vertically and a horizontal staple...or a circular staple line with a non-adjustable band in the middle. This operation was replaced by the adjustable gastric band, the lap band, which is an inflatable device that effectively does the same thing, reducing the size of the stomach, but this operation is adjustable. All of the contemporary operations, the gastric band, the sleeve gastrectomy, the gastric bypass, and in fact the biliopancreatic diversion with duodenal switch, employ some form of restriction that was pioneered in the vertical banded gastroplasty.

The Swedish Obesity Subjects Trial is a very, very highly regarded study in the bariatric surgical literature. This is a study that involved 4000 people, 2000 in the control arm, 2000 in the surgical arm. These people were followed for a period of 15 years. The study shows that there is a reduction in...significant reduction in weight. We're looking at the control group in the blue line up top who actually gained weight over the 15 year period. We're looking at vertical banded gastroplasty in the purple and banding, gastric banding, in the yellow. The results over the 15-year period are identical between the vertical banded gastroplasty and gastric banding, and three minutes to go. So, the decision to discount this, we feel, to a number among the bariatric surgeons in the state of Washington, feel that it was inappropriate to exclude this data.

The obesity rates in this country have been increasing over the past 35 years, despite the fact that we have been impressing upon our patients to change their diet to a low-fat diet and such, exercise, behavioral modification, and despite that, we are seeing a tremendous increase in obesity prevalence. I take issue with the statement earlier. The current level of obesity in this country is 35%. One-third of the United States is obese, one-third is overweight, but we're also seeing an increase in comorbidities. Diabetes is climbing parallel to obesity, as are other obesity related comorbidities. In the state of Washington, if we look at the 2010 numbers for these diseases and compare them to what's predicted for 2030, we're seeing an increase in diabetes, hypertension, heart disease, and obesity-related cancer. I have no idea how arthritis is getting better. I can only surmise that it's because more people are going around in carts at Wal-Mart.

Every single system in the body is negatively affected by obesity, and every single system in the body is improved with weight loss. Those that are most affected are highlighted here, hypertension, type 2 diabetes, but nonalcoholic fatty liver disease is the most prevalent disease in this country, and 90% of it is cured with bariatric surgery. The National Institute of Health incorporates bariatric surgery into its treatment regimen, starting with a treatment at a BMI of 25 with lifestyle modification and progressing to surgery with the same criteria that you indicated.

A growing consensus is favoring bariatric surgery. We've got the American Diabetic Association, the American Heart Association, the International Diabetes Federation, American Association for Clinical Endocrinologists, and the Endocrine Society all supporting the use of bariatric surgery for a treatment modality for morbid obesity.

In Washington, in 2008, we spent 1.5 billion dollars on obesity-related healthcare costs. In 2018, it's projected to be 7.2 billion. In addition, obesity increases direct medical costs across the board, as the costs increase as the BMI goes up. We see it in all areas of medical utilization, as obesity increases so, too, do the dollars that are being spent to treat it. If we look at the reduction in prescription medication use in diabetic patients, we see a precipitous drop shortly after surgery, and that is sustained across the board. I once had a patient get off of 16 prescription medications. The insurance company would have paid for every single one of those for the rest of her life, but they didn't pay for her surgery, and she paid out of pocket for it.

We see obesity cost us in decreased productivity, not only in days of work lost, but more importantly, what we're seeing is presenteeism where people are not able to do the jobs that they were hired to do, and one of my dearest patients was, is an engineering for Boeing who is charged with inspecting the wiring of the aircraft. She was so big that she couldn't get into the aircraft, so she had one of her subordinates go in with her iPhone and take pictures of the wiring, and she approved the wiring based on the photograph from the iPhone. She also told me that she was able to get back into airplanes when they stopped putting ashtrays in the seats, which was about two years ago. So, think about that the next time you fly on a plane that has an ashtray.

Our current approach to obesity is similar to this. When I review patient charts that are coming in, in consideration for bariatric surgery, they all look like this. We have a 34-year-old female in no acute distress presenting for her annual physical examination. The assessment and plan shows that she has heart disease, so she goes to cardiology, diabetes she's going to endocrinology. When she develops the problems of kidney failure, peripheral neuropathy, and retinopathy, she goes to the respective specialists. Her high blood pressure is being managed by her primary care. Sleep apnea goes to pulmonary. Osteoarthritis goes to orthopedics. PCOS and infertility goes to OB/GYN. GERD goes to GI. Breast cancer, there's a five-fold increase in breast cancer associated with obesity. Now, we're employing general surgeons, oncologists,

and radiation oncologists. That's not the way we need to be approaching this disease.

We need to call the disease what it is. The history of present illness should call it out. This is a 31-year-old morbidly-obese female. This is not a character assessment. This is a disease that we are talking about. The assessment and plan ought to be weight loss, because weight loss will take care of heart disease, diabetes, high blood pressure, sleep apnea, osteoarthritis, infertility, and PCOS, as well as GERD, and notice what's not on there. We don't see the nephrologist, the neurologist, and the ophthalmologist, because we've intervened and gotten the weight off before we saw the complications of diabetes. We don't see the breast cancer on there, so we're under-employing the general surgeons, the radiation oncologists, and the oncologists, because we're intervening appropriately to treat this disease before it leads to others.

The Washington State chapter of ASMBS strongly supports the addition of bariatric surgery to the Washington State Health Care Program, and in the words of one of our past presidents, Harvey Sugerman, there is no other modality in all of medicine that can cure so many conditions with a single intervention. Thank you.

Craig Blackmore: Thank you. We've also had two individuals sign up here at the meeting today, and I'm sorry, I'm not reading this well. Is it Brian, is it Song?

Brian Sung: Yes.

Craig Blackmore: Would you like to, and again, name and conflict of interests, etc., please.

Brian Sung: Good afternoon. My name is Dr. Brian Sung. I'm a bariatric surgeon. I'm the surgeon director at Swedish Weight Loss Services at Swedish Medical Center. I am also the current Access to Care representative for the Washington State chapter of the ASMBS. I work very closely with Dr. Michaelson, as we're both champions for the fight against obesity. I want to commend the committee for an ICER for the very, very rigorous report there. A couple of issues, Dr. Lesser, in terms of your presentation, the one last thing that I saw was that Noridian does now cover the vertical C gastrectomy for age over 65. So, for Medicare it is covered. That's a recent development, as of January 1<sup>st</sup> of this year. Other than that, Dr. Michaelson, I think, said everything very eloquently and very succinctly. Just a couple of facts here. Here in the State of Washington, our state constituents, greater than 27% of them, suffer from obesity. Dr. Michaelson talked about the economic effects. Return on investments have been shown for gastric bypass, it's laparoscopic, within two years. The average cost, we saw, is about \$20,000. You take a type 2 diabetic, lifetime costs for a type 2 diabetic are \$300,000, alright? So, a return on investment within two years. I just want to share one thing. The office of personal management does cover through the multi-state health plans and the federal employee health benefit program does cover bariatric surgery and obesity-related healthcare, and they have talked to other qualified health plans to cover obesity-related healthcare, and that

patient should have access to that if they suffer from excess weight. So, if it's efficacious, deemed efficacious, safe, efficacious, and worthwhile for our federal employees, then I think all Americans, and especially Washingtonians, should have the same benefit. Thank you.

Craig Blackmore: Thank you. Then one more, and again, forgive my pronunciation, is it Rob Portinga? OK.

Rob Portinga: I am Rob Portinga. I'm here, I guess, as myself, but also as a volunteer with the Obesity Action Coalition and, I wasn't really prepared to bring a slide or anything, but I don't know if you can see this, this is me about almost seven years ago, July of 2008. This is my last birthday before I had bariatric surgery myself. In this picture, I weighed somewhere in the excess of 380 pounds. I was not a very happy person in that picture, even though it was my birthday. I'm here, like I said, I'm here representing on behalf of the Obesity Action Coalition. The OAC is a 50,000 members strong national nonprofit organization dedicated to helping individuals affected by the disease of obesity, and I appreciate the opportunity to be here to address the members today.

Basically, the topic of obesity, the disease, the treatment of, and the bias and stigma that surrounds it has been a major of me, since getting my own obesity under control. Besides having addressed these issues through my personal blog for the last six years, I'm also a proud member of the OAC, since 2011. I've been volunteering on their bias committee and for their annual conference planning committee for the last two years now, and I get to work with a lot of others with the OAC to help address various weight bias and obesity advocacy issues. Addressing one's obesity is not an easy thing clearly illustrated by the figures spoken about today, as to just how two-thirds of our population in this country are either obese or overweight. Of course, I had attempted various diets. A lot of us that have had bariatric surgery, we joke about how we're experts at losing weight, you know? I could lose 30, 40, 50 pounds no problem. The problem is, those pounds would come back and they'd bring friends. I was also on...before surgery, I was on multiple medications. We talked a little...the group talked about that as well. I'd been on hypertension medication since my early 20s, a couple of medications, diuretics as well. I was on medication for acid reflux. I was diagnosed with sleep apnea, as well. The last time I took any medication for my hypertension was the day I had surgery, April 9<sup>th</sup>, 2009. The surgery helped me lose the weight, and the continued support provides in helping me feel satisfied with smaller portions combined with the education I received, the support from both the hospital, support network, support groups, things like that. This has helped me maintain over 140 pounds lost for over five years now. The combination of better choices, the more activity, the ability to manage my hunger with smaller portions will continue to help me maintain this loss for years to come. Obesity is a complex, chronic disease that deserves to be treated seriously and in the same fashion as diabetes, heart disease, or cancer. Those affected by obesity should have the same access to the same medically necessary and covered treatment avenues afforded all others who suffer from chronic disease and receive that care through public and private health plans,

and while today's discussion is focused on bariatric surgery, I hope you can also address the disease of obesity from all angles, including things like nutritional education, exercise, intensive behavioral therapy, pharmacology, as well as the surgical. Thank you for your time.

Craig Blackmore: Thank you. Is there anyone who did not have the opportunity to sign up that wished to address the committee? Then, we'll turn to the phones and see if anyone has called in. If you've called in on the phone, this is the Health Technology Clinical Committee, and it's the open public comment period around bariatric surgery. Is there anyone on the phone who wishes to address the committee? Alright. Well, hearing no responses, we will close the open public comment period. Next on the agenda is the evidence report from ICER, Dan. Actually, as you're setting up, I also want to introduce our clinical expert. So, Dr. Lindquist, welcome. Thank you for coming.

Richard Lindquist: Thank you.

Craig Blackmore: We always have a clinical expert at the meeting and the reason for that is because the committee members, we are providers of care, and we're experts in evidence-based medicine and policy, but we're not experts in the topics, necessarily, under discussion, and that includes bariatric surgery. So, thank you for being here. Your role is to help us understand the clinical context. We don't ask you for a specific presentation, but questions will come up in the course of the discussion this afternoon, and we'll direct some of them your way, and we appreciate your help.

Richard Lindquist: Thank you.

Craig Blackmore: Then, Dan.

Daniel Ollendorf: Thanks, Craig. Thank you for having me, as always. I know it's just after lunch, and you probably want to do something fun this weekend, but this Ollendorf guy's here dropping 60 slides on you, again. So, I apologize in advance for that, although Dr. Lessler took some of the load off me by taking some of my slides, so thank you.

Daniel Lessler: Just two.

Daniel Ollendorf: Just two, just two. So, we'll go through the scope of our project. We'll describe the results of the systematic review, as well as our comparative review and analysis, talk about ICER's evidence ratings and then provide a summary, some of which you've already heard, on clinical guidelines and payer coverage.

So, you've heard this background already. Over one-third of Americans are classified as obese, and that number is nearly 20% with adolescents. In terms of direct healthcare costs, which is probably a component of that 350 billion number, 350 billion, that should be billion, sorry, direct medical care costs can comprise about 150 billion dollars, uh, billion dollars in the U.S. As you've

heard, historically, treatment options have been limited in their effectiveness in terms of lifestyle and dietary change, and/or restricted by safety concerns, particularly with older-generation weight loss medications.

Bariatric surgery is an umbrella term for a group of procedures that involve modifications to the digestive tract to promote weight loss, first performed in the 1950s, and there has been a steady increase in use and further innovation, as the prevalence of obesity and the alternative treatment options have not proven to be effective. In 1991, NIH criteria that you've already heard described cemented the use of bariatric surgery in patients with morbid obesity regardless of their other comorbidities, and in patients with severe obesity (35-39.9) with a related comorbidity, or one or more related comorbidities.

So, that naturally raises some questions, which is where we tried to come in with our review, in some aspects. Most specifically, what is the balance of benefit and harm in patients with lower levels of obesity, so BMI less than 35, and different types of comorbidities? There is interest also in trying to understand the evidence of durability of treatment effect over the long-term. So, the context for that can be set by a recent systematic review that looked at 1000 studies with a duration of followup greater than two years and found that few than 3% of them retained enough patients for a statistical evaluation. So, I believe the threshold in that particular review is 70%. So, there is a challenge in terms of long-term data, and we'll talk through that in more detail. So, Dan already listed the procedures for you, and they are listed in order of restrictive to malabsorptive, and so these were the four procedures of focus for our review. It was noted that we did exclude the Swedish Obese Subject Study because of its use of gastroplasty; however, there are results summarized from the SOS Study in the review, initially just for mortality but with the final report we have actually produced information on weight loss outcomes for that study, as well.

We've gone over the key questions already, so I don't think we need to go through that here.

So, in terms of our review, our population of interest, involved adults and children undergoing bariatric surgery for obesity with a BMI of 30 or more, and we stratified the evidence where feasible in many different ways, according to program characteristics, according to patient characteristics, etc. We've already talked about the surgical procedures. One important caveat in terms of comparators, we were interested in looking, when we looked at nonsurgical management as a comparator, at some form of active nonsurgical management, whether that was an interdisciplinary program, lifestyle, and diet only, lifestyle diet plus medication, counseling, exercise, etc. That was our focus. So, we excluded studies that specifically used a wait list or other controls that were not undergoing any sort of intervention, and there were some studies like that. We also evaluated any head-to-head comparative studies that compared the surgical procedures of interest.

So, outcomes, overall, in obesity-related mortality, change in body weight, body mass, and BMI improvement and/or remission of comorbidity, health-related quality of life, and then for harms we focused on three specific areas, and you've heard about some of them already, uh, perioperative mortality and complications, procedure revision, repair and/or removal, reversal I it's something that could be reversed, and long-term complications of malabsorption or nutritional deficiencies could be one. It could also be technical complications over the long-term with the particular procedure itself, as well as others.

So, we looked at published studies from January of 2000 through March of 2015. Our focus, as always, is on comparative studies when we can find them. So, we looked at RCTs and comparative observational studies without any further restriction. We did include information from case series to look at some of the long-term data, and so we focused on case series that were two years or longer in duration, and we had sample size restrictions, as well, to try to get an idea of precision.

There was actually a question when we did the slide review with the medical directors about when the bolus of the evidence, the comparative evidence had been generated, because, as it was mentioned, the pediatric review that was done for the committee was done, I think, eight years ago, and so we found that two-thirds of the comparative studies that we identified were published in 2011 or later. So, this is a fast-growing evidence base.

For study quality ratings, we used the USPSTF criteria for comparative studies, as we have done previously, and that's their...there is a specific description in the report. There is also a slide at the end if we want to look at it on how those criteria are applied. For strength of evidence, we are guided by the ARC methods manual, and we use four major domains to understand that, risk of bias, consistency of the evidence, the directness, whether that is a direct comparison of the interventions of interest or direct measurement in key outcomes, or both, and precision, the confidence in the role around any estimate of intervention affect.

So, our prism flowchart showing our results, again, quite a bit of literature base, 275 studies total, 179 of which were comparative studies, 35 RCTs.

So, general comments on the quality and type of evidence. As I mentioned, there is a substantial comparative evidence base, but there are issues of quality and applicability. There always are. So, we actually only rated 15% of the comparative studies to be of good quality, and some of the key concerns that we saw were imbalanced treatment groups. In fact, in some cases, even in some of the smaller RCTs, you had imbalances in baseline BMI, which kind of makes any conclusions drawn about change in BMI a little difficult to interpret. In other cases, there were some systematic differences in either the duration of followup between groups and/or a high rate of loss to followup, and even when...in some studies when these concerns were raised, or when they were

obvious, there was still a general lack of use of appropriate statistical techniques to control the clinical followup differences, whether those be multivariate analysis or survival techniques for long-term outcomes, etc.

So, let's turn to our key questions. The first one, key question 1A, effectiveness of bariatric surgery in adults, 1B will be pediatrics. Not the easiest table to see, especially for those of you in the audience. I apologize, but as we look at the comparison of bariatric surgery to nonsurgical management at the top here, we're suggesting that there is a moderate strength of evidence that bariatric surgery, all told, all procedures together, provides an incremental benefit over nonsurgical management in these comparative studies. So, I don't know if actually have the meta-analysis results presented in slides. I think we do, but in analysis of BMI change, there was a 7.4 unit change in BMI incrementally in favor of bariatric surgery over nonsurgical management. This was in a population that had a mean baseline BMI of about 40. So, close to a 15% reduction in BMI incrementally versus nonsurgical management where there was generally very little change in weight. The rest of these rows deal with... I can't really...maybe the battery just died on the laser. I'm sorry. They deal with comparisons of the individual procedures to each other. So, we're using Roux-en-Y bypass as the anchor comparator, because it's the most common procedure performed in the U.S., and our finding was that outcomes...and Dan alluded to this earlier for sleeve gastrectomy were equivalent to bypass. Gastric banding produced less weight loss than bypass. So, we're labeling it inferior, and biliopancreatic diversion there is a much smaller evidence base. From what clinical experts tell us, it's a technically complex procedure. It's not performed at that many centers in the U.S., but there is comparative evidence suggesting that there is more weight loss with biliopancreatic diversion in comparison to bypass.

So, let's add a little more color to this. So, while the weight loss data are relatively consistent in comparison to nonsurgical management for all four procedures of interest, they are challenged by a lack of long-term data on the durability of effects. So, specifically, there is interest in trying to understand how much recidivism there is. If patients are dropping off the program, then there is bound to be weight regain, but it's obviously difficult for surgical groups to follow these patients if they're dropping out of the program. So, there are challenges I'm not sure we'll be overcoming anytime soon, but there is some level of weight regain after surgery, and again, there's not a lot of hard evidence that we can point at to suggest what that level might be.

The information on comorbidities, and I'll talk about that in some detail when we talk specifically about studies in patients with BMI of less than 35, nearly all focused on patients with diabetes. So, there are some comorbidity data specific to sleep apnea. A study here and there talks about joint pain and arthritis, asthma, as well, but in terms of comparative studies, fair and good quality comparative study, we did not find much beyond diabetes.

We've talked about this a little bit and, um, our discussion of the SOS study is included in this second bullet. Surgery does appear to reduce all-cause mortality over differential periods of followup. Risk reduction is anywhere from 20 to 45%, but there are some issues with the studies available, in terms of what that actual, what the precision at that point estimate might be. There are other studies that were not included in our sample that are widely cited, in terms of mortality benefits. So, we do describe them in the report. One study by Adams and Colleagues, for example, that compared patients undergoing bariatric surgery to nonsurgical controls who had applied for drivers licenses and had BMI reported on their application. So, the challenge there is that we don't know what happened to them, whether they had any sort of intervention and what their baseline health status was. Nevertheless, in the overall discussion of mortality benefit, that study is included, as well.

In terms of weight loss efficacy, purely without regard to harms, which is a different question, biliopancreatic diversion appears to produce the greatest level of weight loss followed by bypass, vertical sleeve gastrectomy, and then finally by gastric banding.

So, here's the results of one of our random effects meta-analyses, and this is really where you see the...alright, I'm going to stop pressing this button, because it's not doing...there we go, OK. This is where you see the mean 7-point incremental change in weight loss with bariatric surgery versus nonsurgical management, relatively consistent findings across these studies. So, there is the figure itself.

Then, in terms of the studies looking at resolution of type 2 diabetes, there is some more variability here. The overall odds ratio for resolution of diabetes was about 3.6. You see that the point estimates do vary, and we're thinking that it can be, in part, ascribed to different definitions of remission in these studies. So, some used an HBA1c threshold of 7%. Some used 6%. Some included cessation of all antidiabetic medications in their definition. Some did not. So, that's probably where some of the variability comes from. It also may, obviously, come from differences in the baseline status of the patient in these studies, as well.

So, let's talk about those studies with BMI of less than 35 specifically. So, we identified nine good quality RCTs and comparative cohorts in our review. As I mentioned, nearly all of these included type 2 diabetes, as an entry criterion. Most studies were of either bypass or, more commonly, gastric banding. All studies did involve a comparison. Sometimes, there were multiple procedures, but they all involved a comparison group that received nonsurgical management. There was a range, but resolution of diabetes was substantially higher in surgical groups, median 42% had resolution versus nonsurgical management where the median was 9%. There were two additional studies that focused on metabolic syndrome as a comorbidity of interest and found significantly greater resolution in the surgical group there, as well.

So, there was also a question around...did you have a question?

Marie Brown: How long are these studies? Are these all within the same timeframe, or?

Daniel Ollendorf: They generally ranged in terms of duration of followup from...there were some six-month studies. Most of them were one to two years.

Marie Brown: One to two years.

Daniel Ollendorf: Yeah, yeah. So, in this same set of studies, we also report on weight-related outcomes, and here you see a percent decrease in BMI across the four procedures following the trend that you see in the higher weight groups that we just discussed, as well. Here, we do see a median of followup of 12 months. Another common measure in these studies is the percent of excess weight loss. So, excess weight loss is defined as weight loss relative to an optimized goal BMI that the patient has prior to surgery.

So, moving on to pediatrics. Now, when the original review was done, I believe, the analytic set was limited to case series only. Now, we do have comparative data, but it's one RCT and one retrospective cohort study, and in the RCT, these were individuals who were age 14 to 18 who received the lap band or nonsurgical management, and there was an incremental reduction in BMI associated with the lap band procedure versus nonsurgical management in this population. Obviously, it's a single RCT. So, we're...I see someone shaking their head. OK. So, we're talking about one RCT. I believe there were 50 patients. So, 25 in each arm, a single small RCT. We found no studies that compared sleeve gastrectomy to another procedure of interest or biliopancreatic diversion to another procedure of interest. There is one retrospective study from a large national longitudinal database that looked at the comparison of gastric banding to Roux-en-Y bypass in pediatric patients and found no significant differences in the outcome between the two.

Craig Blackmore: Dan, do you know the length of followup on the RCT that you mentioned?

Daniel Ollendorf: We can look that up.

Kevin Walsh: It says two years.

Craig Blackmore: Two years?

Kevin Walsh: On the slide, I mean on the slide.

Craig Blackmore: Oh, the next slide? OK. No. It doesn't.

Daniel Ollendorf: Oh, right. Sorry.

Kevin Walsh: Second bullet point.

- Daniel Ollendorf: Two years.
- Craig Blackmore: OK.
- Daniel Ollendorf: I keep forgetting that summary table is followed by a detailed slide. So, I should probably just jump to the details.
- Craig Blackmore: Thank you.
- Daniel Ollendorf: So, two years. There was a question raised during the slide run-through, because metabolic syndrome seemed to resolve at a high rate in the nonsurgical group. So, we took a look at the details of the nonsurgical intervention in this RCT, and it was kind of like whatever that show is, The Biggest Loser. People had frequent check-ins with a multidisciplinary team. They had their own personal trainer. There were frequent nutritional and other dietary counseling efforts. So, I'm not sure it necessarily represents a real-world approach to this, but it was very intense, and that's probably why you see the resolution of metabolic syndrome as high as it is.
- Chris Standaert: Can I make just one comment on that statement, so...
- Daniel Ollendorf: Yeah.
- Chris Standaert: ...you talked before about nonoperative management, but it's like everything else. It's not all the same, and I assume some interventions are more effective than others, and saying most people don't do this one that worked really well does not seem like a good statement to make, because maybe that's what nonoperative should be looking at doing and copying that. So, getting some idea of the magnitude of the better nonoperative approaches is really quite helpful.
- Daniel Ollendorf: Yeah.
- Chris Standaert: Because that...some of the...you can...if you use an ineffective, nonoperative result, you will amplify your surgical results, you know? So, anyway, the statement that we don't do this, therefore we shouldn't...that doesn't represent the real world I don't quite buy, because maybe we should be thinking about that.
- Daniel Ollendorf: True. I didn't mean to mis-state. I think that they were trying to get some intelligence on the metabolic syndrome outcome. So, in terms of the other outcomes, excess weight loss and BMI change, there was, in this study...even in this study there was a substantial difference in favor of bariatric surgery. So, it is true that the nonsurgical approaches do vary in their intensity, and then the number and types of individuals involved. We tried to tease some of that information out in our later key questions around programmatic and other factors associated with success, but it is definitely the case that there is no single definition of nonsurgical management here.

So, in terms of that retrospective study I discussed, you see the baseline statistics here. It was a large study, but this was the comparison of gastric bypass to gastric banding, and they found that those significant reductions in weight and improvement in hyperlipidemia with bypass were no longer significant between group differences at baseline, and the two groups were accounted for. In terms of pediatrics comparative study, that is all that we identified.

OK. Let's turn to what we just talked about a bit, management components associated with success. There is some discussion here of what we found, but let's characterize that in a little bit more detail. So, the literature is very diverse. It's relative inconsistent in terms of which program and/or patient selection factors are associated with greater or less treatment success. Several studies found low rates, relatively low rates of surgical participation and low rates of followup after surgery in patients with diagnosed phobias, anxiety disorders, or other Axis I conditions. Multidisciplinary care, including dedicated dietary support after surgery, and that was specifically called out in some of the studies looking at factors, were associated with better program adherence and greater sustained weight loss. That's a little bit confounded in that there is an accreditation program for Centers of Excellence nationwide. I think there used to be two, and now they may have merged into one, if that's correct, and multidisciplinary care is a requirement to become a Center of Excellence. So, all this to say that going forward in the literature, we're not likely to see, at least in terms of the U.S., a lot of studies that don't do multidisciplinary care. In particular, there were some studies that compared types of support pre- and post-operatively and found that peer support postoperatively was associated with better weight loss outcomes. They did not find an affective peer support preoperative.

So, let's turn to harms then. There were some challenges here, and I do have additional data to talk about because, and this is not necessarily something that's specific to bariatric surgery. I think in the surgical literature in general, there are not a lot of agreed on standardized classification systems for the severity of complications like you would see for regulatory reporting for drugs, for example. So, it's difficult. Most systematic reviews before ours have done the same thing and elected to report overall complication rates for comparison, because it's difficult to try to tease out what would represent a serious type of complication across studies if there's no standardized way for the reporting to be done. Again, I think instead of looking at the table, we'll talk in specifics here, because the numbers by procedure are listed at the bottom of this slide. So, again, we do have inconsistent ratings of complication severity. Harms are also under-reported in many studies for small single center surgical studies. Again, that is not uncommon. Perioperative mortality, at least in terms of prospective study, is especially under-reported, but I have retrospective data to share, as well, and there is a high variability in the available estimates. So, what we found in terms of overall complications was that biliopancreatic diversion had the highest median overall rate, 32%, based on a relatively small sample of

patients. Gastric banding has the highest reoperation rate of the four procedures. Vertical sleeve gastrectomy in terms of the reported studies had the lowest median complication and reoperation rates.

So, here you see, I have a table following this that looks at retrospective study. This is a table that looks at the prospective RCTs and cohort studies. You see over on the right, but again in this large set of patients, so over 30,000 patients total, you see a very small number of reported deaths, which deals with the under-reporting issue. There is better information in the retrospective studies that I'll talk about in a second. Here, you see the numbers in terms of median complication rates for the four procedures, as well as reoperation rates.

Craig Blackmore: Dan, is that...when you say deaths, is that perioperative death or is that death in the, you know, two years of followup, or...

Daniel Ollendorf: Sometimes, that's...

Craig Blackmore: ...we don't know.

Daniel Ollendorf: ...variable, as well. Sometimes, they report it as perioperative death, specifically within 30 days, other times within 60 days, other times within 90 days.

Craig Blackmore: So, we don't know how that compares to sort of life tables on people who aren't getting surgery.

Daniel Ollendorf: Right. I know that in our slide review, Dr. Franklin brought up a study by Moreno and Colleagues. This is a retrospective study. The analysis that they did suggested, based on their own approach to documenting what was and was not a procedure-related death, that about a third of deaths, reported deaths in these studies, were due, technically to the procedure, if that helps. Still, even in that retrospective study, an overall low perioperative death rate, I think 0.1% across the four procedures.

So, this is the identical table, but this time with retrospective studies. You see a huge evidence base here for gastric bypass, but also large numbers of patients are analyzed for the other procedures, as well. Again, you see the same sort of ranking or trend with the procedures. Overall complications are still highest with biliopancreatic diversion. Reoperation rates, although those numbers are a little closer, are highest with gastric banding. Here, you have mortality rates that do differ by procedure, and the highest for biliopancreatic diversion, again, described to us as the most technically complex. Although, I should correct myself, sorry. The rates are very similar with biliopancreatic diversion and gastric bypass.

We also, and I know that Dan described one study for you. We looked at a couple of other cohort studies that did define serious complications, things like abdominal abscess, renal failure, serious wound infections, VTE, MI, etc. This was Carlin 2013. The rates in this study comparing sleeve gastrectomy and

bypass and gastric banding were 1% for banding and about the same, 2.5% for gastrectomy and bypass. Another study looked at complications within 90 days of surgery, serious complications including death, found a similar pattern. It did include biliopancreatic diversion in this analysis, however, and it did have the highest rate relative to the other procedures, as well, 6.5% versus 3% or less for the others.

One of the discussion points around gastric banding is the requirement over the long-term in patients to have frequent adjustments to have reversal...removal of the band and require a conversion to another procedure. So, we identified a separate systematic review that looks specifically at gastric banding, found that followup data suggested that over ten years of followup, so this is a systematic review of multiple studies, the long-term overall complication rate for gastric banding was 43%, and the reoperation rate was 37%. So, additional data there.

Chris Standaert: Well now, did you... a lot of these are diversion procedures. So, did you find data on long-term effects of malabsorption and those sorts of things, like long-term data on other potential adverse outcomes other than immediate and postoperative outcomes?

Daniel Ollendorf: We did not...did not find a lot of information. There were some studies that looked at nutritional deficiencies, but they were relatively short-term in nature. So, in terms of long-term data on malabsorption, we did not uncover a lot of detail, no.

So, turning to differential effectiveness and safety. This is kind of overlapping with the management components associated with success. Again, you can see the detailed table in the report, but we'll call out certain things that we found with the literature.

So, again, not different than many surgical procedures, there is an effect...there is a learning curve, there is an effective certain experience in volume on outcome. So, the learning curve in studies, and this does vary by procedure, but the range has been reported to be between 70 and 250 procedures before complication rates and outcomes begin to stabilize. Again, not in any way different from other surgical procedures. Outcomes are better with high volume surgeons and centers than with low volume surgeons and centers, and the threshold that's been most commonly reported is about 50 procedures per year.

So, another interesting note, probably more from a logistical standpoint, is around certification and accreditation. So, the original Medicare NCD required that bariatric surgery be performed at accredited centers. That has been revised, and it may be, in part, because of the research suggesting...research comparing performance at accredited versus non-accredited facilities, suggesting that outcomes are similar. Again, I mentioned before that multidisciplinary care is an accreditation requirement. So, it happens more

frequently than not. So, it's going to be difficult moving forward to try to do comparative study with that. We did hear, and I think Dan already paraphrased this, but information on pre- and post-operative support, there has been a lot of discussion and study of preoperative weight loss and its potential beneficial effect on outcome, and the evidence is truly mixed. I do have some data on that somewhere. Right. Here we go. A systematic review of 15 studies found that five showed a positive effect of preoperative weight loss on outcome. Five found no effective difference. Two found a short-term effect that was not sustained in the long-term, and one found a negative difference. So, truly mixed evidence. As I mentioned, we talked about this earlier, but postoperative dietary and counseling support, particularly peer counseling, seems to be of significant benefit for patients.

So, in terms of patient factors, themselves, demographics, no consistent evidence showing differential outcomes by treatment approach when stratified by age, gender, or race ethnicity. It has been remarked, and it is reflective in coverage policies, that there have been very few studies done of bariatric surgery in the elderly. So, there is very limited in evidence in patients over 65. In terms of BMI levels, excess weight loss is generally lower at higher BMI levels, but there is no consistency in terms of weight loss in the few studies we found that actually stratified patients by preoperative BMI. So, in many of those studies, which also compared to nonsurgical management, there was significant...statistically significant reduction of BMI, regardless of what the starting BMI was.

Craig Blackmore: Dan, I'm confused by those two bullet points. Aren't they contradictory, or am I misunderstanding?

Daniel Ollendorf: That, oh, I see.

Craig Blackmore: The first says that weight loss is lower at high BMI, and then you say there's no consistent weight loss pattern.

Daniel Ollendorf: So, I should have been clear. Sorry. So, in the first bullet, that was looking across studies, and the second bullet looks within studies. So, when we looked at mean preoperative BMI, we found that...again, we didn't do statistical testing, but numerically...

Craig Blackmore: Mm-hmm.

Daniel Ollendorf: ...the percent of excess lost was lower at the lower BMI levels. It was higher at the lower BMI levels.

Craig Blackmore: Percent, but not absolute, is that the difference?

Daniel Ollendorf: Right. Right, but then in those few studies that actually had a large population and stratified their population by preoperative BMI, we found no consistency in weight loss patterns.

We did find a couple of studies looking at specific cardiovascular comorbidities. They appeared to effect outcome to a greater extent in bypass patients than in gastric banding patients, and there was one study, I believe just one study, looking at program adherence and comparing surgical procedures and found that there were poor outcomes among those with gastric banding who did not adhere to the preop program, but this effect did not appear to translate to gastric bypass, but again, a single study.

Kevin Walsh: Can I clarify the next to last bullet point? Does that imply that the people who had the Roux-en-Y procedure who had cardiovascular comorbidities did worse than the gastric banding patients who had...

Daniel Ollendorf: Correct.

Kevin Walsh: ...cardiovascular comorbidities?

Daniel Ollendorf: Correct.

Kevin Walsh: OK.

Daniel Ollendorf: Yeah. So, we were trying to look at the differential effects across comparative groups here.

So, let's turn to cost and cost-effectiveness. So, there is literature estimating the cost-effectiveness and the costs of bariatric surgery. We also did our own model, which I'll talk about in a little bit of detail, and that was to try to fill in some of the gaps for some of the procedures where there were no published studies. Generally, when compared to nonsurgical management, surgery appeared to meet typically-accepted thresholds for cost-effectiveness, they range between \$2000 and \$30,000 per quality adjusted life year gained. In comparison of the procedures to each other, again, using gastric bypass as the most common procedure performed, sleeve gastrectomy appears to be slightly less effective, but also less expensive, than bypass. Gastric banding is also less expensive but less effective, and biliopancreatic diversion appears to be more effective but more expensive. So, let's talk about that in a bit of detail.

We looked at two published studies. One was a systematic review of 13 individual economic evaluations and these were comparisons to nonsurgical management and found that the surgical procedures, regardless of which one, produced incremental cost-effectiveness ratios that were consistently below \$50,000. When those cost-effective ratios were at their highest, this was typically over shorter time horizons. So, the longer the patients were followed in these models, the more cost effective surgery became, and in some cases when surgery was performed at lower levels of BMI, cost-effectiveness ratios increased, meaning the cost-effectiveness worsened somewhat.

Kevin Walsh: I have a question.

Daniel Ollendorf: Yes.

Kevin Walsh: Is it true that remission is not factored into these models?

Daniel Ollendorf: Well, the models really differed in their structure and approach, and in some cases, remission was incorporated as a component. I'll talk about how we dealt with it in our own model, but essentially the quality of life benefits and the potential cost offsets associated with remission were described in some of these models, yes.

We also identified a claims databased evaluation looking at about 60,000 Blue Cross patients nationwide and found that there was a significant upward increase in total healthcare costs in the surgical group in comparison to a matched nonsurgical group, but the cost then declined after three years of followup, but importantly, there has been some discussion about whether bariatric surgery is cost-saving in the long-term, and at least in this analysis that was not a finding. So, the costs were higher in the surgical group across all six years.

Chris Standaert: Help me understand the difference. These say the exact opposite things. So, can you help me with why they say opposite things?

Daniel Ollendorf: Yes, I can.

Chris Standaert: Thank you.

Daniel Ollendorf: So, the second bullet is talking about the surgical group only, and it was a year by year...this was a year by year analysis, so looking at costs in year one, two, three, four, five, and six.

Chris Standaert: OK.

Daniel Ollendorf: So, for the surgical group, costs went up in years two and three after surgery and then declined to the preoperative levels of cost thereafter.

Chris Standaert: So, there's no control here. They didn't match it to people who didn't have surgery.

Daniel Ollendorf: They did.

Chris Standaert: To look at their costs.

Daniel Ollendorf: That second bullet only relates to the trend within the surgical group. The third bullet talks about the comparison and finds that even though there is decline to preoperative levels in the surgical groups, costs were uniformly higher after the index date, or the start date, for the surgical group versus the nonsurgical group.

- Chris Standaert: Which...but this wouldn't seem to match with actually some incremental cost-effectiveness ratio of less than (inaudible), because it costs more. These patients are more expensive if they have the surgery than if they don't.
- Daniel Ollendorf: Well, when...
- Chris Standaert: In six years.
- Daniel Ollendorf: ...something has an incremental cost-effectiveness ratio, it is typically more costly. So, it's a comparison of both the costs and the benefits.
- Chris Standaert: So, it's not...the magnitude issue is the question then. So, it's more costly, but they don't give us the magnitude? They don't...
- Daniel Ollendorf: So, essentially what...taken together, these two studies would say bariatric surgery appears not to be cost-saving but does appear to be cost-effective, if that makes sense.
- Chris Standaert: Thank you.
- Craig Blackmore: And then, if I might ask, for the claims-based evaluation, is that...what's that capturing? Is that capturing...I mean, we've heard about, you know, a decrease in the number of medications after surgery as a potential benefit and various other things. How much of that is encompassed in the claims-based evaluation?
- Daniel Ollendorf: Patti, maybe you can confirm, but I think it's all payments for all services.
- Craig Blackmore: All payments that Blue Cross had to make.
- Daniel Ollendorf: Right.
- Craig Blackmore: Presumably includes...
- Daniel Ollendorf: Includes medications, includes outpatient services, management of other physicians.
- Craig Blackmore: And then under the systematic reviews, the economic evaluations, what were the quality improvements that contributed?
- Chris Standaert: Yeah.
- Craig Blackmore: I mean...
- Daniel Ollendorf: So, most of them did assume a survival benefit.
- Craig Blackmore: ...survive and more, you know, functional quality of life on the basis of participants. Is that the driver?

Daniel Ollendorf: Yeah. I think it's a mix of improved because this is quality adjusted survival. It's a mix of improved survival and improved quality of life, and there's actually, we were able to use for our own model a relatively rich literature base that looked at costs, quality of life, and other factors stratified by BMI. So, there's a fair amount of primary research that's been done.

So, we'll get back to you on the Blue Cross study in a second. I'll talk about our simulation model now. So, we developed a two-part model. We looked, first, at the short-term effects of surgery versus nonsurgical management on weight loss comorbidities and adverse effects over one year post-surgery and then examined the longer term effects of that BMI reduction over a 10-year period. So, we focused on adults, because that's where the evidence base lies. We stratified our analysis by...we did both anybody with BMI of 30+ but also within BMI categories as listed here. We looked at our four procedures of interest and then compared them to conventional weight loss. We were able to get information on agency payments from PEBB for surgery, as well as for complications for surgery, and we looked at the published literature for the cost, which, as I mentioned, are tied to the BMI level.

So, some key assumptions here. We assumed that...we decided to be conservative and assume that there was a BMI reduction after treatment that would erode slightly over time for all interventions because of biliopancreatic diversion's malabsorptive effects, we assume that that would be a constant BMI reduction; however, we did test all of this in sensitivity analyses, though. We did assume a 30% reduction in all-cause mortality for surgery versus conventional management. We also tested that in sensitivity analyses. Perioperative risks included the ones that we were focused on in our evidence review, and as I mentioned, we used this literature base that looked at quality of life effects, survival, and costs tied specifically to preoperative BMI...or postoperative BMI, sorry. We focused on direct medical-care costs only. So, there is some literature suggesting work loss or productivity improvements, which we did not include in our model, and we focused on diabetes, hypertension, and hyperlipidemia in our analysis of resolution of comorbidities and their effects on costs and quality of life.

So, you see the results here, and obviously, because of the cost of surgery over this ten-year time horizon, conventional weight loss treatments are still the least expensive, but also the least effective approaches, and in comparison to standard care or conventional weight loss, you see the cost-effectiveness ratios cost per QALY gained ranging in roughly the same range that we saw in that systematic review. We also made comparisons to gastric bypass and found, again, the sleeve gastrectomy is somewhat less expensive and also slightly less effective than bypass. The same for gastric banding, although the erosion in quality of life is a little bit more with gastric banding, because it has a lower weight loss effect. Then, for biliopancreatic diversion, in comparison to gastric bypass, about \$78,000 per QALY gained.

So, this next slide is...oh, sorry. This was for all patients with a BMI of 30 or over. When we did our stratified analysis looking at the starting BMI, we found some differences in the cost-effectiveness ratios. So, they were highest at lowest levels of BMI, but they were still within generally-accepted thresholds. So, this is an example for gastric bypass versus standard care. You see at the lowest level of BMI, it's \$53,000 per QALY gained at the highest BMI, 40+. It's \$31,000 per QALY gained.

David McCulloch: Dan, I would suspect...the problems with models is, you can put anything in you want and just invent stuff out to ten years. There are no data using standard therapy that have great outcomes at ten years. Whereas, with bariatric surgery, there are data. Some patients followed up for ten years. I just think that top line of apparent effectiveness of standard care is fiction.

Daniel Ollendorf: Well, let's...so, if, I guess the question would be, though, if that is over-stating the effectiveness of standard care, and that's a conservative approach to estimating the effectiveness of surgery, and even with that conservative approach, we're seeing cost-effectiveness ratios that fall within generally accepted ranges.

David McCulloch: Well, I totally agree with that, yeah.

Daniel Ollendorf: But, let's go to the sensitivity analyses for a second, which may help. So, this is what's known as a tornado diagram where some of the key parameters in the model are varied across a range, and then you can see the effects on the cost-effectiveness. So, in this particular diagram, we're looking at gastric bypass versus standard care. When we varied the time horizon...so the two most sensitive parameters were time horizon and the cost of gastric bypass itself...when we varied the duration of followup from 5 to 25 years...so, at 25 years, cost-effectiveness was at this most favorable level. At five years, it was up here. Generally, in the U.S., these days, a range of 50 to \$100,000 per QALY gained is considered within cost-effectiveness threshold. So, this does not exceed those boundaries, and similar effects when you look at the cost of the procedure itself. I do want to call your attention to two important parameters. So, we looked at the BMI trajectory. So, what B...what would happen to BMI during the ten-year period of followup. At our most conservative, we assumed that patients would gain all of their weight back after five years, and in comparison to standard treatment, even that has a cost-effectiveness ratio less than \$75,000 per QALY gained. So, a complete return to previous...to preoperative weight after five years would still be cost-effective relative to standard care. Again, in all likelihood, because it's standard care, it's just not very effective.

Chris Standaert: But that would be through reduction in something over that five years that improves their long-term outcome? Is that...

Daniel Ollendorf: Right.

- Chris Standaert: So, in those few years where their weight down, they accrued some benefit that lasted a lifetime to help them, because the cost is higher. So, something had to get better?
- Daniel Ollendorf: Right. It's the, it's the improvement on the denominator. It's the quality of life improvement for that first five years that made this parameter less sensitive than we thought it might be going into this. So, they had a beneficial effect for long enough that the cost-effectiveness ratio is not put out of bound, so to speak. We also looked at the mortality benefit. So, at our most conservative, we assumed no mortality benefit relative to conventional therapy. At our least conservative, we assumed a 50% reduction in mortality. So, the base case was 30% reduction and you see that this was the least sensitive parameter. If there was no mortality benefit, again, these are all individual sensitivity analyses. So, we did not change more than one thing at once, but assuming no mortality benefit does not affect the cost-effectiveness findings.
- Craig Blackmore: So, if I might ask a couple questions. First, I wonder how you handled discounting in the model.
- Daniel Ollendorf: So, there was a 3% discount rate.
- Craig Blackmore: And then...
- Daniel Ollendorf: Which I believe we also varied. It's the second to the bottom bar on...
- Craig Blackmore: Discount rate, OK.
- Daniel Ollendorf: Yeah.
- Craig Blackmore: And then the other thing is that we're...one of our charges is to look at different age populations. So, in the model, did you look at different mean ages, and I'm thinking about competing mortality in the older group in particular.
- Daniel Ollendorf: I'm trying to think of what our base case age was. I'll have to go back and double check that. I don't know that we did a sensitivity analysis on age, per se.
- Craig Blackmore: OK.
- Daniel Ollendorf: And as I mentioned, this was just for adults. We didn't do one for pediatrics because of the limited evidence.
- Craig Blackmore: Alright. Thank you.
- Daniel Ollendorf: So, moving to our integrated evidence ratings. This is our matrix that you've seen before. When we look at evidence ratings for adults, and this is really, you know, obviously a guide for you. You can take it on its face and obviously you're going to use your own judgment. We felt that the preponderance of the evidence suggested that for patients at BMI levels of 35 or greater, that bariatric

surgery was incrementally... provided an incremental improvement, or better than an incremental improvement, that's what B+ means in our matrix, and a reasonable comparable value. For patients who had a BMI level between 30 and 35 and type 2 diabetes, because of that had a significantly greater level of resolution, we considered it incremental and of reasonable value, but for patients at those BMI levels that were lower and had other comorbidities other than diabetes, we considered the evidence to be insufficient.

So, maybe of less import, I'm not sure if you're going to be doing coverage policies comparing procedures, but there are comparisons of the procedures, as well. We found vertical sleeve gastrectomy to be comparable to bypass, gastric banding to be inferior to bypass, and biliopancreatic diversion to be incrementally better. You might argue for comparable because of its higher complication rate, as well.

Craig Blackmore: This is kind of a, kind of a trade-off argument, right? I mean, the band is the least invasive and has the lowest complication rate, and it's probably the least effective and the biliopancreatic diversion has the biggest weight gain and is the most invasive and had the highest complication rate.

Daniel Ollendorf: That's definitely a trade-off across procedures. I'll note that, and Dr. Michaelson or Dr. Lindquist should be able to confirm this, the gastric banding procedure volume is plummeting nationwide. I think Dan's figures for the state are showing the same thing.

Chris Standaert: It has a higher reoperation rate.

Daniel Ollendorf: Higher reoperation rate and lots of patients not achieving their desired weight loss. So, that may be (inaudible) already. I don't know. So, in terms of adolescents and children, because of that one RCT that did show a benefit, we considered that surgery had the potential to be more effective. Promising but inconclusive is our rating under the label P and potentially a reasonable value, but there's no real cost-effectiveness data. And then for the individual procedure comparisons, the evidence was insufficient, and there were no studies...no comparative studies that we identified in children under the age of 12.

So, quick summary is the practice guidelines from a variety of societies, and I think Dan also alluded to these, as well: Consistent support for bariatric surgery at the morbid and severe levels, some consideration in some of these guideline statements for lower levels of BMI in patients with diabetes or metabolic syndrome, but specific mention that surgery should not be performed for glycemic control, alone. The VA and Department of Defense considers the evidence insufficient for anyone older than age 65 or with a BMI less than 35. So, that runs a little counter. Then, some older recommendations from the Endocrine Society recommend bariatric surgery for adolescents but at higher BMI thresholds, so greater than 50 without comorbidities or greater than 40 with severe comorbid conditions and failure of conventional treatment.

Payer coverage policies. So, you heard about the NCD and those criteria are listed here, as well. It sounds like there's been a recent update to the LCD for Washington State, the local coverage determination suggesting that laparoscopic sleeve gastrectomy could be covered in patients who are both younger and older than 65.

I don't know, Josh, you had asked for some of the language around that LCD decision, which I think I have listed here. So, the rationale from CMS, the available ev-...this is for laparoscopic vertical sleeve gastrectomy. The available evidence does not clearly and broadly distinguish the patients who will experience an improved outcome for those who will derive harm, such as postoperative complications or adverse effects from laparoscopic vertical sleeve gastrectomy. However, taking into consideration the seriousness of obesity, the possibility of benefit in highly selected patients in qualified centers, we believe that local Medicare contractor determination on a case by case basis balances these considerations.

Private payers. So, national and regional payers generally follow the NIH criteria, greater than 40 or greater than 35 with comorbidities. Most will require patients to have attempted medical weight loss for at least six months, sometimes longer prior to surgery. An increasing number are requiring mental health evaluation prior to surgery. Generally, in adolescents, when surgery is covered and it's not uniformly so by a payer, it's restricted to those who meet the higher BMI thresholds and have nearly or completely finished bone growth. In terms of regional private payers, Regence specifically considers biliopancreatic diversion investigational and does not cover it, and those are my slides.

Craig Blackmore: Thank you. Questions for Dan?

Michelle Simon: I've got a question. The BMI over 40 or 35 seems to be widely used in the guidelines. Is there research that establishes those thresholds somewhere?

Daniel Ollendorf: Well, I think the available research that formed the original NIH consensus statement, which was then updated I think once, if not twice. Essentially, it was focused on those patients as the initial candidates for surgery. So, that's really where the bulk of the research was then, and I'd argue that it's still there. Probably, in fact, in part restricted by the fact that most payers only cover surgery in patients who meet those criteria, so.

Kevin Walsh: But I didn't see... I didn't see any evidence that you could tease out the distinction that they're making between requiring it to be a comorbidity in the 35 to 40 BMI range but not needing a comorbidity between 40.

Daniel Ollendorf: Beyond 40? Yeah, to tell you the truth, I'd have to go back to the consensus statement to see whether there's any description of why they made that distinction, and I...

- Kevin Walsh: I was looking for it, like, the whole time and never thought I found it.
- Richard Lindquist: Yeah, I...I'd just throw out a couple of comments here to speak to both these questions is that the original data for 40 and above were 35 with comorbidities and relates to that 1991 NIH document and aside from some revision in '98, it's really never been looked at. The AHA TOS guidelines sort of replaced it, and the, the use of those BMI criteria is pretty much a legacy, and it's not really based in any physiologic data, and the study...and again, I have to really commend you. This is really a nice piece of work, but the data here was interesting because it showed that at 30-35 you still had benefits, and that's not based on BMI criteria. That's based on metabolic criteria and diseases and modification of comorbidity and then the financial analysis was favorable, as well. So, that...and vertical sleeve gastrectomy, which has been overlooked, actually has data that's comparable to the...to the roux in many areas. So, it makes you wonder about it. So, the criteria, a lot of times, are legacy and made up.
- Male: (inaudible)
- Craig Blackmore: I'm sorry. The period for public comment has ended. So, any other questions from the committee members.
- Chris Standaert: I have a couple, but they're in sequence here. So, they run in sort of statistical things. So, the outcomes I saw were weight loss and change in BMI and weight loss is calculated as total weight loss and some things have a percentage of excess body weight and whatever, um, and I saw something on diabetes. I didn't see anything else. So, the quality of life, like things like ambulation, social engagement, patient satisfaction. I didn't see any...any data on any of those, and I'm curious about things, like, so, you...you go calculate QALYs, and that's quality of life. So, I don't know...Craig asked the question before. I don't know what the other quality of life measures are being used to assist in that are.
- Daniel Ollendorf: Yeah.
- Chris Standaert: Other than mortality, and there are a lot of assumptions in that one, because we don't have...our long-term data past two years in these patients is sparse it looks like.
- Daniel Ollendorf: Right. There has been limited quality of life study in these comparative trials, and those are...there's another outcomes section for each of our key questions in the report that focuses on quality of life, as one of those outcomes specifically. It's relatively limited evidence in these comparative studies, but there is suggestion of a quality of life benefit, and I can give more detail on that.
- Chris Standaert: I mean, they...do they look at, you know, patient preferences and what...so, did these surgeries meet patient expectations of what they wanted or are patients satisfied with it. I've certainly seen patients who were. I've certainly seen

patients who weren't. They are very complex surgeries and things. They...their bodies are changed.

Daniel Ollendorf: Sure.

Chris Standaert: And some...I didn't get any sense of sort of that patient-centered outcome issue of this where, is this doing what people want it to do in their lives. Is it really improving their lives in the way they would like and high recidivism rates sort of argue that maybe that doesn't always happen? I was just curious whether they...you just didn't give us any of that in here. You gave us the weight and BMI and...

Daniel Ollendorf: Other outcomes.

Chris Standaert: ...diabetes is what you gave us.

Daniel Ollendorf: Right. Well, why don't I...we can take a look and see, try to tease some things out of the report and talk about them.

Craig Blackmore: I mean, what...

Daniel Ollendorf: We'll get back over there.

Craig Blackmore: ...I guess, what are we...what did you use in your model, the other half of that?

Daniel Ollendorf: So, that information, there are primary studies of patients who are obese at different levels of BMI, and involve a collection not only of quality of life data but linkage of that to patient preference instruments. So...

Craig Blackmore: So, not necessarily surgery patients, but...

Daniel Ollendorf: Right.

Craig Blackmore: ...patients who map through a particular BMI.

Daniel Ollendorf: Right. So, we...we basically tied that...we assumed a percent of BMI change based on the data that we analyze in the evidence review, and it's...with that postsurgical BMI, we assumed a level of cost, a level of quality of life, and a survival associated with being in that BMI range.

Craig Blackmore: So, postsurgical 32 is the same as somebody who has a 32 and has a...

Daniel Ollendorf: A nonsurgical 32, right.

Kevin Walsh: I have a question about the SOS Study, and I'm looking at Page ES 17. The reason I'm asking is, it's the only long, one of the only long-term studies that has a very large end.

- Daniel Ollendorf: Right.
- Kevin Walsh: So, in my mind, if we're being asked to look at covering this surgery because of its purported benefits, and one of the purported benefits is improvement in diabetes, to study that for less than ten years seems ludicrous to me. So, the SOS Study goes out for ten years. So, I just want to make sure I'm looking, I'm understanding the data correctly. So, they're saying while 72% of patients with type 2 diabetes experienced remission at two years of followup. So, I translate that into saying 28% did not.
- Daniel Ollendorf: Right.
- Kevin Walsh: The rate of relapse among patients with initial remission and ten years of followup was 50%. So, that to me says that over 50% of patients who had that surgery failed.
- Daniel Ollendorf: No. So, 50% of patients (inaudible)...
- Kevin Walsh: On patients, 28% and then 50%...
- Daniel Ollendorf: ...remission and reverted.
- Kevin Walsh: ...of...of 72%.
- Daniel Ollendorf: Right.
- Kevin Walsh: So, together...
- Daniel Ollendorf: I assume...
- Kevin Walsh: ...those numbers are greater than...
- Daniel Ollendorf: ...but that's also assuming that all patients at two years are available at ten years, which I don't think was the case, even in the SOS Study.
- Kevin Walsh: Well, then, we should throw out every study that you looked at, I mean, if that's true. I agree, that's a valid point, but then we're left with nothing.
- Daniel Ollendorf: Right.
- Chris Standaert: I mean, there is a problem there. A lot of these studies don't...have a high dropout rates. So, what do you assume of those people who dropped out and couldn't be contacted, and do you assume people who stay with the program, and these are programmatic things, are much more likely to be successful than the ones who become disengaged, unhappy, they were anxious, they were depressed, they had other...you know, they fell off for a reason. So, that's why study, you know, it's a problem. Yeah, I agree with you.

- Kevin Walsh: What it also means to me is that these are the best...this is almost Dreamland numbers.
- Chris Standaert: It's the best possible...
- Kevin Walsh: That it's not really...
- Chris Standaert: Yeah.
- Kevin Walsh: ...the total body of people who went through surgery, because we're not following them.
- Chris Standaert: Only the people who stayed with the program, yeah.
- Daniel Ollendorf: I guess for that particular conclusion, you could say that among those who stayed in the followup paradigm, who continued to be tracked, there was a relative high recidivism rate, in terms of diabetes.
- Richard Lindquist: You also don't know when that occurred. It may have been...it may have been disease free for eight years and then on eight year and one day developed a recurrence of diabetes.
- Chris Standaert: One more question. On slide 21, so the nonoperative things again. So, what is the units on that bar? Difference in means...mean...
- Daniel Ollendorf: I'm just going back to...
- Chris Standaert: So, a difference in means. Is that a mean change in BMI, a mean weight by pound, a mean percentage of weight?
- Daniel Ollendorf: So, this is...right. So, this is the...the difference between...so these are patients who had comparable baseline BMI. So, this is a measurement of mean BMI at study end.
- Chris Standaert: So, a change in mean BMI.
- Daniel Ollendorf: A change in BMI.
- Chris Standaert: Oh, it's seven.
- Daniel Ollendorf: Right.
- Chris Standaert: Right? Is there MCID for BMI?
- Daniel Ollendorf: Oh.
- Chris Standaert: (inaudible) actually results in substantial health outcomes, is there one?

- Daniel Ollendorf: Dr. Lindquist is probably better to answer that of minimum clinically importance difference.
- Richard Lindquist: Generally, no, not based on BMI.
- Chris Standaert: OK.
- Richard Lindquist: But based on percent of body weight loss, you find significant reductions in...in health harm that even modest 5% improvements of weight loss, 10% is a big marker, 20% is a big marker. I do nonsurgical weight management, and if I can get 10% I'm a very happy man, and so these numbers are markedly higher...the surgical numbers.
- Daniel Ollendorf: Patty, were you able to find the information in the Weiner Study?
- Patti: (inaudible) by various expenditure categories, including inpatient cost, professional office, outpatient, and pharmacy costs, and they found that pharmacy costs reduced 30% during the three years following surgery.
- Daniel Ollendorf: But total costs were still higher in the surgical group?
- Patti: Yes.
- Craig Blackmore: Any other questions for Dan?
- Michelle Simon: I have one. I'm still trying to wrap my arms around the long-term effects of this, and there's a study, a JAMA study I found in 2007... a JAMA surgery study... death rates and causes of death after bariatric surgery for Pennsylvania residents 1995 to 2004. I'm wondering, did you incorporate that study? Does that sound familiar?
- Daniel Ollendorf: The first author's name?
- Michelle Simon: The first author's name is Bennet Omalu.
- Daniel Ollendorf: We can take a look.
- Michelle Simon: OK. Well, I did take a look at it, and it's reviewed 17,000 patients who had weight loss surgery, and they found that the death rates were higher for people who had this surgery afterwards, and what they particularly found was that in that general population, three suicides would have been expected, but in this group there were 16 suicides, and in fact, an additional 14 drug overdoses, which were suspected to be attributed to suicide or an attempt at suicide. So, it suggests there's quite a lot more suicide in this group. Is there anybody else that knows other information or data about that long-term effect?
- Craig Blackmore: That's compared...that's...

- Michelle Simon: Compared to the general population.
- Craig Blackmore: ...so not controlling for BMI.
- Daniel Ollendorf: It would not have been in our review then if there was no active comparison group. It wasn't a point of focus. I don't... I don't know if there's been any research specifically on suicide risk.
- Richard Lindquist: When I...that's...that's interesting. I was unfamiliar with that, but there has been reported that there are higher suicide rates or have been at times, and as a clinician, I try to figure out, well, what does that mean? For one mean, that studies an old study, and the surgical approaches and techniques are different. The type of programmatic approach is different. Right now, in centers, it's required to do a psychological assessment, and a lot of those earlier studies didn't have that. As a clinician, I look at it from an expectation management point of view. If I have someone who has a psychological problem that's prone to depression, and they think that surgery's going to fix them, that's not a really good assumption, and so they can have surgery, still have a miserable life, and that wouldn't be fixed. So, that's the way I put it together clinically. So, I, you know, I would be more interested in the more recent studies, but that's a psychological risk, I think, across the board that you've identified.
- Gary Franklin: Craig, can I ask a question. The last time we looked at this, we were concerned about Roux-en-Y and the malabsorptive effects on micronutrients and such in kids, in adolescents, and the longer-term impact of that. I haven't heard much about that. Do we know any more about that now than we did the last time we looked at this?
- Daniel Ollendorf: In terms of comparative studies, there was really, there's no information. I'll take a look at...there's a section in our report that deals with case series specifically, and I can see if there's anything there that's gleaned.
- Gary Franklin: You know, issues of bone loss, some cases of Wernicke's encephalopathy. I didn't know if there was any evidence, you know, related to, you know, how well supplementation occurs. For example, after Roux-en-Y in adolescents and the relationship between that and effectiveness.
- Daniel Ollendorf: Yeah.
- Craig Blackmore: I mean, the only randomized clinical trial that we have on adolescents is the band.
- Daniel Ollendorf: Two years. Yeah, the only RCT is the band, right. Yeah.
- Craig Blackmore: But that, I mean, it was a big issue last time was this concept of altering absorption in somebody who wasn't skeletally mature, and the sort of unknown potential effects of that, and even if we...and I'm not saying we should, but even if we accept this RCT as good evidence to push our coverage limit lower, it does

not address the malabsorptive procedure from the malabsorptive aspects. It's only addressing the banding. So, that remains unaddressed, as far as we can tell. OK. Any other questions for Dan? Are we going to take a quick break?

Michael Souter: Just one more.

Craig Blackmore: Yeah.

Michael Souter: I'm just trying to get my head around the weight regain that we...that we have. Do you have any idea, I mean, I was struck by Kevin earlier saying that it was a failure. Do you have any idea of kind of the average weight gain across the specialties? You maybe mentioned it but I've...I've kind of malabsorbed it.

Daniel Ollendorf: I didn't really talk about weight regain specifically because again, there's not a lot of detailed information.

Michael Souter: Are we talking about 100%, 50%, 25%? I mean, you know, that's...that's a lot of...

Daniel Ollendorf: I think that...and this is a general statement. I'd have to go back and see...look at some of the studies we do report on, but I think that...that in the clinical community, the feeling is that it's about 10% on average weight regain. There are obviously some patients who gain a lot more.

Michael Souter: Mm-hmm.

Daniel Ollendorf: Some patients who don't.

Michael Souter: OK.

Marie Brown: Weight gain meaning completely back to what they were before.

Daniel Ollendorf: No, no. They regained 10% of their original ...

Marie Brown: Oh, OK.

Daniel Ollendorf: ...weight loss.

Chris Standaert: Total over time or per year sort of thing?

Daniel Ollendorf: I think it's total over time, but again, remember that most of the evidence does...doesn't go beyond two years.

Chris Standaert: Yeah, a year, yeah. It's very ballpark-y.

Craig Blackmore: OK. Alright. It's 2:30. Let's take ten minutes and meet back here at 2:40.

- Alright. I'm going to call the meeting back to order. So, first of all, are there any further questions from committee members for any of our presenters?
- Richard Phillips: On the pediatric study, the evidence...the quality of evidence was rated as low, and I was wondering if our...if Dan could amplify that a little bit, why that might have been a low-quality study, randomized control trial.
- David McCulloch: I mean, small numbers.
- Richard Phillips: I know it was 50, but I just want to hear it from him that...it was a small number, but the entire surgical arm had outstanding results, like, I'm just trying to figure out why. I wanted to know if he could give me more information.
- Daniel Ollendorf: The rationale. Oftentimes, when a study got a lower quality rating, it was because of imbalance between treatment groups. So, let's...we'll take a detailed look. That's not the quality rating, no. You have to go down.
- Craig Blackmore: Any other questions while they work on that? OK, well while they're...while they're working on that...so, this is sort of a good time in the process for one of the committee members to provide a summary of at least their perspective on where we are as a starting point for discussion. So, I would welcome one of you to...to do that. Any volunteers?
- David McCulloch: I can make a few comments, Craig. I mean, I don't think there's very much doubt that in adults with BMI over 35 who have diabetes and comorbidities, I mean, bariatric surgery is tremendously beneficial by any definition you want to do. I mean, I think the debates, I think, are going to be for people without diabetes, what are relevant comorbidities, and then the whole issue, as we said, it is rather random cutoffs for years, 40 and above without, 35 to 40 with diabetes or comorbidities. There are ongoing studies obviously looking at people with type 2 diabetes, BMI between 30 and 35 randomizing them. So, those are the areas where I think there'll be controversy. I don't think there's going to be much controversy or debate about which...and again, the agencies are ready...they would be happy to have the 40 and above with no comorbidities, 35 and above with diabetes and other comorbidities. So, I don't think there'll be a debate there. I think the debate might be around pediatrics because of unknown long, long, long, decades long issues of safety and side effects, but I think most of this, I think, will be straightforward.
- Craig Blackmore: Does anybody else want to reflect on that?
- Richard Lindquist: I'd comment...
- Craig Blackmore: I'm sorry. This...thank you, but...
- Richard Lindquist: I get it.
- Craig Blackmore: ...the committee knows that procedurally...

- Richard Lindquist: OK.
- Craig Blackmore: ...the committee is deliberating. We will be probably continuing to ask you questions, but this is sort of procedurally where we're at. So, committee member...any other committee members want to reflect on that?
- Michael Souter: Yeah, I'd concur with David. I think that there's not a lot of intellectual effort involved to actually kind of reap the benefits for the kind of over 30 and over 35 with comorbidities. The question is going to be determining that kind of debating. As far as the peds go, I remember having this discussion when...at our original grouping on this question quite a few years ago and, uh, and I think that for me, we chose the lap banding solution there as really a kind of lesser of most evils, and a question where there really was no data, we've got a little bit more data now, but I do find myself a little bit conflicted when I look at some of the poor outcomes with lap banding and some of the...kind of the problems that lead to the lap bands coming out, and I think that might be a question I'd like to kind of turn again to our clinical expert and look at kind of the primary reasons why lap banding may be coming out and whether or not that's still the right decision in this peds group or whether we should be countenancing something a little bit more invasive but with still the possibility of eeking out some kind of marginal benefit over a kind of chronic life of malabsorption, as well. So that's...I'm just kind of perusing that in my head.
- Craig Blackmore: So, I think, well, does anybody else want to comment, and then I'll sort of try to have a road map here. Go ahead.
- Chris Standaert: I mean, that's sort of a...I mean, that study certainly showed there's benefit in the things they measured. Certainly, diabetes is a huge issue if it goes on. Once again, I really wish...this is a lifelong massive biological change in somebody. I really wish they were following these people forever to find out what happens over 50 years of malabsorption. We're still talking about 30-year-olds getting this done, and 20-year-olds, and what is the recidivism rate? What is the real quality of life rate? Does it affect cancer? Does it affect bone density? Does it affect, what does it affect as people age, and we have no idea, and I think that's a problem, and it makes...although I see the benefit and certainly untreated refractory, you know, morbid obesity has lots and lots of medical complications, and morbidity is a high mortality. I wish there were better stuff here, and I wish...this has been around a long time. I wish people had just been watching, because that's sort of very disquieting that nobody...that they haven't been, frankly. I just want to...so that's my perspective, but I see the benefit in the studies we have.
- Craig Blackmore: Does anybody else want to comment? OK. So, procedurally, I think we should have two big groups. We should do peds and adults separately, because they're kind of different issues. I think I'd like to start with the adults and I think what we're all saying here is, and again I'm... I don't want to lead the committee on, but I think the consensus I think I'm hearing is that we're, again, back in that

area of cover with conditions. We're not...I'm not hearing a consensus for no coverage. So, we're probably in the consense-...in the cover with conditions realm and the sorts of things that have been laid out as potential conditions are starting BMI, and we've heard about 30, 35, and 40. We've also heard about comorbidities, and the big one is type 2 diabetes, and then there's other comorbidities, and they've been described as either obesity-related or not, and different studies and different guidelines, and different consensus groups have used different combinations of these to come up with some boundaries of appropriate care, and I think, barring comments otherwise, that we're kind of in that same boat. So, anybody want to reflect on that, or is that pretty much where we are in terms of the adults? So, does anybody want to start off with a straw proposal for conditions, and if I could get a...

Chris Standaert: I don't want to, but is adult 21 or 18?

Daniel Ollendorf: 18.

Chris Standaert: So, for patients (inaudible) called them out differently in almost everything else we look at, we define adults as 18. So, for the studies you guys are talking about where adults are 21, because the agency director separated out 19 and 20-year-olds for some reason.

Daniel Ollendorf: We wrote our key questions to match the original definition that was used in the original pediatric review, but with the limitations on studies we saw, I think the RCT was age 14 to 18 and the retrospective observational study was 11 to 19.

Chris Standaert: So, the adult study, did they define adult as...

Daniel Ollendorf: Typically, yeah. Greater than 18.

Chris Standaert: OK. Then we just (inaudible)...

Michael Souter: Although some...there's been some argument in this, and this is, you know, there's no (inaudible) hard data to support this line, but there is a variability in where people actually reach the end of their growth curves in that population. So, you have some fairly immature 18-year-olds who still can then continue to have, you know, differential rates of growth, as opposed to their peers.

Chris Standaert: Right.

Michael Souter: And that, you know, maybe, you know impacted by, you know, the...the metabolic consequences of these interventions in that group. So, I think there is...there's no great data to support it, but there's that kind of theoretical basis in which to say that, you know, maybe we should be calling them out as a different population.

- Craig Blackmore: So, when we addressed this last time, seven years ago, we made...we were only asked to address pediatrics, which was defined as under the age of 21, and we separated out 18 and younger, or under 18 I guess, from 18 to 20-year-olds, you know, somewhat arbitrarily, but those are sort of universal definitions. So, I think we need to be conscious of that distinction. We can lump the 20-year-olds...19 and 20-year-olds with the adults or not, but we need to be explicit in how...in what we're doing. We just need to be clear about it. So, I would like to start with the, you know, the over 21's, and then when we get to the pediatric piece of this, decide where the 19 or 20-year-olds fit in. So, let's start with this idea of over 21. That's, you know, if that's OK with the committee as a starting point. So, can we get a word document up there, and we'll go through our exercise and rhetoric there.
- David McCulloch: Craig, I, I would propose we just at least start with a straw proposal with what was done on slide 24, which is the state's recommendations for adults and see if we agree on what...one can modify that.
- Craig Blackmore: So, can we get, can we get that up? Slide 24. OK. So, we're going to...we're going to start with the adult part. So, OK. So, I'm going to guess, well, tell me. We're probably all comfortable with over 40? Is that what I'm hearing?
- Group: Yes.
- Craig Blackmore: Alright.
- David McCulloch: One other thing. Are we saying gastric biliac diversion, Roux-en-Y, lap-band, and vertical sleeve gastrectomy or what?
- Craig Blackmore: Right. So, we can do this bit first or we can talk about the procedures first.
- David McCulloch: Right, yeah.
- Craig Blackmore: Do we have a preference?
- Marie Brown: Let's do this bit first.
- Craig Blackmore: OK. We'll do this bit first. So, we go to the over 40 and then...so, I think the two issues are, well, let's go to the other extreme. Does anybody think we should be covering under 30? OK. So, the two questions, I think, are how to handle the 35 to 40 and what to do with the 30-35. In the 35 to 40 we can either cover unconditionally, or we can cover with conditions, and there are some suggestion conditions here. One is at least one obesity-related comorbidity. Other studies and guidelines we've looked at have made that explicit to type 2 diabetes, and then we could also choose to include failed medical management, however we define that, or not. So, what are the thoughts of the group on 35 to 40? Are we happy with this?

- Kevin Walsh: I wasn't impressed with the distinction...the...I think that if we cover 35 to 40 we cover them with no conditions, because I don't think that the comorbidity improvement was that dramatic between the over 40 and the 35 to 40 groups to parse this out.
- Craig Blackmore: So, you say just cover?
- Richard Phillips: Yeah, I agree. I would just change number one to greater and equal to 35 and just eliminate two.
- Craig Blackmore: Anybody want to push back on that?
- Joann Elmore: (inaudible) comorbidities.
- Craig Blackmore: Does anybody...anybody disagree. Is there a countering of opinion on the committee here?
- Chris Standaert: I mean, is there some study or evidence to draw the line at 40 in any of the things? You didn't, all the stuff you gave us, you didn't give us a line at 40. So...
- Joann Elmore: (inaudible)
- Chris Standaert: ...the studies have entrance criteria of 35. They draw a line at 35. That seems to be different?
- Daniel Ollendorf: So, the consensus statement follows what's listed there now. When we looked at studies that stratified by BMI category, we didn't find consistent... a consistent pattern in terms of better outcomes for 40+ versus 35 to 39.
- Chris Standaert: And we have...
- Joann Elmore: Individual studies but what about (inaudible).
- Daniel Ollendorf: Right.
- Joann Elmore: To find differences.
- Daniel Ollendorf: Yes.
- Chris Standaert: We have the...the NCD is 35 or over.
- Daniel Ollendorf: Right. The NCD is 35 or over with at least one obesity-related comorbidity.
- Chris Standaert: So, it's similar to what's there.
- Joann Elmore: But that's without comorbidity.

- Richard Phillips: Again we...we also assumed that they've all failed medical therapy, or is that not...
- Craig Blackmore: I mean, I don't know what that means.
- Richard Phillips: Yeah. See, I don't either.
- Craig Blackmore: I mean, nobody wants to have a BMI of 35 presumably, or most people don't want to have a BMI so they've been doing something. Now what...what they've been doing and if that constitutes medical management is another question.
- Chris Standaert: I mean, these...so, if you keep reading that slide, they talk about...I don't know this. I'm not familiar with this part of the agencies' criteria, but specified centers. So, these are largely now covered at centers that have preoperative evaluations and preoperative programs and preoperative psychological screening and all that sort of stuff, which sounds like a good idea. That you put people through a preoperative evaluation, which involves a trial of sort of medical treatment and looking at diet and other sort of things before the procedure even, and doing a psychological screening, and then adding in the procedure when appropriate based on your screening protocol. It sounds quite reasonable, but it almost looks like it's built into the programmatic part of it.
- Marie Brown: Although the strongest data was having a multidisciplinary program after the surgery.
- Chris Standaert: Well the psychological factors indicate there was poor compliance too, though. So, you want to find those before you do it.
- Marie Brown: Right, absolutely.
- Chris Standaert: So, I like the preoperative psychological screening, I think, is important I can imagine.
- Craig Blackmore: Alright. So, am I hearing then that the committee is in favor of unlimited coverage over BMI of 35 in the context of a comprehensive program, will all this fit in italics? Is that where we are?
- Kevin Walsh: Can we...can we...I'd like to put that wording in, I mean, that we...
- Craig Blackmore: The bottom bit, the one...when covered...
- Kevin Walsh: Right.
- Craig Blackmore: ...patients must abide by all the surgery program criteria and...
- Kevin Walsh: And, and I...well, never mind.

- Michael Souter: The only thing going through my head is that when we were...or rather, when I was reading...going through this, the evidence to support those with 35, as having a benefit from this, was based on trials where they entered people with over 35 who did actually have the comorbidity, I thought.
- David McCulloch: Yeah, and...and most of them were diabetes.
- Michael Souter: So, in many ways, you know, we're...we're kind of saying that...to do it for over 35 without any comorbidities, that seems to be a different threshold from that, which the evidence is there in the literature.
- Chris Standaert: I don't have a problem with the way it's written. I mean, the 40 without is really pretty high, and the 35 to 40 with at least a comorbidity, and then all of them in a programmatic setting.
- Michael Souter: Yeah. So, I know what you're saying, Kevin, but there's no difference between the over 35s and the over 40s, but that's based on trials where they actually had said...they entered the trials having had a comorbidity. So, there's somewhat...
- Kevin Walsh: Right. But we were talking about this before the break. Isn't it true that historically that the criteria that include comorbidity in that BMI group between 35 and 40 was almost arbitrary, historically?
- Richard Lindquist: Yeah. Historically, the...that 35 cutoff has been pretty arbitrary and was decided back in '91 or '90. I would have to go back to the conversation earlier about the studies and the literature in that group. Practically speaking, there's probably not going to be anybody in that group that isn't going to have a comorbidity, but I'm not sure how you write that in.
- Kevin Walsh: Well, that was the other...that was the other thing I was going to say, Michael, that when I look at subpopulation and my patient panel was BMI over 35, nobody...there's no one without at least one of these additional comorbidities.
- Chris Standaert: Hypertension, diabetes...
- Michael Souter: So, then there's not really much incentive for change from that then. They meet the definition.
- Chris Standaert: Right.
- Kevin Walsh: OK. I...I see the logic. It's a little twisted in my mind, but that's OK.
- Craig Blackmore: So, I'm hearing a lot of discussion but I think I'm hearing 35 to 40 with at least one obesity-related comorbidity is language we're comfortable with? Is that true or not?
- Michelle Simon: I guess... I guess I would just push back a little bit. I think BMI can be quite a rough measurement in somebody who's, like, a body builder is going to have a

- BMI off the scale. Do they need gastric bypass surgery? I don't think so. So, I think a comorbidity would be a good way to kind of limit that.
- Craig Blackmore: I agree, personally, but.
- Chris Standaert: Yeah.
- Craig Blackmore: How about failed medical management?
- Michael Souter: As you said, I don't know what that means. I'm...
- David McCulloch: In any studies where they looked at that, they said it actually doesn't help you distinguish who's going to do well postsurgery or not.
- Craig Blackmore: Well, I think if we're saying they have to enroll in a, you know, in a program that involves rigorous preoperative evaluation and postoperative multidisciplinary care that, you know...those are in...
- David McCulloch: That's ex-...that's exactly right. Basically, you want to make sure this is somebody that is motivated once they get the surgery to keep doing a bunch of stuff and I'm not a nutcase, and that's what the...the preop programs do. So, it's a technical term.
- Craig Blackmore: So, is anybody...do we want to keep failed medical management or what do we want to do there?
- Chris Standaert: No.
- David McCulloch: I don't think we need it. I think having the requirement of a pre...
- Chris Standaert: It's a pretty low bar anyway.
- David McCulloch: ...pre-auth.
- Michael Souter: So, would you want to insert then, David, something more to the converse of it, you know, that somebody who is enrolled in a program and...
- Craig Blackmore: I'm assuming we're going to keep that italic language.
- Michael Souter: OK, then, that's fine.
- Seth Schwartz: There is also a database argument for taking out the failed medical management, because we've seen very clearly that the data supports the people who have surgery do better than people that don't have surgery, and not everybody in those groups had extensive stuff, so.
- Craig Blackmore: Or, we don't know what they had.

- Chris Standaert: We don't know what they had.
- Seth Schwartz: Regardless, even the ones that had medical therapy that were having, you know, alternative management strategies did worse than the surgery group. So, why do we require that they fail at first? I mean, I think if they had an appropriate assessment.
- Craig Blackmore: Even if they succeed at medical management, they might still...
- Seth Schwartz: They might still do worse.
- Chris Standaert: Right.
- Seth Schwartz: I mean, that's what the data says.
- David McCulloch: That's correct.
- Chris Standaert: It's also very wishy-washy. It's easy to meet that bar. If you want to make somebody meet the bar you just say they tried five diets and it didn't work. Yeah.
- Craig Blackmore: OK. So, if we could erase the word 'and' and point B under 2 please.
- OK. That brings us to number three, the 30-35 BMI group. So, what is the feeling on that particular cohort?
- David McCulloch: My guess is, we don't have evidence in this group at this point. I mean, there are lots of ongoing studies of looking at people with BMI of 30-35 with diabetes, for example, and we may well, if we review this in a few years, come back and say there is or is not sufficient data now to justify that, but at this point, I don't think we should go out on a limb in the absence of published evidence to say we should cover it.
- Craig Blackmore: Does anybody want to push back or is there...is that representative of where we are? Richard?
- Richard Phillips: I thought the cost-effectiveness data on this showed some benefit for patients with BMI of 30-35 with secondary diabetes mellitus.
- Craig Blackmore: The modelling data suggested that.
- Richard Phillips: Yeah.
- Craig Blackmore: Whether the modelling is supported by the real data is another question.
- Chris Standaert: The modelling data has many, many, many assumptions, which has...
- Richard Phillips: I understand that.

Chris Standaert: ...troubled me, and they get this every...it's sometimes amplified as you go further statistically.

Michael Souter: I think for me, what was important was Table 6 in the evidence report there, then what's going to open page 64, which just looks at various outcomes by baseline mean BMI and, you know, the...the evidence base for making decisions based on that 30 to 35 group there. You're...you're talking about, like, one paper for improvement in hypertension of fair quality, you know? One good paper and one poor paper for evidence of percentage weight loss and so (inaudible) loss. So, I think that David's point is a good one. I think this is a developing field. There may be something that comes up in future years that will allow us to change, you know, the threshold here, but I don't see an evidence base for extending this, as yet.

Chris Standaert: In those people, also, I would imagine are more amenable to some sort of other measures to drop some a bit, and even if you drop their BMI four or five points, they're getting dramatically on their health curve compared to people who are 45.

David McCulloch: Right.

Chris Standaert: And so they...they made...

Richard Phillips: You know I was sort of amazed by this...

Chris Standaert: ...a different disease stage (inaudible).

Richard Phillips: ...that group actually getting benefit, and I was just wondering if I could ask our clinical expert. It amazes me that people with BMI of 30 to 35 would actually undergo this procedure for diabetes. Are these people really out of control diabetics, or how do you select those...that particular group of patients.

Daniel Ollendorf: So, I'll hand it over to you in a second. I just wanted to point out, so I also have a summary of those studies on slide 23 if anybody wants to look.

Craig Blackmore: Thank you.

Richard Lindquist: I think the spectrum of people in that 30 to 35 BMI group with diabetes are going to be all over the spectrum. You'll have some that will be very bad and some that will be relatively mild. The issue clinically is that diabetes does not respect BMI, and it does not really inquire as to what the BMI is. For example, you can have an Asian with a BMI of 27 with type 2 diabetes that could potentially benefit from an acute intervention. So...but, typically, if a person is going to have diabetes in that 30 to 35 group, it's probably significant diabetes. They're on medication and it's a...it's past beyond metabolic syndrome or prediabetes into diabetes. So, that...that's a, you know, a set criteria for the

diagnosis of diabetes. They've passed the threshold. Does that answer your question?

Richard Phillips: Yeah.

Craig Blackmore: Any other comments.

Richard Phillips: And I don't disagree with what everyone else said about if it doesn't past the muster with a lot of evidence, but it is still there, you know? It's interesting evidence, so.

Craig Blackmore: Anybody else want to comment? So, I'm not sure I'm hearing a consensus on the 30 to 35 group. I'm hearing some opinions for coverage if there's diabetes or some other potentially obesity-related comorbidity. I am also hearing we don't have sufficient evidence. I guess we could just have a show of hands. Does anybody else want to comment before we try to go forward? Alright, well then I guess I'll just ask for a show of hands. Raise your hand if you think what is up there is appropriate, noncovered for BMI of less than 35. So, that looks like most of us and a couple undecideds. OK. I'm going to leave it there, then, for now. Yes, Joann.

Joann Elmore: Two questions. One, I wish the group could talk me into again the bit about taking out the...I agree it's a very vague requirement to have failed medical management. The reason being, is that there are rare patients who are very overweight, and by golly they can do it if they're motivated and if we work with them, they can change their diet. They can exercise, and they can lose the weight without the surgery. So, I hate just giving up on that and saying, oh just surgery is the cure-all. I also think that medical management may fail, but part of it might be a little bit educational to the patient and might benefit them postop. So, the first question for the group is, can you please talk me into that again, because I know we took it off, and I understood why. Then, the second is, do we need to specify older-age group, like some of the other groups? Those are my two questions for the group.

Chris Standaert: I mean, I actually like, I mean, I hear what you're saying, but I think you get this idea. It's, like, when...as soon as you take it out it becomes...this looks like the default, you know? So, wouldn't you...again, we don't know what happens in 30 years of this procedure. We don't know.

Joann Elmore: Mm-hmm.

Chris Standaert: So, you're committing somebody to a lifetime of whatever the effects of this are, and you don't know what those are. So, shouldn't you try pretty hard to talk them through another way and work them through another way, and I agree with you. I've seen people who have lost 100+ pounds without surgery. It took a lot of time. It took a lot of effort. It took a lot of goals, but they did it, and I agree with you. They're out there, and you'd think you'd want to encourage them rather than create a system where it's the other way around. I

don't know if we're creating that system, but I agree. Even having the statement means you have to acknowledge that you tried, which is something...

Joann Elmore: Even some type of educational...

Chris Standaert: ...there's something to that.

Joann Elmore: ...even if they fail, so keep talking me into it you guys.

Craig Blackmore: There's nothing in this wording that says that one shouldn't try.

Joann Elmore: Mm-hmm.

Craig Blackmore: This is about whether we will pay for surgery in people in this group...

Joann Elmore: OK.

Craig Blackmore: ...and should we have a barrier that says you have to fail medical management when we haven't actually seen any data that failing medical management is a predictor of outcome for that. So, it doesn't mean you can't or shouldn't, but...

Michelle Simon: Yeah, and this isn't an algorithm on weight loss. It's really just about bariatric surgery, right?

Joann Elmore: Mm-hmm.

Craig Blackmore: I mean, I would...

Marie Brown: Maybe the way that that bottom paragraph is framed minimizes it a little bit. So, maybe it needs to be a number four, the way we usually do things, which is they must be...they're covered and if they are and put it up there as a number, if they're enrolled in a program, blah, blah, blah, blah.

Craig Blackmore: The other point is the one Seth brought up earlier and that, and that is the surgery may be indicated, even if you succeed at medical management. So, by saying failed medical management...

Joann Elmore: OK. You guys me talked me...

Craig Blackmore: ...you know, what, what does that mean?

Joann Elmore: ...into it. Then, the second question is age. I'm fine (inaudible).

Craig Blackmore: Right, which...which we haven't talked about...

Joann Elmore: Yeah.

- Craig Blackmore: ...but...so, let's focus on this, and I think I'm hearing that we're comfortable with where we are, and we need to talk about different age groups.
- Michael Souter: So, at the risk of being contrary, I'm...I've actually gone back on myself here, because I was, you know, saying that...that noncovered for BMI 30 to 35, but then I was...I was looking at the table and failing to really read the text properly and looking at the text, the table, rather the slide 23 is drawn from. You know, seven randomized...good quality randomized control trials demonstrate...actually, there's many other topics if we had seven good quality randomized control trials, we'd be leaping up and down for joy because somebody actually gave us a platform to stand on. So, I may have been somewhat, you know, preemptory in just dismissing the, you know, the...the weight loss table, etc., and the hypertension table without actually looking at the diabetes data. I think that's...that to me makes an argument for at least covering BMI for those in the 30 to 35 range with type 2 diabetes.
- Joann Elmore: Mm-hmm.
- Marie Brown: What quality were those seven?
- Joann Elmore: It's on his slide right there.
- Marie Brown: Good quality, OK. Good quality RCTs.
- Michael Souter: Good quality randomized control trials.
- Marie Brown: OK.
- David McCulloch: I mean, I think you're right Mike, and I was not wanting to push that far yet. I think in two or three years there's going to be 15 studies showing that even at the BMI of 30 to 35, if you get type 2 diabetes and the outcomes are good.
- Seth Schwartz: Yeah, I was looking at that same data. That's why I was on the fence when we had that...
- David McCulloch: Right.
- Seth Schwartz: ...that vote, and I think, you know, this is this question mark of...just like we were talking about is what are...what are mandating versus what's going to be good clinical judgment in the experience of patients...people that take care of these patients. So, you know, if a patient gets into one of these programs with a BMI of 31, you can imagine if it's a reasonable program, they're not going to rush that patient into surgery, but if they've got uncontrolled diabetes and they're not responding well to therapies, it seems unfair to say, OK, this patient is doing everything they can. They have complications related to their obesity. They're having issues, and there's good data to say that they're going to get better if we operate on them, but we can't until they get better.

- David McCulloch: Yeah. I mean, I...I have to tell you, I've had several incredibly-motivated type 2 diabetic patients who are trying their damndest with diet. So, they're maintaining their BMI of 34, and they won't get covered for bariatric surgery unless they slack off on their diet, get their BMI up to 36, then they'll be covered, and there's times when that's probably the long-term smart move on their part.
- Michael Souter: So, can I make a proposal that we put coverage for BMI of 30 to 35 with type 2 diabetes?
- Craig Blackmore: Yeah, so let's write it down and then we can talk about it.
- Chris Standaert: So, is...am I reading this slide right, on slide 24, the followup is 12 months?
- Joann Elmore: Mm-hmm.
- Chris Standaert: I mean, I...and I know we have studies, but this, again...
- Joann Elmore: Right.
- Chris Standaert: ...12 months versus 40 years.
- Joann Elmore: Right.
- Chris Standaert: So, and...and...
- Joann Elmore: That's why I want to wait.
- Chris Standaert: ...will it be...will this be a treatment for diabetes, right, not even so much to try to fix obesity, you're trying to save the diabetes. Will it be a treatment for diabetes?
- David McCulloch: Absolutely.
- Chris Standaert: That's, like, a whole other question. Like, is it...are you better off with this than you are the complications of diabetes forever is a different question, but I'm not sure that's answered for us.
- David McCulloch: No, and yeah.
- Chris Standaert: Just throwing that out there.
- David McCulloch: I think we're going to have data on those questions in the next four to five years with longer followup, because a lot of people are advocating that.
- Craig Blackmore: So, I'm hearing two choices. Choice one is noncoverage 30 to 35, and choice two is what we're seeing here, covered with type 2 diabetes and noncovered without type 2 diabetes. Further discussion, or do I just have us all vote?

- Kevin Walsh: Well, if you...if you like the diabetes numbers, why don't you like the sleep apnea numbers?
- Joann Elmore: What were they?
- Kevin Walsh: 89% improvement in the 30 to 35 BMI group.
- Michael Souter: What are you looking at?
- Richard Phillips: Where was that?
- Kevin Walsh: Page 65.
- Marie Brown: What do you...would you repeat your point?
- Kevin Walsh: Well, I'm saying that Michael made an argument, David agreed, that there's potential benefit to treating patients with a BMI between 30 and 35 who have diabetes because of the studies that are shown here. Unless I'm reading the numbers wrong, it looks like the percentage of improvement with sleep apnea for that same BMI range is much greater than the improvement in diabetes. So, I'm proposing if you're going to cover diabetes, why not throw in sleep apnea? It's one poor study.
- Chris Standaert: But we...we went through...we went through sleep apnea, and it was really underwhelming in terms of...
- David McCulloch: Yeah.
- Chris Standaert: ...diagnosis and benefits of treatment and the whole thing. So...
- David McCulloch: Right.
- Michael Souter: These...these studies actually included type 2 diabetes as an entry criterion. That's the reason for the type 2 diabetes not because it was a symptomatology that improved. That was because it was an entry criterion to the studies, which we would use an evidence base to support that. That's the only reason I said type 2 diabetes. It has nothing to do with the symptoms. It's to do with the entry criteria. That defined the evidence base.
- Kevin Walsh: Right. And the point I was try...yeah. I understand that. So, it's the only...
- Michael Souter: (inaudible)
- Kevin Walsh: ...it's the only, right. It's the only criteria they chose to...
- Michael Souter: Yes.

- Kevin Walsh: ...use as an entry criteria. So, therefore we cover it.
- Michael Souter: Well, it's a...it's a...
- Kevin Walsh: Because that's the only thing in the study that...
- Michael Souter: ...criterion...it's a criterion that defines a population, which has seen an observable benefit, but you can see that there have been studies done on patients who have sleep apnea.
- David McCulloch: Right.
- Michael Souter: Where this has actually shown a benefit, because those studies haven't been done. If somebody does them, then that's great, but until they're done I don't think we should actually be adopting that as a criterion. The sleep apnea benefit may be entirely coincidental. It doesn't necessarily correlate...the two populations don't necessarily coincide. They probably overlap making a big bend diagram, but.
- Craig Blackmore: So, well, other thoughts?
- Marie Brown: Wouldn't we change, then, number three to cover for BMI over 30 with type 2 diabetes? I mean, we don't need to put 30 to 35, just over 30.
- Michelle Simon: Well...
- Craig Blackmore: Well, the 35 to 40 is a little more lenient, because it says one obesity-related comorbidity. So, that would include diabetes but also sleep apnea and...
- Marie Brown: OK.
- Michelle Simon: I think four should just say noncovered for BMI 30 to 35. You don't need the rest of that, without type 2 diabetes, I don't think. It's going to be one or the other isn't it.
- Chris Standaert: You just need to say...should just say noncover BMI less than 30.
- Craig Blackmore: OK. Well, let's wordsmith it, but I want to...
- Chris Standaert: Are we going to do this?
- Craig Blackmore: ...we have to decide if we're going with this approach or if we're going to go with a noncovered 30 to 35.
- Michelle Simon: Two different options. So, this is option two, and option one we had up before, and that's noncoverage in 30 to 35. So, I'm looking for discussion around that, or else I'm just going to ask for a show of hands. This is where we're going to end up. So, discussion, Richard?

Richard Phillips: Yeah. In looking at this...these studies, the nine studies, coming off of all diabetic management occurred in between 26 to 73% of all patients, diabetic patients, in those studies, which is remarkable considering that 9% was what happened with the medical therapy. But the thing that, you know, and I raise this question. I'm in favor of inclusion of this initially, but the issue is really that there's only 12 months of followup, and that's my whole...my biggest problem in supporting it and voting for it is that hey, we're basing it on something that has a diabetic lifelong disease problem that's only got 12 months of followup, and is that a reasonable thing to do.

Chris Standaert: I agree with you.

Seth Schwartz: Well, I guess, you know, well my challenge here is that we talk about these cut points and BMI as being somewhat arbitrary, and yet the disease process of obesity is not...it doesn't cut off like this, and while the long-term data in general is not great, we've seen long-term data that shows that it's successful in the majority of patients, certainly in the morning significantly obese patients. So, I don't see a compelling argument for why the long-term data would be different for this group. Now, it may very well be, and that may be one of the things we find out is that it turns out if these patients do perform differently, but I don't see any compelling reason to treat them differently right now based on simply the fact that they were a 34 instead of a 36. That doesn't make any sense to me. The other issue I'm thinking about is that one of our concerns in this...in this group is that...the safety data. I think that there are some real safety concerns here, and...and we haven't seen the most...the glaringly good presentations on what the complications of these surgeries are, the long-term consequences of these surgeries really are, and I'm struggling with that a little bit, because they have been doing these surgeries for quite a while now, at least twenty plus years, and you would think...it's kind of the reverse argument, but I would think that if we're seeing significant metabolic complications related to changing the adjusted tracks in these patients, that at least some of that would be reported. Now, maybe that's not right, but...but I would think that we would be hearing about that. So, while I share a lot of your safety concerns about this, I mean, I'm not...I don't really expect it to blow up and be this huge thing that all of a sudden everybody's having these terrible, you know, metabolic conditions related to this...this operation. So, now, in children I think it's a...it's a better...it's a different issue, and I think when the timeframe for a patient is 20 when they get the operation versus someone who's 50 when they get the operation, probably varies and...and we haven't teased out those age differentiations yet. Again, I think there's some arbitrariness to making that distinction and ruling out these patients when we have data that...that they do well, at least from the same objective measures we're using in the...in the patients with more severe obesity.

Chris Standaert: I don't know. I still...it's sort of...I don't know what the long-term data you're talking about. I mean, we don't have ten-year data, so, and we don't have...

- Seth Schwartz: The Swedish data...
- Chris Standaert: ...and diabetes...
- Seth Schwartz: ...the Swedish study that they excluded, we had that, and we had...
- Chris Standaert: Well, they excluded it because there wasn't (inaudible) followup. I mean, and...and (inaudible)...
- Seth Schwartz: No. The excluded it because...
- Chris Standaert: ...when you look at...
- Seth Schwartz: ...it was a different (inaudible).
- Chris Standaert: ...and when you look at the numbers, you start out with 2000 and you have 100 at fifteen years on the slide. It's...it's not a lot. So, and numbers of diabetes recurring and what happens with diabetes over time after the surgery, and does diabetes come back and all those things are sort of there, and our studies really are largely on patients with 35 and over. Somebody picked it arbitrarily, and Medicare may have picked it arbitrarily, but that's where our data lies, which is why...that's where I would go.
- Michael Souter: I can't agree. I think that, you know, Seth's point's a good one. We would...we've got data to support that, you know, longer-term resolution of diabetes in more than one year in the over 35 group. So, you know, you can be 36...you can have a BMI of 36 and yet when we're demonstrating that you do have a discernible effect on diabetes in the 30 to 35 group, but it's only for a year, you're making a somewhat difficult assumption in my view to support, which is that...that...somehow mysteriously that diabetes is at more risk of, you know, being...of recurring just because they happen to be a couple of percentage points less on the BMI scale. That doesn't make sense to me to consider that. You may say there's evidence, but there's some things that we don't necessarily need good evidence for, such as when...
- Chris Standaert: So, do you go...
- Michael Souter: ...you parachute.
- Chris Standaert: ...but do you go to 28? Do you go...you have type 2 diabetes. Do you go to 28? Do you go to 27? Do you go to 29? Do you go to, I mean...
- Michael Souter: There's no way...
- Chris Standaert: ...you draw a line...
- Michael Souter: ...I don't see evidence for the 28's.

- Chris Standaert: ...somewhere. You draw the line somewhere.
- Michael Souter: But we have evidence for the 30 to 35. So, that's the point I'm making.
- Chris Standaert: I hear it.
- Joann Elmore: I agree that we have evidence. We have seven RCTs, two of which are very poor, one of which only has followup to three months. I really think this is coming, but I don't think it's ready now to be approved. I...and I realize it is totally an arbitrary cutoff and it is problematic. It's not idea. I don't think we have any better way of doing it. We have to give something that's concrete to the state so that they can make these decisions. I mean, this is a surgery that has morbidity and, you know, we don't know what's going to happen 10, 20, 30 years later. Maybe in a couple of years, we'll be able to approve it.
- Craig Blackmore: But we do know what happens type 2 diabetes.
- Joann Elmore: Mm-hmm.
- Marie Brown: That's true.
- Craig Blackmore: In 10 or 20 years.
- Joann Elmore: (inaudible)
- Craig Blackmore: And we know what happens to the diabetics 10 and 20 years down the road.
- Richard Phillips: Can I ask our clinical expert a question about this?
- Craig Blackmore: Yeah.
- Richard Phillips: Is this treatment of diabetes, is it...would you consider it investigational or experimental or is it commonly used across the country for the 30 to 35 BMI/
- Richard Lindquist: I think within the obesity treatment community, it's not considered controversial. It's not covered by insurance. So, you don't have a lot of evidence because it hasn't been paid for. The comment about not having adequate data, that's right. We don't have it. We do know what happens with type 2 diabetes at two years and five years and seven years. So, clinically, it does not make sense to use 35 as a cutoff. It makes clinical sense to include 30 to 35, just saying.
- Craig Blackmore: Any other committee member comments?
- Kevin Walsh: I just want to go back to that SOS study that said there was more than 50% remission of diabetes in the...in the surgery group at ten years. So, the posit that you made that, you know, diabetes is a bad thing over time is true, but that

SOS study seemed to me to be saying, but the benefit of surgery decreases over time.

Michael Souter: And what's that remission defined? Is it going back to complete dependence upon the same scale of medications there were before, or was it that they needed some degree, because I would argue that if you improved control by reducing dosage, etc., then that's a step forward, but, you know, I wanted to know what that was.

Marie Brown: 50%.

Kevin Walsh: Remission of diabetes.

David McCulloch: So, there are a lot more studies of looking at di...we've looked at diabetes in Group Health...within Group Health and Kaiser, all of Kaiser, and other studies, and it...when you get the studies, there are a whole bunch of people that don't have diabetes. They meet the (inaudible) know that hemoglobin A1C is down below 6.5, they're off insulin, blah, blah, blah. If five, six, seven, eight years later, they can't...the two things that are going on with diabetes are either genetically determined, relentless loss of beta cell function over decades, on top of which there are varying degrees of insulin resistance. So, if you pick people correctly, and that's why diabetes makes even more compelling evidence to consider this for some patients, even if the BMI is 30 to 35. You can get them earlier in the diabetic history when they still have quite a lot of endogenous insulin left. You remove the insulin resistance with the gastric bypass, or bariatric surgery, the diabetes firstly goes away. Yeah, it may well come back ten or fifteen years later, but the lifelong benefit of having had five or ten years of incredibly low blood glucose, low blood pressure, low lipid is highly likely you're going to see that benefit further out. So, the fact that it comes back later, yeah, just like women with gestational diabetes, you know? Ten or fifteen years later many of them develop type 2 diabetes. So, I don't find that a compelling argument for not doing it, because with a natural history, yeah, it'll come back at some point, but it'll be milder, and you'll have had the benefit of years and years of really good blood glucose.

Craig Blackmore: OK. So, again, I'm going to ask for a show of hands. I'm going to ask you to raise your hand if you think we should cover the type 2 diabetics in the 30 to 35 range or not. So, cover...so, cover for BMI of 30 to 35 with type 2 diabetes. It looks like most. OK. So, I'm hearing the majority of the committee members are comfortable with this particular set of conditions in adults. So, then the next question becomes, is there an upper age cutoff where we think the surgery should be covered?

Joann Elmore: Wouldn't we just leave it up to the clinicians?

Craig Blackmore: I mean I...

Marie Brown: Do we have any evidence about anything in relation to age?

- Seth Schwartz: Were there exclusion criteria in the studies?
- Craig Blackmore: Yeah, the one thing we have is who they studied, where the data comes from.
- Daniel Ollendorf: So, the populations in these studies were largely under 60.
- Richard Phillips: There was the VA study though wasn't there, too, which was over 65?
- Daniel Ollendorf: Guidelines.
- Joann Elmore: Guidelines do not allow it, like, over 65.
- Chris Standaert: But Medicare covers it, which is largely an over-65 population. So, it must be...nobody's reporting it in these patients who are covered by Medicare?
- Michelle Simon: I thought they changed the LTD as of January. It's not covered over 65?
- Daniel Ollendorf: That was for one specific procedure, but the general NCD criteria do not have an age item. Most of the studies were done in adults under 60.
- Seth Schwartz: Can I ask our clinical expert how you handle this scenario with older patients clinically?
- Richard Lindquist: I don't have a good answer for that. It's tricky. There are, you know, there are 70-year-olds who are very...who would benefit, perhaps, long-term. You think they're going to live long enough to be able to get the long-term benefits from the weight loss and the morbidity disease control. There are others that you question, really, what's going to happen and whether you're using your resources wisely. Clinically, it's a tough decision. You have to go by what you see when you talk with that person. Do they understand what they're getting into? Do they understand the surgery? Do they have other things that are going to present clinical risks that they're a bad surgical risk? Do you, you know, and honestly my observation around the country, there are places that just operate on anybody, but a good program will try to screen people. I don't think there is any particular age arbitrary cutoff though, you know, but for purposes here you have to come up with something probably. We just started seeing patients for vertical sleeve gastrectomy above the age for 65 for Medicare, and we have a limited number of them, so far, but their outcomes aren't any worse than the under 65 group. So, sorry I don't have a better answer.
- Seth Schwartz: Not really to speak to age, but we did see...I think there was some data on the relative comorbidities, and it was within the patients with cardiac disease that they had a higher mortality, or higher risk of complications with the...or was it poor outcome or higher risk of complications with the gastric bypass.
- Craig Blackmore: I think the worse surgical candidates you pick the worse your outcomes are going to be, but I don't know...

- Daniel Ollendorf: Higher complication rate.
- Craig Blackmore: ...yeah. I don't know that we, you know, if we use an age cutoff we have to justify it, and I'm not sure how we're going to do that.
- Joann Elmore: I suggest we don't. I suggest we leave that to the clinicians.
- Craig Blackmore: And some people are going to operate on people they shouldn't operate on, but I'm not sure we can control that with a blunt instrument. So, I don't know. Does anybody feel strongly about having an upper age limit?
- Group: No.
- David McCulloch: So, what about the lower age limit?
- Craig Blackmore: So, the lower age limit. Alright. So, we'll move on. So, this...there's no upper age limit here. So, now, we're going to go to the pediatric population, and we need to consider two different groups, and this is in part because this is how we did it last time. So, we can merge them together, but at least initially we need to discuss the 18 to 20s and the below 20s. Sorry, the below 18s, and we've only heard any data at age 14. I believe, the one randomized clinical trial in peds was age 14. So, I think certainly we wouldn't cover below age 14. Nods, please?
- Group: Correct.
- Craig Blackmore: And then we will...so we'll consider, discuss, 14 to 18. We'll discuss 18 to 20, and we'll come up with some kind of decision. So, let's start with 14 to 18. So, thoughts on that group.
- Daniel Ollendorf: We actually rated that a good quality RCT. I'm not sure where the thought that it was a poor quality RCT came in. So, we just double-checked the report.
- Craig Blackmore: So, this is the...we're talking about the bariatric one by O'Brien, it looks like?
- Daniel Ollendorf: Right. Small 50 patient RCT, but we rated it good quality.
- Richard Phillips: So, low quality is in error, then? What's on the report is an error, is that correct?
- Daniel Ollendorf: Is there an error? There was a Messiah Study that was fair quality.
- Craig Blackmore: OK. So, I think if we look on slide 26, you had said the strength of evidence was low, not necessarily that it was a low-quality study.
- Daniel Ollendorf: Right, because it was just one study.

- Craig Blackmore: One study and relatively small numbers, 25 patients got the surgery. So, that's not a huge wealth of evidence. So, thoughts on 14 to 18.
- Michelle Simon: I am uncomfortable, I guess I will say, making a permanent change in a person of this age knowing that they have a long life to live, hopefully. I understand there may be nutrient absorption issues, which are not so far clearly defined yet, but I'm not persuaded by this one study that we should cover it.
- Craig Blackmore: OK. Any other comments?
- David McCulloch: I would just, I mean, I think most of the people that we see who are adults, the ones I see who are adults who have BMI over 30, 35 at age 40 to 50, they weren't that fat, that overweight when they were young. So, I think people who are that overweight at a young age are just a different group of people, and I have no doubt that short-term...these are amazingly powerful surgical treatments. You're going to get the short-term changes in weight loss and hypertension, etc. I have more worry about just having no clue what they'll...what they'll be like in 20, 30 years on, so.
- Craig Blackmore: I think what we're talking about...potentially, what we're talking about, maybe, is doing it at age 15 versus age 21, and for me, we're adding a lot more risk of unknown things, unknown absorption, unknown skeletal growth issues by doing it earlier, and yes, there's a theoretical benefit of doing it earlier for those first couple of years, but I'm not seeing a compelling argument that it's worth taking on those completely unknown risks.
- Michael Souter: I agree.
- Seth Schwartz: I agree with that, and I think the other question is, what is the, what is the long-term benefit. I mean, we know that in older patients who have...who are developing diabetes and these other complications that a few years can make a difference in the long-term, but in a 15-year-old versus an 18-year-old, is that difference going to have a lifelong effect on them?
- Craig Blackmore: I don't know.
- Seth Schwartz: And I don't know the answer to that one. I don't know if any of the medical doctors do, but I mean, if we have less compelling arguments for the risk of that, and we have greater concerns about the safety issues, I think that...that flips the balance for those kids a little bit, in my mind.
- Chris Standaert: Yeah, I think you have the medical issues. I think you have consent and psychological and other issues at 14, which are very different from 25. It's not the same thing as a life-long altering thing. It is interesting, in some of these studies they have though, these are different people. So, the one, the 890 patients with a BMI of 51. I mean, this is extreme. So, clearly, this is a different disease than in an adult with diabetes and a BMI of 35 or 37 or whatever. It's a

different disease, and maybe this is the right thing when you have a BMI of 51 at age 17. Maybe this is what you should be doing. I just don't know.

Craig Blackmore: Right. I don't...I don't...

Chris Standaert: I don't know if I'm...

Richard Phillips: I tend to think that over 51...over 51 is probably reasonable. That's my personal view, and I sort of go along with what the Endocrine Society had mentioned. If they have skeletal maturity, and that's really the big issue. There's a lot of unknowns about this, but the people I've seen with a BMI of 50, I mean, they're almost bedbound...bedbound, you know? They're...they're really in sad shape, and they need something heroic sometimes. So, if...my personal feeling would be to cover them for a BMI above 50 if they meet all the criteria, but I can't say that there's a lot of evidence for that, and I, you know, it's obvious that there's...in the studies that were done, the surgical arm, they did spectacularly well in the one study, you know?

Chris Standaert: Mm-hmm.

Richard Phillips: It's just one study but, you know, it's...it's really hard to make strong statements, but that's just more of an opinion that it is anything else.

Seth Schwartz: I can understand what you guys did the last time, you know, by sort of hedging and saying, yeah, lap banding is OK but nothing else because of the fact that it doesn't alter the metabolic situation for these kids as much. So, the risk profile is quite different, and it's reversible, theoretically. What we didn't see is really...we saw in the adult population that clearly lap banding is not as effective as bypass or some of the other procedures, although it still is relatively effective. I guess I'm curious...I don't...we didn't see any data on that for pediatrics. Has there been any data for lap banding in the pediatric population?

Daniel Ollendorf: Lap band was the modality in the RCT.

Seth Schwartz: That was what was...it was lap banding? OK. OK.

Chris Standaert: What gets problematic is when you go to complications. The lap band seems to have the highest rate of, you know, short-term revisions and other operations and other things compared to the other surgeries.

Seth Schwartz: Well, not with complications, with revisions.

Chris Standaert: Huh?

Seth Schwartz: Not of...not the highest rate of complications.

Chris Standaert: No, revisions, revisions.

- Seth Schwartz: Highest revision rate, yeah.
- Chris Standaert: Revisions, yeah.
- Michael Souter: Well, those revisions aren't necessarily due to complications. They're due to things like, OK, the band has slipped. The (inaudible) not fitting any more. You've got a lot of reflux when people have this. So, that's kind of like a...a question I had for the clinical expert was all of the lap bandings that he sees that require revision, you know, what's a kind of breakdown of the causes for that?
- Richard Lindquist: So, the reasons for revision for lap band will be intractable vomiting or reflux, it has to be removed. The band will slip, which is basically moves out of position, erosion into the stomach, problems with the port becoming infected or something like that. Those are typical reasons, and I think that probably...I'd actually...I looked at the numbers on these. I think slippage is probably the highest single cause, or failure, yeah.
- Craig Blackmore: So, I...I've heard sentiment for not supporting this in this age group. I've also heard supporting it with a very high threshold, 50 was one number given. Any other thoughts? OK. And then again, I'm going to ask the committee, you know, who...who...who's in favor of any coverage in the 14 to 18, and we can pin it down a little more, but if...if you think there's some circumstances in that group that we should be covering this, can you give me a show of hands for the yeses.
- Richard Phillips: Just one thing. That's the only study that have...
- Craig Blackmore: Yeah.
- Richard Phillips: ...of the randomized control trials. I understand that was in the age group of 14 to 18, was it not?
- Craig Blackmore: Yeah.
- Richard Phillips: So, basically I'd have to say that's the only place where there's any evidence, you know, that addresses the issue.
- Craig Blackmore: Yeah. So, specifically in the 14 to 18s, and can I just have a quick show of hands, people who think we should continue talking about coverage in this group.
- Chris Standaert: And so people with a very high BMI of 50.
- Richard Phillips: That, yeah, I would say a subset of that group, but I would not...
- Chris Standaert: Do we not do the...is that not OK?
- Richard Phillips: ...not...not for all kids.

- Chris Standaert: Existing decision is lap band is covered in?
- Craig Blackmore: No, nothing.
- Chris Standaert: No. Nothing is covered. Lap band is the 18, 19, 20s.
- Seth Schwartz: I thought the existing policy does cover for lap band.
- Michelle Simon: 18-20.
- Craig Blackmore: So, I'm...do we think we should cover...any coverage in any subgroup in the 14 to 18s? Anybody? Am I seeing enthusiasm? I'm seeing... so we're kind of split-ish. So, what would it look like? What subgroup in 14 to 18 would we cover if...and we can put it up there and talk about it.
- Richard Phillips: Well, I think it would be along the lines of what the Endocrine Society had mentioned, which would be, you know, a BMI above 50, failed lifestyle modifications, use of pharmacotherapy, and qualified by psychological stability, and I think there was also somewhere I read where it was about having satisfied skeletal maturity criteria.
- Craig Blackmore: OK.
- Richard Phillips: But those are the criteria that I would look at.
- Craig Blackmore: So, let's capture this. So, BMI of 50+, again failed medical management...
- Seth Schwartz: Skeletally mature.
- Craig Blackmore: ...and skeletally mature. That was...that was the basic, right? Some kind of...
- Richard Phillips: Yeah. Lifestyle modification, pharmacotherapy with or without. Let's see, past psychologically stability testing, and of course going through the multidisciplinary teams.
- Chris Standaert: Psychological stability, you say?
- Seth Schwartz: And I, and I would say, I mean, it's kind of obvious, but lap banding only.
- Richard Phillips: Yeah.
- Craig Blackmore: OK. So, E...E there might be lap band only.
- Chris Standaert: Isn't pharmacological and medical management?
- Craig Blackmore: Can we make that failed conservative treatment or something?

- Chris Standaert: Yeah. Yeah, don't put pharmacological. Then psychological stability is the last one.
- Craig Blackmore: Then, F would be lap band only. LAGB.
- Richard Phillips: Can I ask the expert a question here about this? The...you're...you're basically an adult...you treat adults basically, but do you manage at all or involved at all with the pediatric groups?
- Richard Lindquist: In my training, it covers some degree of pediatric care. My exposure's been somewhat limited as to numbers. Most of the ones I've had have been referred in for possible surgery for things like pheochromocytoma, things where they have biological drivers towards obesity that...that they've failed all the other treatment strategies and...and...so, I haven't had many.
- Richard Phillips: Is there...is there any organized program for transition between the pediatric and adults just so there is long-term followup?
- Richard Lindquist: No. No, there isn't.
- Richard Phillips: Oh, OK.
- Richard Lindquist: No, there isn't, and in fact, there are no pediatric obesity programs in the State of Washington. No, actually that's not quite true. There's one at Children's, but it's a small program. There are no surgical programs that I'm aware of in this state.
- Craig Blackmore: So, any other thoughts on what this would look like if we go to...if we adopt this condition coverage in the 14 to 18. Would this be the set of conditions that we focus on? Have we captured that?
- Chris Standaert: Frankly, this isn't done in these very morbidly obese adolescents?
- Richard Lindquist: It is done, it's just they...I don't...I don't know if there's anybody in the state actually doing it right now. I'd have to kind of ask around. There are a couple of centers in the country where people have focused on the bariatric surgery, probably the authors of the paper, I'm guessing, but there's...there's not a...because it hasn't been covered and because kids...pediatric surgeons are different. Kids are not small adults, right? We've heard that and so most of the surgeons who are trained are actually trained with adults. So, there's just not a lot of resource for pediatric bariatric surgeons. There are a few centers around the country. So, there's just not...there...there's just not a lot of data. I...I think that if...I think clinically if there were more options for kids to get treatment, then we might gradually develop the expertise in it, but that's a chicken and egg and sort of a delayed process.
- Craig Blackmore: Michael.

- Michael Souter: Given the relation to surgical volume and outcome.
- Chris Standaert: Right. Yeah, yeah. If we don't have a center doing them, then maybe we shouldn't have people in here doing it. If we needed Alaska...if you had to be enrolled in a center that has everything and it doesn't exist...then we have the chicken and egg question, but we're kind of...are we going to get somebody hurt because we're?
- Kevin Walsh: Yeah. I think those are both really good arguments. I think the one challenge...we're not talking about little kids. There is a little difference when you're talking about, you know, 14, 15, 16 year-olds who are skeletally mature. So, we're not talking about, you know, necessarily having to happen in a pediatric hospital (inaudible) managed kids in this age group. So, I think that argument is a little, you know, hard to say, and presumably if you're going to...if they're going to have to go through one of these programs, they're going to be dealing with a surgeon that's experienced in the procedures.
- Richard Lindquist: And I should clarify that there...there are surgeons who have been trained with pediatric procedures. They just may not do them at this time. So, the training may be there.
- Craig Blackmore: Any other thoughts? Are we happy with this set of criteria to vote on? Not to approve, but...or not? OK. Well, then again, I'm going to ask for a show of hands. Do we include this limited coverage in the 14 to 18 and...or do we not cover basically in the 14 to 18? So, if you're in favor of this limited coverage for 14 to 18, can I have a...raise your hands please. So, only about three. So, it sounds like there's not consensus to do that or enthusiasm to do that. So, we're back to noncoverage in the 14 to 18 range. So, we can erase bullet point two when you're finished with writing 14 to 18, yeah. Perfect. So, that brings us to the 18 to 20 group. Last time, we came up with this criteria. We fund...or we supported the band...the band only because it seemed to be less invasive and it didn't have the malabsorptive concerns that you get with some of the other procedures potentially reversible in theory anyway, and we only covered 18 to 20 because of the same concerns we've talked about. So, now we have a little more data, perhaps. Do we want to continue with this? Do we want to cut coverage, expand coverage, different procedures? What do you guys think?
- Chris Standaert: I wasn't here. I sort of get it. It's sort of a little arbitrary. I mean, adult bone density, males are 24 to 25 before they hit that. So, it's...you're picking an age, but it's not really correlating. I think you certainly have some people that are quite biologically mature at 19 and some who are not, obviously, and I would hope that the physicians would be taking that into consideration as they treat them, but I didn't hear data of separating out 19 or 20 from 22. So, I'm not opposed to it. I just...it's...it just strikes me as a touch arbitrary, but it certainly could be OK.
- Michael Souter: You know, I mean, when we did this there was really no data. We were just kind of blowing in the wind but with that kind of (inaudible)...

Craig Blackmore: Oh, no, no. We were acting on the best available evidence, and the best available evidence was not terribly strong.

Michael Souter: No, it's not, but I think we were very mindful of the possible consequences when there was no data. I think we've got some data now, you know, that...that makes me question whether this is a valid assumption.

Craig Blackmore: So, what...so what do you mean by that? What...

Michael Souter: Well, I... I...

Craig Blackmore: ...are you suggesting as an alternative?

Michael Souter: I'm...I suppose that when you look at some of the...kind of the revision procedures, albeit for the fact that they're not because of complications, but they are treatment failures in a sense that there may be an argument for more clinical effectiveness in treating somebody in that age group with a more durable procedure. So, I don't necessarily know that we should be limiting this to laparoscopic adjustable gastric banding. I think that there may be an argument for doing things like, you know, the vertical sleeve gastrectomy, even the Roux-en-Y.

David McCulloch: I think that's exactly, Mike. I mean, I...I worry...so, because we're sort of I'm not sure if this is a good thing to do so let's do the lap band because it's the least potential. I mean, it's the least effective procedure and over time has more, you know, erosion of the band, slippage, I mean, I...my guess is if you follow these people out ten years you have 90% who have either failed and redone. That's where we just...we need more data. I can't agree with what Richard said. There may be a subset of really obese kids. They really need to get Roux-en-Y or vertical sleeve gastrectomy done, but we won't know that until we've done that far. It doesn't sit well with me to sort of say, well, OK. We'll allow them to be covered for a pretty mediocre procedure.

Craig Blackmore: Richard?

Richard Phillips: The other thing is, the only pediatric studies we have basically covered up to age 18. So, therefore, the people 18 to 21, they are covered by our findings in the other literature, which is the adult literature, and in that regard, I don't think we have the evidence to really restrict it to the lap band. I think we have to basically provide the same availability to the 18 to 21 years olds that we do to the rest.

Chris Standaert: Yeah. I mean, really, to...by our other criteria, if they're going to be a BMI under 40, they have to have diabetes essentially by 19 years old, in which case you probably should be thinking you need something more dramatic and more durable and if not, then they have a BMI of 44. If they have a BMI at age 19 and they're...they go through the whole thing. I mean, they...again, they may need

a more durable intervention to really change the quality of their life. So, I don't know. It just seems arbitrary.

Joann Elmore: So, just put adults above 18.

Craig Blackmore: I...I don't disagree. I want to specify that there is a lot of evidence that's come to light since our prior decision, which I do think was quite appropriate given the information we had at the time. It doesn't mean we have to continue that decision, but I want to clarify that most of the evidence that we are looking at now, or much of it, has come to light in that intervening time period. So, I'm hearing a proposal that we consider people over the age of 18 in our adult group where we consider them...we approve coverage. I don't want to call them adults, because some people don't call them adults, but adults...patients over the age of 18. Thank you.

Joann Elmore: 18 and over or over the age of 18?

Craig Blackmore: 18 and over, yes. Sorry. So, that's one proposal. Another proposal would be to continue what we have, and another consideration would be to come up with some new set of criteria. I'm asking the question. Any other thoughts or any other potential conditions?

Michelle Simon: The only thing that I would say is when we talked about pediatrics, we were specifying skeletal maturity, and I think we know that age 18 isn't necessarily the cutoff when everyone's skeletally mature. So, do we want to consider some language in here about proving that or does that not matter?

Craig Blackmore: Thoughts?

Seth Schwartz: Again, looking at the adult studies, they certainly didn't make that distinction. At least, we didn't hear about that. So, I guess we could ask, was that specified in the younger patients or is that not even mentioned?

Daniel Ollendorf: The lower boundary in most of the studies was 21, but as far as I know, there was not any specific entry criterion about skeletal maturity. That does exist in the coverage policies that are...that we reviewed, though.

Craig Blackmore: I mean, it's easy to put in. I'm not sure how relevant it is. Most, you know, 18, 19-year-olds are skeletally mature or very, very close to it. We can specify if we choose.

Richard Phillips: I think the 18-year-olds, 18 to 21-year-olds with morbid obesity are more likely to be candidates for some of these non lap-band procedures, metabolic procedures that is, and I think that's the reason I would advocate that they be in the adult age group even though their treatment may be different than say a 60-year-old's may be. So, in other words, I'm uncomfortable with putting them up there and letting the decisions be maybe different than other adults, but I think they belong in that group.

- Chris Standaert: And you're getting...it's a small number of open growth plates at 19 or 20-year-old's. There's a small number of people...
- Richard Phillips: Absolutely small.
- Chris Standaert: ...with open growth plates (inaudible).
- Craig Blackmore: I'm not...I'm not arguing.
- Chris Standaert: It's really small, and again, these are...you're only really doing it in non-ill patients over...with BMI over 40. I mean, you're in a...that's not a big category of people.
- Richard Phillips: Not at all.
- Chris Standaert: And they clearly have a significant disease. So, I don't...
- Michael Souter: I don't have an issue with it. I'm OK with it as it is.
- Michelle Simon: OK.
- Craig Blackmore: OK. I think we've covered the bases. So, let's review noncovered patients under 18 years of age, cover...
- Richard Phillips: You're going to also cover the technology, or you wanted to...did you not...
- Craig Blackmore: We do have to cover the technologies, you're right. OK. Let's clarify this. So, number one, we have noncovered patients under 19 years of age. Numbers two and three you can get rid of, because now we have included everyone 18 years of age in that category there, greater than or equal to 18 years of age. So, that covers everybody. So, then we need to talk about the different procedures.
- Chris Standaert: Do we need to say not covered for BMI less than 30 or is that just implied?
- Craig Blackmore: Noncovered for BMI...
- Chris Standaert: We usually don't...let's say it's covered.
- Craig Blackmore: Let's specify. So, number five is not covered for BMI under 30. So, then the next issue was the different procedural options, which there are several and there is a little bit of comparative data. So, what do you guys think? What...what's a proposal for how to deal with this?
- Michael Souter: I don't think we should distinguish. I think that there is a tradeoff between effectiveness but then again...then again the side effects that go along with that, and I think that needs to be judged on an individual patient basis by the, you know, the clinician and the patient involved at that time.

Craig Blackmore: This is more of an informed consent or shared decision making issue. It might depend on how old you are. It might depend on what you want to do. Anybody want...

Richard Phillips: I agree with that. I think some of this...this world is changing. I know, for example, that the...and perhaps our consultant would know better than I about this, but some of the...like the vertical sleeve gastrectomy is a local coverage decision elsewhere in the country for patients over age 65, whereas it's not used in this state. I think there's...it's a really changing field, and it's almost incumbent upon the experts to make the decisions as to whether to use a restrictive versus a metabolic versus a combined restrictive/metabolic procedure based on the patient's level of morbid obesity. I would be inclined not to restrict the technologies.

Craig Blackmore: Does anybody want to make a counter-meaning argument to that? OK. So, I believe we have conditions up there that cover the range of BMIs and that cover all the different ages, and we have a little caveat about coverage that says we want them enrolled in a program, and we're going to make sure they get postoperative care that's associated with positive outcomes, and...

Marie Brown: Is there a reason that you don't want to make that number six, that paragraph underneath it?

Craig Blackmore: We can make it a number six.

Marie Brown: OK.

Craig Blackmore: You want a number six?

Marie Brown: Uh-huh.

Chris Standaert: Does it make a difference...

Marie Brown: Just to give it a little more credi-, oomph.

Craig Blackmore: Oh, you're scaring me. Then make...you're going to make pediatric bullet point number seven, and then we'll have a...

Seth Schwartz: I'm just wondering if it'd be clear if you just had two subheadings, covered and noncovered, and covered as the four that are...or the three that are under that and then noncovered is the other three?

Michael Souter: Under six and (inaudible).

Craig Blackmore: Yeah.

Chris Standaert: Move seven to six.

Seth Schwartz: Well, I think, no. I think, yeah. That'll actually be listed as a noncovered indicator.

Craig Blackmore: So, we will...if we...if we approve this, we will charge staff with summarizing it...or not summarizing it, transforming it into the draft findings and decisions document that will fit the format and we'll take the working from what we have here. OK. So. . . so any further discussion? OK. Then, we're going to move to our decision-making tool, which is in your packets, and we've been through this already once today, but basically, our coverage and reimbursement determination analytic tool is designed to help us get through the decision-making process, and our decision-making is based on the principles of is it safe, is it effective, and does it provide value? We have gone through a discussion of the data and the outcomes, and staff has prepopulated the tool with the outcomes that we considered in our decision-making process under safety, efficacy, as well as consideration...special population considerations and costs. Are there other outcomes that we have considered that haven't already been documented on this document? We definitely talked about quality of life as an outcome under efficacy and effectiveness. It's not explicit on here. What else...anything else that was of importance in our discussion? I think safety, I would also list, growth in pediatrics and malabsorption and long-term ...

Chris Standaert: Long-term nutritional malabsorption.

Craig Blackmore: ...nutritional malabsorption certainly was a concern.

Chris Standaert: Especially with reflux and other things, too.

Craig Blackmore: And issues of reflux, other complications.

Chris Standaert: Gastrointestinal complications.

Craig Blackmore: So, was there anything else that instrumental in our decision-making here? OK. OK. Then, we get to the Medicare coverage guidelines and we are consistent with some of the guideline, though we thought the evidence was a little different around some of the BMI cutoffs. We, for example, covered below 35 for...if we adopt this. Let's go on to the vote, and we'll come back to the reconciliation. We have definitely considered guidelines from other societies in our deliberation. OK. So, the first voting question is on the effectiveness, safety, and cost-effectiveness and you should vote if you believe that any of these surgical procedures is more effective in any population, you should vote more, and if it's less than all, you should vote less, and equivalent and unproven are self-explanatory.

Josh Morse: Ten more.

Craig Blackmore: Alright. Safety...so, if it's to be more safe under some circumstances you would vote more and less safe overall you would vote less.

Josh Morse: Nine unproven, one more.

Craig Blackmore: And then cost-effectiveness.

Josh Morse: I see two more, three more, seven unproven.

Craig Blackmore: Alright. Any further discussion?

Josh Morse: I'm sorry. That would be nine.

Craig Blackmore: No, no. It's...

Josh Morse: Three and seven. . . did I say three?

Craig Blackmore: Yep. Any more discussion? Richard?

Richard Phillips: (inaudible) one criteria there of the BMI 30 to 35, type 2 diabetes, and age over 65 create a problem for Medicare patients?

Craig Blackmore: We don't have an age criteria.

Richard Phillips: I know we don't, but if, if we cover number four up there, does that give us, put us in the...contrary to the Medicare coverage decision?

Craig Blackmore: Yes.

Richard Phillips: And so we just...do we have to specifically say we're not going to do that, or?

Craig Blackmore: Well, I was going to circle back.

Richard Phillips: Oh, you're going to do it...

Craig Blackmore: If we decide to do this, then we have to say why, but...

Richard Phillips: Got you.

Craig Blackmore: ...I wanted to see if we were going to do that first. OK, but then we do...

Richard Phillips: I didn't hear that.

Craig Blackmore: ...circle back. Yeah, yeah. We do need to circle back. OK?

Richard Phillips: Great, thank you.

Craig Blackmore: Any other...any other points? OK. So, the...the choices are not covered, meaning not covered, covered unconditionally, we will pay for it under any

circumstances or cover it under certain conditions, which we have predefined and discussed.

Josh Morse: Ten cover with conditions.

Craig Blackmore: Alright. So, that is approved. Now, we have to reconcile that with the National Coverage Decision, and we did differ a little, particularly in this 30 to 35 group where we allowed for coverage with type 2 diabetes and that's based on what we saw in the evidence where we had some evidence in that specific population that there was a benefit in terms of reduction in type 2 diabetes. So, that was the evidence that drove what we did. Other areas where we disagreed, I think we were close. We had a little bit of a difference in how we defined...we were a little more restrictive in requiring diabetes as a comorbidity, not just any comorbidity in the 35 to 40 range, but again, I think this is based on our review of the evidence, which we discussed in detail. Then, some of these other guidelines do vary. People use different cutoffs, 30, 35, 40, and different definitions of comorbidities, and again, we're similar but our...our response to the evidence isn't always identical. OK, and we've charged staff with generating a draft findings and decision document for us, which we will approve or not at our next meeting, and I thank you all for your attention and participation, and we are adjourned.

Chris Standaert: No, we have to do...

Craig Blackmore: No. We're not adjourned. Sorry. Dr. Lindquist, thank you, sir, for joining us. Thank you for...everyone for being here. Next agenda item, draft key questions lumbar fusion re-review. Alright, Josh, what have you got for us?

Josh Morse: So, in your binders in the back, you do have a draft set of key questions. There is an open comment period right now for this topic on these...on this draft. The ICER is here today, and they happen to be the assigned reviewer. So, we have an opportunity to review these and provide some feedback right now.

Craig Blackmore: If you like.

Chris Standaert: I'll say a couple things. So, this is a lot of what I do. It's...I don't do this, but I see people with all sort of back pain. So, one, you expanded the scope to include people with leg pain, which gets very confusing, right? So, you have to go what are the indications for fusion? So, if the indication for fusion is to treat axial low back pain, that's a very distinct group. If the indication for fusion is to essentially treat the iatrogenic instability, which comes with a primary decompression for the leg pain, that's a very different group of patients. So, you're fusing, but you're not really fusing because they have back pain, you're fusing because you're decompressing their nerve, and you have to destabilize to decompress it, so you fuse. Note, that they are distinctly different groups and distinctly different clinical indications, and I don't know if there are a lot of RCTs in that second category frankly from osteophytic spurring or discectomy where they get fused. You may not find a lot in there. If you go to, like, the sports

study and stuff, they weren't fusing for this, and there's a lot of fusion in spinal stenosis now, people decompressing the spine and fusing. Again, very different from the primary bad disk. We're going to fuse you for your axial back pain is a very distinct group. I thought that's what the focus of this would be. So, I worry a bit about that.

Daniel Ollendorf: I have to say that...so, and we've talked to a number of clinical folks about this. So, many of them have shared your concern. I think our concern was that for some of these studies, we're going to have a mixed bag in terms of population. So, we felt if radiculopathy seemed to be the one condition that would show up in some of these mixed populations, and we were trying to think of a way that we could try to preserve as much information as possible, but...

Chris Standaert: They're in a very different patient group.

Daniel Ollendorf: Yeah, and so we've had...we've talked to a few surgeons and others who have said the same thing. We're happy to take them back out if that...

Chris Standaert: Yeah.

Daniel Ollendorf: ...would make most sense.

Chris Standaert: And the other issue is, with the nonoperative stuff. So, you...so, I had that question about nonoperative care here because of the back stuff, right? So, you look at the surgical, the...the RCTs on surgery versus nonoperative care. The nonoperative care wings vary widely by surgery. So, if you try to make a meta-analysis, you try to lump them, you really shouldn't, because there are some that are very active treatment arms. So, if you go to the Broxson-Fritzl Study, there is a very active treatment arm, or Broxson-Fairbank versus Fritzl, which is very passive. Sport is very passive and nonstructured, and you can categorize the nonoperative groups as highly structured as cognitively-based as whatever versus really nonstructured, non-whatever, I mean, you can split them.

Daniel Ollendorf: Right.

Chris Standaert: And I've seen systematic reviews where they lump them and say oh, look what happens, but you're...the nonoperative groups are really apples and oranges in these papers and they're very different, and I think, you know, frankly you do a big service to everybody calling out if there are things that are effective, it's helpful to say these, this nonoperative intervention was more effective than others or whatever. That's very helpful to call out, because it raises the bar for what people are expecting and what they may be asking. Again, if you lump them, I could see this going into some...again, a meta-analysis of some sort. The nonoperative arm is going to be very muddy, and it's going to be kind of almost worthless because they're so different.

Daniel Ollendorf: OK.

- Michael Souter: The only question I have is just about the fusion procedure itself. Are we talking...what type of fusions are we talking about? Does that include things like using the, you know, BMP etc., or are we just, you know, more of genetic proteins? Or are we simply just talking about kind of the mental work?
- Daniel Ollendorf: We're proposing to err on the side of inclusion. So, we're not going to restrict by time of fusion material, instrumentation, or we'll stratify by those sorts of characteristics of we can.
- Craig Blackmore: Yeah.
- Chris Standaert: Yeah. I mean, the studies use somewhat different techniques, and some studies will allow a range of techniques within the study, the studies I know of. You may have found some I don't know of, but yeah.
- Craig Blackmore: I guess related to that is the history of prior surgery or fusion or diskectomy, or there's a lot, I mean, it's sort of an extension of what you said, but there's a lot of these that seemed to be done a second procedure.
- Daniel Ollendorf: Right. I think we have that as initial versus repeat surgery as a stratification in key question four.
- Richard Phillips: I have a question about the comparator aspect of it. Any rationale for even considering joint replacement, or has that pretty much fallen out of...
- Chris Standaert: Total disk arthroplasty.
- Richard Phillips: Yeah.
- Chris Standaert: I mean, you guys deliberately chose not to include those papers. There are a number of papers where the, there isn't a comparative to a nonoperative arm. There's a comparative between fusion and total disk arthroplasty. The disk arthroplasty studies that came out were all designed as non-inferiority versus fusion studies, and that's how they built them all.
- Daniel Ollendorf: Yeah.
- Chris Standaert: So, a lot of studies...
- Daniel Ollendorf: That was a separate review topic.
- Chris Standaert: ...yeah, but the topic is separate, so they're...I assume you're not looking at those studies.
- Richard Phillips: Is that...is that not a... a comparator. I mean, in other words, what are your options? What are we comparing our fusion to? Nonoperative therapy?

- Chris Standaert: I assume they're comparing to nonoperative care. I think they're...it's tricky because the...the total disk arthroplasty is a whole separate decision process, and in that one, it's probably comparing fusion to nonoperative care, too, and there are only...there are a couple studies of arthroplasty to nonoperative care and there are a number of studies of arthroplasty to fusion. So, but if...if the scope of this is not to include arthroplasty, then what do we...they're going to have to think of what they do with this thing. I assume one criticism you may get is that you're not including those studies and therefore it looks, but...if this is...it looks like this is designed really to compare to nonoperative measures fusion to (inaudible).
- Daniel Ollendorf: That was the initial review of the scope, yes.
- Chris Standaert: I see the potential problem, but...
- Craig Blackmore: Right.
- Chris Standaert: ...clinically, there aren't lots of total disk arthroplasty for the lumbar spine has not really ever caught on. It's a very...
- Richard Phillips: Right, it's...
- Chris Standaert: ...it's a very dicey procedure to do. It's hard to do technically. It...it's, you know, much harder to do than a fusion. Versus cervical spine, it's much more...it's a much more...much better...different suggestion but much better rationale in the cervical spine. That's caught on more widely, clinically anyway.
- Craig Blackmore: Any other comments? Alright. Thank you, all. This time, we really are adjourned. No, we're not. Wait a minute. Timeout.
- Josh Morse: There's still an item on the agenda. One (inaudible).
- Craig Blackmore: I should look...I should look at my agenda. My apologies. We are not...we are not adjourned. Sorry.
- Josh Morse: We have...so, we've incorporated...I just want to point out, we've incorporated the draft key questions at your request from the retreat. This is an opportunity, when it arises, we...we provide this chance and when it's really successful, we have the assigned group here to receive your comments directly. The other thing we agreed to was updates on where we are with current topics. Do we have a presentation for that today, or?
- Woman: Yes, we do.
- Josh Morse: Oh, it is. OK.
- Woman: Let me look at my handouts here.

- Josh Morse: OK.
- Woman: And I also (inaudible).
- Josh Morse: These will all be fast so that you can adjourn the third time...and final time. So, we are at the end, basically, of our new cycle, which is action meetings November through May. We do have one meeting in July, which will be the phone conference like we had last summer. You can see the topics that we've sketched out into next year. It's not complete, but again, tympanostomy tubes and the lumbar fusion re-review. Those are in progress right now for November. We have just scheduled a re-review of cardiac stents and a topic called...or a device called Novocure for January followed in March by the re-review of spinal injections and the review of a new topic, extracorporeal membrane oxygenation. For next May, we currently have the one topic scheduled, which is a procedure with a device called bronchial thermoplasty, which is for asthma. There may or may not be another one scheduled for May. We're not quite through with scheduling yet. So, these were the topics. I think we presented this earlier a month or two, a couple months ago. These were the topics that were selected this year by the director for going forward. So, you can see the two re-reviews, which we prioritized earlier in the cycle, especially the cardiac stents. It hasn't been looked at in some time, and there has been quite a bit of development in the evidence there, and then the other new topics that we scheduled.
- David McCulloch: It's hardly worth our while reviewing number three. It's bound to be positive. It's new, and it's a cure. Do we really want to waste our time?
- Josh Morse: Yeah, yeah. So, we'll...good point, thank you. I'll take that off the schedule then. Problem solved. So, this was the context for tympanostomy tubes. I don't know that I need to go into this. OK. Again, there's the schedule.
- Richard Phillips: What's the rationale for the tympanostomy study? Is it utilization's too high, or?
- Josh Morse: The trigger for this...the way this got on the prioritization list prior to it being actually prioritized and selected was there was some comment about this in the literature following the Choosing Wisely topics that this was one that was not looked at that perhaps should have been. I think that put it on the...on the list. It is on a list of...it does show up on other lists around procedures to look at.
- Seth Schwartz: I can speak to that, as well.
- Josh Morse: And there is some variation, I think, we've seen in our data but, yeah.
- Seth Schwartz: So, the concept is it is the second most commonly procedure performed in children, nationally secondary to circumcision. So, there's a lot of questions given the volume of patients that get it, why, you know? Is it...is it properly indicated, and so actually the, our academy just put out a guideline on this

thing, did a big review, and ARC actually has done a report...a review of this, as well. So, I think, primarily the data comes around the...the early use of tubes, so in children who have an effusion that's present for a shorter...for a really short duration, there's a thought...there's been a concept that nationally there probably is overuse in that setting. So, that's really where it comes down to. Not that they're inappropriate in general, but that there's probably overuse in certain settings. So, there's actually pretty good data out there right now, as well as new guidelines that clarify what the appropriate use is of that...that intervention. Who's our expert, do you know?

Josh Morse: We don't have an expert identified, yet. You did give me a couple names at the last. I'll talk to our vendor and see if we've got that squared away. So, the other is the one you just considered, you just looked at the key questions on, and this is an update of the lumbar fusion topic. Again, public meeting scheduled for November. We should have a draft report towards the end of summer when everybody wants to read a big report. Cardiac stents, this is another re-review. Again, scheduled for January, draft report targeted for October.

Richard Phillips: As you go through this list, how many new people are going to be...or how many of us are going to be gone at each level for each of these reviews?

Josh Morse: So, let's save that so that we can add that to the agenda. I'll comment on that...how about we get to that after I go through this. So, Novocure, the new cure, this is scheduled also for January. This is a treatment, right now, that's, I think, only approved for glioblastoma, but there are other studies underway. So, this would be the same schedule cycle, as the cardiac stents draft report in the October timeframe. So, we'll probably...we'll have key questions in the...near July, it looks like, if we are able to stay on schedule. So, that is something we could receive comment on in the phone call meeting in July. Spinal injections, this is some new literature on this topic scheduled for next March, and then the ECMO topic, another new topic scheduled again for next March. Then the asthma bronchial thermoplasty topic scheduled for next May. So, that's the plan for next year. So, to your question about...so we have two committee members who will be reaching the limit of their terms in the next...over the course of the next six months. By the end of the year, at least two will turn over. Marie-Annette is retiring. I don't know if you want to make a comment about that, but...

Marie Brown: Well, re-retiring.

Josh Morse: OK. So, her last meeting is currently scheduled for July. So, that would be the most...the first new appointment.

Richard Phillips: OK.

Josh Morse: So, three likely by the end of the year.

Richard Phillips: And then the...the bulk...the bulk of us...everybody that is going to be replaced will be done by after the January 15<sup>th</sup> meeting, is that correct?

Josh Morse: No. That's not...no. It'll actually be prior to the January meeting.

Richard Phillips: Oh. Prior to the January meeting.

Josh Morse: Correct.

Richard Phillips: OK.

Josh Morse: Yeah. Yeah.

Craig Blackmore: I'm waiting for permission. We are adjourned. Thank you.

Josh Morse: Thanks a lot.