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Craig Blackmore: Good morning, everyone. We're going to call the meeting to order here and ask the committee members to grab their coffee and take their seats. So, this is the meeting of the Health Technology Clinical Committee, and the meeting's now in session. First item on the agenda is a meeting overview.

Josh Morse: Good morning. I'm Josh Morse. I am the program director for the Health Technology Assessment Program. I'm going to give a brief presentation with some updates from the program and how the program works.

Today's topics are upper endoscopy for gastroesophageal reflux disease and upper GI symptoms. That will be this morning. In the afternoon, we'll have robotic-assisted surgery. A bit of background on the program, Margaret... Margaret, can you advance the slides?

The HTA program was created in 2006 through legislation to use in evidence report, this clinical committee to make coverage decisions for the state agencies that purchase health care. These decisions are based on the safety, effectiveness, and cost-effectiveness based on the scientific evidence.

The HTA program is housed within the Health Care Authority, an agency of the State of Washington. Multiple agencies participate in this program, including the Health Care Authority, Department of Labor and Industries, and the Department of Corrections. The agency's implement are mandated to implement the decisions from this program.

The primary purpose of the program is to ensure that the medical treatments and devices paid for with state health care dollars are safe and proven to work. The program provides a resource to the agencies that purchase health care. We develop scientific evidence reports on medical devices, procedures, and tests, and we facilitate this independent clinical committee to determine

which medical devices, procedures, and tests meet the test of safety, effectiveness, and cost effectiveness.

Health care technologies are considered a primary driver of cost in health care. Up to half or more of real long-term spending growth may be attributable to new technologies.

The primary objective of the program is to achieve better health for Washington patients provided through providers having access to a centralized place to learn about proven health care services. We strive for transparency and to minimize bias. We seek consistency among the state agency purchasing policies, and we are evolving and flexible.

Annually, the director of the Health Care Authority selects new technologies for review. We then seek technology assessment reports from evidence vendors. We bring these reports to the committee in open public meetings. Following the final determination of these decisions, the agencies implement the decision.

The clinical committee decision must give the greatest weight to the most valid and reliable evidence. Objective factors for evidence consideration include the nature and the source of the evidence, empirical characteristics of the studies and the trials upon which the evidence is based, and the consistency of the outcomes within comparable studies.

Additional evaluation factors include how recent the information is, how relevant it is to Washington's populations, and the bias that may be present in the studies.

Selected technologies from the past year's selection are shown here. I have some brief updates on program improvements. Recently, the program was engaged in a quality to review. This was a two-part review that included a comparison to other HTA programs across the world, as well as outreach to our stakeholders to assess how well the program is meeting its mandates. The review included a three-part assessment beginning with the stakeholder review, including a three-part assessment beginning with an online survey followed by key informant interviews and facilitated discussions. This project was

completed in January, and we published the report on our program web pages. It's available at the web address shown on the screen.

More on this project, we have the recommendations here and the slides. The overall findings found that the program processes and products are consistent with the components of other well-established national and international programs. The purpose and the mandate of the program were supported by our stakeholders. They're understood in their support for this independent decision-making body. The program's processes are transparent, but we have found they're not well understood, particularly by stakeholders who are not closely involved with the program. Some key changes we've made, since learning these things from the stakeholder engagement project, we've expanded one of our comment periods from two weeks to four weeks for the draft reports. This will begin implementation in July, and we are now publishing all comments and disposition of comments from key questions. We will be making further changes. We have a work plan, which will be posting online to our stakeholder engagement webpage. Thank you.

Craig Blackmore: Thank you, Josh. So, a couple of other procedural issues. I'm Craig Blackmore, the chair of the committee. The committee meeting is being recorded and transcribed, and so we ask that whoever is speaking please identify themselves into the microphone so that we can understand that when the transcripts are being compiled. This is a public meeting. We welcome people from providers, members of the public, individuals who are affected by our decisions. There is an opportunity for public comments on the work that we're reviewing, and we'll make it clear when that is. If there's anybody here who wishes to make comments, there is a sign-up sheet outside and we would ask you to add your name and information and then when that time arises, we will bring you up and give you the opportunity to speak.

First item of business on the agenda is previous business from our previous meeting. That has two components. First is approval of the meeting minutes from before, and then the second would be the actual finalization of the decisions that we made in the previous meeting. So, I will ask the committee for... well, first of all, the minutes are available in the packet to the committee.

They have been distributed to committee members in advance of the meeting and we've all had the opportunity to review those. So, I will invite a motion to approve the minutes or comments if there are any concerns raised by the members of the committee.

Marie Brown: Motion to approve the minutes.

Craig Blackmore: Do we have a second?

Man: Second.

Craig Blackmore: We'll vote. All in favor of approval of the minutes, please raise your hands. Minutes are approved. Second item is approval of our previous decisions... excuse me, of the decisions we made at the March 16 meeting. The first of those is on sleep apnea diagnosis and treatment. We received public comments. Those have been distributed to the committee members and are available within your packet. I'll invite the committee members at this time, if they have any comments or not on the public comments that we've received, and then I would also welcome a motion to approve the draft decisions and findings document that is before you in the packet.

Man: I move to approve.

Man: Second.

Craig Blackmore: All in favor of final approval of the sleep apnea diagnosis and treatment draft findings and decisions, please raise your hand. Any opposed? And abstention presumably, as you weren't present.

Woman: Right.

Craig Blackmore: Very good. Did you get that?

Josh Morse: Was that 7 approved?

Craig Blackmore: 7 approved, 2 abstained. We missed the count on that. So, in favor of approval of the findings and decisions document?

Josh Morse: 7 approved.

Craig Blackmore: And opposed? And abstentions raise your hand so I know you're abstaining.

Josh Morse: 3 abstaining.

Craig Blackmore: 3 abstentions. Okay. Next is the draft findings and decisions around bone morphogenic protein for use in lumbar fusion, and again, this has been distributed for public comments, and we have received comments and those comments have been distributed to the committee members in advance of the meeting for their information. It's before the committee members in the packet. Any comments on the comments?

I guess I would say there's just one point of clarity that came up in some of the comments. We used the... there was a question as to whether our intent was to cover L5-S1 or if our intent was to cover larger... to allow for coverage of a larger region of the spine based on the FDA approval for... for the device, for the BMP, and I think it's pretty clear from the transcript, which I've reviewed, and from our discussion that our intent was to cover primary anterior open laparoscopy fusion at one level between L4 and S1, and we used the FDA to help us come to that decision, but our decision was specific to those levels. Our decision was not to merely follow whatever the FDA had recommended. So, I... that's a comment. I think what is represented in the findings and decision is true to our intent around that.

Does anybody have any other comments or concerns? And I would entertain a motion to approve the draft findings and decisions around bone morphogenetic proteins.

Man: Move to approve.

Woman: Second.

Craig Blackmore: Okay. So, all in favor of approval, please raise your hands.

Josh Morse: 7.

Craig Blackmore: And any opposed?

Josh Morse: Zero.

Craig Blackmore: And abstentions?

Josh Morse: 2.

Craig Blackmore: Okay. Okay, that closes the previous meeting business. That gets us to the scheduled and open public comments for the first topic under discussion today. The first topic under discussion today is upper endoscopy for gastroesophageal reflux disease and upper gastrointestinal symptoms. We are ahead of the identified window for open and scheduled public comments. I'd like to do a couple things. First, I would like to introduce our clinical expert. Or, actually, I will ask our clinical expert to introduce himself, Drew. And, I guess the other point I didn't mention is you always have to speak into the microphone, because we are being recorded and finally, for members of the public, as well as Drew, I will ask you as well, please identify yourself. Tell us if you represent a group or an organization and tell us if you have financial disclosures relevant to the technology under discussion.

Drew Schembre: Drew Schembre. I'm a gastroenterologist, and I'm chief of gastroenterology at Swedish Medical Center, and I'm a clinical associate professor of medicine at the University of Washington. I have an interest in esophageal cancer, precancerous lesions, gastroesophageal reflux. I think all gastroenterologists have some interest, financial and otherwise, in upper endoscopy as a topic, but I have some royalty payments from a medical device company that don't directly relate to upper endoscopy.

Craig Blackmore: Thank you. And thank you for joining us. It's an important role. Your job is to help the committee to understand the technical aspects of upper endoscopy. We're not gastroenterologists and obviously, there are technical and clinical components to this that will need your expertise to help us to understand. So, thank you for being here. So, I'd like to open the scheduled and open public comments period. Do we have...

Josh Morse: This is Josh Morse. We had no scheduled public comments.

Craig Blackmore: So, we are going to check and see if anybody has signed up. If anybody wishes to speak to the committee and hasn't signed up,

please raise your hand and we'll get you signed up. So, we have nobody requesting to address the committee. We're ahead of the usual window, so we'll ask the question again in case somebody was tracking on the agenda. Actually, we also need to check on the phone. Those of you on the phone, welcome to the Health Technology Clinical Committee meeting. This is an opportunity if there is anybody there who wishes to address the committee around the topic of gastroesophageal reflux, please let us know at this point. Not hearing anyone, we're going to proceed. The next item on the agenda is the agency utilization and outcomes.

Steve Hammond: Okay. I'm looking for the slides. In the meantime, I am Dr. Steve Hammond, chief medical officer of the Department of Corrections. Do we have a pointer or...? It doesn't seem to point, either, but I've got a pointer. Okay. I'll just ask for the slides to be advanced. So, we can go to the next slide, please.

And, the title of this talk is upper endoscopy for... I just lost it, but it's for GERD and GI symptomatology. GERD and GI symptoms are very common in the primary care setting, estimated to be at a prevalence of 10-58%, various estimations. Upper endoscopy is a moderately expensive and invasive procedure, and this topic came up for... was nominated for review by the HTA program because it was thought that a good evidence review would be helpful in developing rational utilization management procedures. Next slide please.

And again, that is why the evidence review was requested. Current policy by the state agencies, basically upper endoscopy is a covered service without restrictions by Labor and Industries Uniform Medical Plan and Washington Medicaid. As you know, when we nominate a topic, we set a level of concern initially when the topic is nominated, level of concern regarding safety, efficacy, and cost effectiveness. Safety concerns were generally low regarding this procedure, although there was some concern that overly aggressive management could expose patients to risk of harm from unnecessary diagnostic procedures and treatment. On the other hand, there was some concern about the risk of overly-conservative management and the possibility of missing important diagnoses, which could lead to worse health outcomes. As regards to effectiveness, the concern level was medium to high. There was question about the benefit of early upper

endoscopy with a report of GI symptomatology and concern about the effectiveness of repeated endoscopies. Cost concerns also were medium to high. Given the high prevalence of GERD and upper GI symptomatology, the potential for utilization is high. Our goal would be to avoid waste of health care resources, but at the same time to optimize health outcomes. Next slide.

So, looking at the agency utilization data, we found that a fairly large number of diagnoses were attached to the CPT code for upper endoscopy. We, first of all, looked at the array of diagnoses associated with this procedure code and tried to split them between those diagnoses, which seemed to be likely to be related to GERD and upper GI symptomatology and those diagnoses, which seemed unlikely to be related to these entities. For example, an upper endoscopy for the purpose of scleral therapy for esophageal varices would not be considered likely to be related to GERD or upper GI symptomatology. Endoscopy for dilatation of strictures would be another example of a diagnosis that would be thought to be less likely to be related to GERD or upper GI symptomatology. So, among those diagnoses that we thought most likely reflected GERD or upper GI symptomatology, we further wanted to look at those diagnoses, which we thought were most likely predominantly related to symptomatology and what we term here as general symptoms, as the basis of the diagnosis versus those diagnoses that seemed more likely to be based on objective findings. Again, this is, as you probably know, coding is done by practitioners, and there are no hard and fast rules for listing diagnosis codes, but we wanted to try to look at possible differences, or at least get some idea of the level of utilization more likely to be related to objective findings versus utilization more based on symptomatic report. Next slide.

So, these are the data for the PEB, which is the Uniform Medical Plan population up top. We looked at the years 2007 through 2010, and so we looked at PEB and then the Medicaid population. First, in the upper row here, is the enrollment population of the different plans, and what we found was interesting and fairly consistent that in the range of 14 to 15% of the enrolled population in both plans carried a diagnosis that was thought to be related to GERD, and then we also looked at the percentage of the population, which underwent upper endoscopy in each of these years and saw quite consistent utilization across the four

years. Again, a little bit higher in the PEB population than in the Medicaid population, although really quite a bit of similarity there also. We could only speculate on what might be the cause of the different levels of utilization that we see. We can also point out that... well, I think it's shown better on subsequent slides, the utilization trends. So, this is another... these are just patient counts, as compared to percentages of the enrolled population on the previous slide and, again, we see a slight-to-moderate rise in utilization, and this also includes the L&I data. A much smaller number of cases of upper endoscopy being done in L&I patients, which is not surprising given that GERD and upper GI symptomatology would not commonly be considered to be an occupational injury or illness. Next slide.

So, here we have the cost data, and again, over the four-year period, this time listing the three plans, we see the totals are in the range of about 14 million overall for the four-year period. So, it's significant expenditure for upper endoscopy. We see the patient counts. Also, I would focus your attention on the average cost per procedure, particularly this row where PEB is considered to be the primary payer, probably more accurately reflects the total cost of this procedure, and it is striking that the cost for the PEB plan and for L&I is significantly higher, actually more than twice as high than the amount paid for the procedure by Medicaid. Next slide.

So, this is a graphic representation of pretty much the same data, looking at patient counts for upper endoscopy for PEB over the four-year period, and the blue bar represents all upper endoscopies, and then the red one represents those that were attached to diagnoses thought to likely be related to GERD and/or upper GI symptomatology. So, a couple of points here. One is that quite consistently about half of all upper endoscopies seem to be related to the GERD/GI symptomatology diagnoses, and there is a moderate upward trend with a fairly stable total enrollment population. Next slide.

Similar data for the Medicaid population, again, an upward trend in overall utilization across the four years. This may reflect, it certainly does reflect to some degree, the rising enrollment in the last couple of years of this time period. But also, again, shows that roughly half of the upper endoscopies had associated

diagnoses that were likely to reflect GERD or upper GI symptomatology. Next slide.

So, again, same data but this time instead of case counts looking at expenditures, very similar pattern. Next slide.

And for the Medicaid population. Next slide.

So, this now looks at comparing those diagnoses that we thought were most likely to reflect objective findings, mostly on endoscopy, as opposed to diagnosis based on symptoms, and interestingly again, these break out quite evenly. So, about half of the upper endoscopies in our database, this is for PEB, were attached to diagnoses that seemed to be based on symptoms, as opposed to the other half, more likely based on objective findings. Next slide.

And a similar pattern for the Medicaid population, although perhaps maybe a little more predominance of the symptom-based diagnoses in the Medicaid population. Next slide.

So, another concern we had was the degree to which endoscopies were being repeated. We wanted to look at that, and there are a couple of interesting findings here. One is that the large majority of... in the large majority of cases only one upper endoscopy was done in the four-year period. Now, these are the PEB findings, and this is for Medicaid. For PEB, though, we see 71% had only one endoscopy during that period or alternatively 29% had repeat endoscopies, and we can see some had quite a few. Interestingly, in the Medicaid population only 3% had repeat upper endoscopies. Again, I can only speculate as to why that may be, but if one looked at it in an economic... took an economic perspective, the... well let me just say that this suggests... this discrepancy between repeat endoscopies and the two plans, suggests that there may be some discretion in repeat endoscopy utilization and one could point out that with the much lower payment rate for Medicaid, there may be less economic incentive to repeat endoscopies, but admittedly that is speculative. Next slide.

So, what are the... what guidance can we get from other payers? There's an old Medicare national coverage decision, which

actually is not dated on the CMS website. It just says that... where does it say? That it's a longstanding decision and the effective date is not posted. But, we think this comes from the era in which NCDs were not explicitly evidence based, and the coverage policy is that it's covered when reasonable and necessary for the individual patient. Aetna is a little bit more specific about what they cover upper endoscopy for. They're the usual types of indications that are discussed in the evidence report, and Blue Cross/Blue Shield has no restrictions on coverage of upper endoscopy. Next slide.

So, what might be the benefits of upper endoscopy? It does give an objective evaluation of a condition that is typically diagnosed initially on the basis of reported symptoms, and upper endoscopy allows the possibility of early detection of serious pathologic conditions in which outcomes could be improved by earlier diagnosis. What is the risk? Again, if it's being done unnecessarily, there's a risk of waste of health care resources with little benefit. So, this is sort of a summary. I have what the agency saw as the main points of the evidence report that early endoscopy for general symptomatology compared to a trial of treatment does not appear to improve outcomes. There are certain factors, such as alarm symptoms, such as anemia, unintentional weight loss, intractable vomiting, dysphagia, etc. or advanced age, which while not strongly predictive of more serious pathology could be a reasonable indication for upper endoscopy. In the absence of objective findings on prior endoscopy, there's little evidence to support repeat endoscopies and given that we don't have really good data on how risky it is to forgo endoscopy in the presence of advanced age or alarm symptoms, I will just say that there is uncertainty about how risky that is or how beneficial it is to do endoscopy in those cases. Next slide.

So, summary of the agency views: GERD and related upper GI symptoms are very common. The benefit of early endoscopy for symptomatology alone in the absence of alarm symptoms or advanced age is not evident. Repeat endoscopy in the absence of objective findings is not supported. Endoscopy in the presence of advanced age or alarm symptoms may be prudent in the absence of strong evidence that it's safe not to do endoscopy in those situations. Next slide.

So, our recommendation is that upper endoscopy, again for GERD and upper GI symptomatology be covered with conditions, those being failure of a trial of treatment to improve or resolve symptoms or presence of alarm symptoms or advanced age greater than 55 seems reasonable based on the literature, or objective findings of serious upper GI pathology, such as ulceration, stricture, and dysplasia. Next slide.

I think that's the end. Yep, thank you. Questions?

Joann Elmore: This is Joann Elmore. Two questions for you. The first has to do with the data that might potentially be available to share with our committee. You summarized the utilization and the cost and then you present your thoughts on recommendations, and some of the recommendations are coverage with conditions that relate to both age of the patient and prior treatment with PPIs, and the question for you is, can you show us the data already stratified by age so that we can see what number of EGDs are being done in patients less than 55 years of age? Secondly, can you show us data on patients that might be linked with pharmacy data to see how many of these patients getting EGDs were treated with PPIs or some sort of, you know, in other words, had received medical management for the three-month window before the EGD?

Steve Hammond: Okay. And I'm going to ask Margaret to help me with this, because the data we presented were what we culled out, as what we thought really were the most meaningful for this question. But, as I recall, the age distribution of upper endoscopies was spread... well, it was spread through from really childhood to... I think we only looked at 18 and over if I'm remembering correctly. Is that right, Margaret?

Margaret Dennis: No. This is Margaret. We have all of the data stratified by age in the report, and...

Craig Blackmore: So, can you help the committee find that in the report? Somebody...

Margaret Dennis: It's on the fourth page of agency data, which starts on page 14. So, it's on page 17 as the PEB age breakdown and on page 18 as the Medicaid age breakdown.

- Craig Blackmore: Thank you.
- Steve Hammond: So, I don't have that to look at right now, but, as I recall, the frequency of upper endoscopy was... as I recall, it peaked somewhere in middle age, 40s-50s-60s, but I...
- Joann Elmore: Right. The predominant usage is in 50 to 64-year-olds for PEB with... I'm trying to get a percentage just in my head here. It looks like it's maybe 20% usage; 20-25% above 65? And then Medicaid is similar.
- Steve Hammond: And then I think we did not attempt to look at medication usage in our data pool, and Margaret's shaking her head. Do you want to explain any further?
- Margaret Dennis: Uh, this is Margaret. We did not try to look at drug usage. It's very difficult to look at in our data.
- Steve Hammond: Okay. Thank you.
- Craig Blackmore: I guess I might add another question, and that is do you have data on the prevalence of gastric or esophageal cancer in this same population?
- Steve Hammond: You know, I was looking around for the long list of diagnoses that were associated with upper endoscopies, and I don't know if that's in the report, but...
- Margaret Dennis: It's not. It's not in the report.
- Steve Hammond: Okay. As I recall, it was a fairly low percentage of the upper endoscopies, but I believe that there were some cancer diagnoses associated, but I... Margaret, can you help me with that?
- Margaret Dennis: Yeah. We restricted the data that we presented to GERD diagnoses and did not include cancer diagnoses.
- Steve Hammond: So, they were not presented, but we saw some didn't we, associated with upper endoscopy?
- Margaret Dennis: I think early on we may have pulled all upper endoscopies and looked at all the data, but I don't recall the percentage of cancers.

- Man: Somebody would have had to code them both with GERD and cancer for you to figure out that they were cancer or identified on a scope for GERD, though. So, if somebody scopes them and they find a cancer, or found a Barrett's or found a whatever, they might not code GERD. They might code... I would assume.
- Craig Blackmore: But even knowing...
- Man: The prevalence of cancer.
- Craig Blackmore: You know, these are not common cancers.
- Man: No.
- Craig Blackmore: And just understanding would be another piece of information.
- Steve Hammond: I can remind the committee that about half of the upper endoscopies were associated with diagnoses thought likely to reflect GERD or upper GI symptomatology. So, those that were simply diagnosed as being for cancer would have been in the other half.
- Craig Blackmore: Other questions?
- Michelle Simon: Yeah. I have a question. This is Michelle Simon. It seems from the data that you suggest perhaps there's an increasing utilization of endoscopy for GERD. Am I correct in that?
- Steve Hammond: There seemed to be a sort of a slight upward trend that I think was beyond the upward... upward trend and utilization beyond the enrollment. I'd say it's not a steep rising trend, but at least that's what I saw looking at it. I think it's statistically significant, but maybe Margaret wants to comment on that also.
- Margaret Dennis: This is Margaret. It looked to me like most of the rise was due to the population rise, but there did seem to be...
- Michelle Simon: That's what I thought.
- Margaret Dennis: ...a trend to more usage in the less objective symptoms.

- Michelle Simon: Okay. Thank you.
- Joann Elmore: So back to my question. This is Joann Elmore. So, according to figure 3B, approximately half of the patients currently getting EGD are above the age of 55, and that's a rough estimate, because the...
- Craig Blackmore: No. It's more than that.
- Joann Elmore: It's more than that?
- Craig Blackmore: It's two-thirds.
- Steve Hammond: It's about 80.
- Craig Blackmore: If you count the Medicaid and the PEB, it's about...
- Joann Elmore: And that's important because that shows what percentage we're talking about if we're interested in their binary cut point of 55. And then the second question is related to the prior use of treatment. Do we have any data on the percentage of patients getting these EGDs that had prior medical management failures?
- Steve Hammond: I don't think we do, because we were not able to pull the pharmacy utilization data and correlate with... that's... my understanding is that's technically a pretty formidable task, and I see Margaret nodding affirmatively. She's the one that does our data pulls.
- Man: PPIs can be over-the-counter, too. So, you never... you wouldn't be able to track it even if you had the pharmacy data.
- Craig Blackmore: Any other questions for Dr. Hammond? Thank you. So, we are... this is Craig Blackmore again. We are now within the predetermined time for the scheduled and open public comments, so I'm just gonna allow another opportunity in case somebody had come in expecting to speak in that time interval. So, just one last time, is there anybody who had wished or intended to address the committee from the public?
- Christine is going to check the phone for me one more time if we could, please. Actually, I think it is still un-muted. We didn't re-

mute it did we? This is not the official transcript. This is the backup. So, I'm gonna ask the question. Is there anybody on the phone who has joined the meeting who wishes to speak to the committee at this time? If so, please let us know. Okay, we're going to mute the phone so we are not disturbed, and we are going to move on. The next item on the agenda is the vendor report, and who do we have for that? Can you introduce yourself and you can stay there at your seat or...?

Robyn Liu:

Thank you. Good morning. My name is Dr. Robyn Liu. I am a clinical evidence specialist at the center for evidence-based policy at Oregon Health Science University in Portland. I would like to also introduce my colleagues, Heidi Krizh and Kendra Bunker sitting next to me here at the table who will be assisting me with answering questions that you may have about the evidence report, and I'll begin when we have the slides loaded. Wonderful.

So, we were asked by the HTA Committee to investigate the evidence of upper endoscopy for GERD and upper GI symptoms. Just an overview of the order of my presentation. I will give a quick clinical background, discuss the methods that we used in our evidence review. I will then go through all of the key questions that you all addressed to us, our findings, a review of existent specialty society guidelines, review of existing coverage policies, and then finally a summary.

So, clinically there is sometimes a distinction made between dyspepsia and gastroesophageal reflux disease. The categories can be a little fuzzy, but in general, dyspepsia encompasses epigastric pain or burning, postprandial meaning after eating fullness and/or early satiety, meaning getting full after just eating a little bit, nausea, vomiting, upper abdominal bloating, heartburn, or regurgitation of acid. And then gastroesophageal reflux disease, or GERD as I will refer to it, is a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications, and this is a definition from the Montreal Consensus Panel in, I believe, 2005.

This is a photograph demonstrating the process of upper endoscopy. You see the patient lying on their left side, the endoscopist advancing the camera through a bite guard in the mouth while there is a surgical assistant and a nurse standing by.

EGD, esophagogastroduodenoscopy, or upper GI endoscopy, is used to distinguish GERD and dyspepsia from more serious pathology, which could encompass adenoma carcinoma of the esophagus, Barrett's esophagus, and other findings. There are other diagnostic tools to help make these distinctions, which would include possibly symptom questionnaires, computer modeling, empiric trials of therapy, such as a proton pump inhibitor, or esophageal pH monitoring.

I'm not sure how to make this little box go away on the screen. Can you click the X maybe? This is your PICO that you gave to us for this question. Population being adults with an initial presenting complaint of upper gastrointestinal symptoms and/or GERD. Sorry about that. So, the intervention then being, of course, upper gastrointestinal endoscopy. The comparator being medical management without endoscopy in some form or fashion, which could include any of those other diagnostic tools that I listed, and then the outcome being clinical symptom resolution, health care utilization, and development of serious pathology and quality of life indicators. These were... we were asked to look at all of these outcomes. Thank you. I think we got the slides figured out now. Yes we are. Mm-hm. Thank you.

Okay. So, given this PICO, you then posed to us five key questions, number one being what is the evidence of effectiveness for early treatment strategies that include upper endoscopy compared with empiric medical management? Number two, are there clinical signs and symptoms that are useful to identify patients for whom early endoscopy is effective to improve health outcomes and/or disease management? Question number three, for what diagnoses and within what timeframes is repeat endoscopy indicated versus other tests or no follow-up tests for surveillance of disease progression and/or treatment response? Does repeat endoscopy change treatment and outcome? Number four, what are the potential harms of performing upper endoscopy and the diagnostic or treatment plan and workup of adults with upper GI symptoms and what is the incidents of these harms? You asked us to include consideration of progression of treatment in unnecessary or inappropriate ways. And finally, I'm sorry, there are six questions. Key question five, what is the evidence that upper endoscopy has differential efficacy or safety issues in subpopulations, including

consideration of gender, age, psychological or psychosocial comorbidities, other patient characteristics or evidence-based patient selection criteria, especially comorbidities of diabetes, high BMI, and chronic congestion of alcohol, provider typesetting or other provider characteristics and payer or beneficiary type including worker's comp, Medicaid, or state employees. Finally, the last question is what is the evidence of cost and cost effectiveness of endoscopy compared to other treatment strategies when used in the diagnostic or treatment planning workups of adults with upper GI symptoms?

So, those were the key questions we were tasked to answer. I'll go over the methods that we used in our evidence review. Our search strategy starts with systematic reviews and technology assessments identified using a best evidence systematic review methodology. We keyed in on the most recent and comprehensive high-quality SRTA identified and then updated that systematic review or technology assessment by a Medline literature search for individual studies. If the systematic review or TA could not be identified, a 10-year search for individual studies was completed. A five-year search for guidelines was used using our center for evidence-based policy core sources and then we did a policy scan identifying relevant policies for CMS, Aetna, Blue Cross Blue Shield, and Group Health.

For key question number six, which has to do with cost and cost effectiveness, we identified all relevant economic evaluations, cost effectiveness analyses and economic simulation models and included those. The exclusion criteria that we used to narrow our scope after all of these studies were identified, we excluded long-term treatment of GERD, because your PICO specifically mentions first presentation. We excluded confirmed Barrett's esophagus diagnosis for the same reason. We excluded wireless capsule endoscopy papers because, again, the intervention in your PICO is specifically EGD. We excluded studies of patients with prior GI and antireflux surgeries, again specifically because you asked for initial presenting complaint. And then we excluded studies... we made the decision to exclude studies of exclusively Asian populations and that is because there is about a seven times... a seven-fold increase in prevalence of gastric cancer in Asia as compared to the U.S., and we felt that these studies would skew

results in a way that was not relevant to your Washington population.

Once the relevant studies were then identified, we assessed the methodological quality of the studies with instruments that we adapted at the center. Based on those used by [inaudible] in the UK, studies were rated as good, fair or poor. So, just to be very explicit, when we're talking about quality of evidence and strength of evidence, it's slightly different. Quality refers to the risk of bias in the individual studies or systematic review. So, how well was the methodology of the study itself and how well did they minimize the risk of bias, and that gives you a good, fair, or poor quality. Same thing for the guidelines. And then when we talk about strength of evidence, we are referring to how likely is this to represent reality and how likely is it that further evidence is going to change our conclusions, and that would be high, moderate, or low strength of evidence. So, I just want to be very explicit about that in our methods.

We also have an instrument for methodological quality of guidelines and rated those as good, fair or poor, and we have a separate instrument for economic studies adapted from the BMJ checklist and a nice economic evaluation checklist. Also rated those as good, fair, or poor, and then used the modified grade system for overall strength of evidence and, as I said, we rated high, moderate, low and very low for each key question and outcome. So, I just want to make sure everyone's clear on the difference between quality of the study and the strength of evidence, because one is good, fair, poor and one is high, moderate, low, and sometimes that could be confusing.

So, overall, we reviewed about 1,400 citations, identified through our Medline searches and core source searches. The vast majority of these studies, both included and excluded, were retrospective observational cohort studies. The same thing happened to me, it's okay. And so being in a retrospective observational cohort necessarily downgrades the strength of evidence because it's not a randomized clinical trial. Out of those 1,400 citations, we identified 3 systematic reviews and 7 individual articles, as well as 4 relevant specialty guidelines.

Okay, so I'm ready to jump into the findings of the evidence now. For key question number one, which has to do with what is the effectiveness... evidence for effectiveness of EGD? We found a good quality systematic review, which included a meta-analysis of proton pump inhibitor empiric trial versus early endoscopy, and there was found to be no difference in a symptomatic cure at 12 months. The same systematic review also incorporated a meta-analysis of early endoscopy versus test and treat for *H. pylori*, and this is a strategy where a patient presenting with upper GI complaints will be tested for the presence of helicobacter pylori and then if they're positive be offered some kind of eradication therapy prior to undergoing endoscopy to see if eliminating the bacteria will, in fact, relieve their symptoms.

When they did the meta-analysis with trial level data, they found no difference in effect, but there was a high degree of statistical heterogeneity. When they obtained individual patient data from the authors of those five RCTs and did the analysis there, they did uncover a small statistically significant benefit to early endoscopy for symptomatic relief with a relative risk of 0.95, confidence interval 0.92-0.99. So, statistically significant but very small benefit to doing an early endoscopy versus test injury.

Continuing with key question one, going into the individual studies that update the systematic review, there was a fair quality cohort study, which looked at six different tests that are available to diagnose gastroesophageal reflux disease. I don't have the individual tests listed on the slide, but they were basically looking for what test is the most sensitive for diagnosing GERD and found that 24-hour pH monitoring by itself, as an individual test, is the most sensitive for making the diagnosis. However, that's rather invasive and costly. They also found that putting some tests in sequence by doing a challenge with a proton pump inhibitor followed by endoscopy followed by histology from a biopsy gave you a 100% sensitivity for the diagnosis of GERD. So, this study is not looking at symptomatic relief but is looking specifically at diagnosis.

Overall, the evidence indicates that endoscopy is not superior to noninvasive strategies, for the diagnosis and management of upper GI symptoms, and we've rated this as a high strength of evidence based on a good quality systematic review.

Key question number two asks us to identify signs and symptoms, which may indicate candidates for early upper endoscopy versus empiric medical management. There was a good quality systematic review including 17 cohort studies. Those studies were individually rated as fair to good quality. This systematic review basically discovered that alarm symptoms, clinical opinion, and computer modeling programs are all actually poor predictors of malignancy. There's really not a very good way to tell which patients are going to have malignant findings and which patients are not. However, they don't really have a good substitute for using alarm symptoms, and the authors do not suggest throwing this out entirely as criteria for making clinical decisions about endoscopy. They do suggest that an age cutoff of 55 is the most logical alternative strategy given that malignant findings in Americans under the age of 55 are extremely rare.

As an update to that systematic review, we identified some other cohort studies that I'll run through now. There was a good quality prospective cohort study of about 4,000 patients, which aimed to better delineate those age cutoffs that were found in the systematic review by gender and so they actually felt that for males the age cutoff could be decreased to 35 and for females the age cutoff could actually be increased a little bit to 57 years old. These authors noted that about a little under 70% of cancer patients will have an alarm symptom. So, just over 30% of cancer patients will not have an alarm symptom, and that if you look at patients without alarm symptoms, close to 1% of those will have a malignant finding on their endoscopy. So, again, the alarm symptoms are not, by any means, a perfect strategy for identifying EGD candidates.

Again, going through a couple more prospective cohort studies that were not included in that systematic review but met our inclusion criteria, one study from Rossi in 2002 looked at the pretest probability of the American Society for Gastrointestinal Endoscopy, the ASGE guidelines. So, if you take these guidelines and apply them to a population of patients, what is the pretest probability of ending up with a relevant endoscopic diagnosis, which would include malignancy, Barrett's esophagus, or erosions? They found if those criteria in the guidelines were present, the pretest probability of endoscopy was 47%. If those

guideline criteria were absent, then your endoscopy would yield a relevant finding 29% of the time. And so this indicates there is some benefit to using those guideline criteria, which basically aligns with the alarm symptoms.

The fair quality prospective cohort done by Bauer in 2005, the main finding there was that 15% of patients with cancer had no alarm symptoms at all. And I apologize, as I did not... I should have at the beginning of this key question introduced what alarm symptoms are. I think you know, but, unexplained weight loss, a mass in the abdomen, gastrointestinal bleeding, things that would indicate to you that something ominous is happening to the patient.

Final fair quality prospective cohort study from 2006 found that Barrett's esophagus, which is looking for risk factors basically, Barrett's esophagus is most likely in males greater than age 50 with reflux predominant symptoms, as opposed to heartburn predominant or bloating predominant, and symptoms of greater than five years in duration. So, we rated the strength of evidence for this key question moderate overall, as far as identifying candidates for endoscopy.

Key question three asked us to look at indications for repeat endoscopy. We found exactly one good quality prospective cohort study of 300 patients, which looked at patients who had an initial presenting complaint of dyspepsia with an index endoscopy and then these patients were interviewed nine years later. One-third of the patients in the study had had a repeat endoscopy within the nine years. The study did not identify what the findings on that second endoscopy were, but when they interviewed the patients, they asked them about their symptomatology and those who had a repeat endoscopy and those who had not had a repeat endoscopy within the nine years following their index procedure, had no difference in symptoms. So, the repeat endoscopy made no difference in their symptomatic outcome if they had benign findings on the first study. This is a low strength of evidence, because it's based on just one cohort study of 300 patients.

Key question number four asked us to look at harms of endoscopy. The systematic review meta-analyses and economic evaluations that we evaluated in our search by and large failed to

report any harms. The only piece of evidence we could find in the literature in our search was from one good quality economic evaluation, which I'll discuss later under key question six, but in their economic modeling they used a 0.02% incidents of severe harms and modeled the cost of that harm incidents on a surgical repair of a gastrointestinal perforation. I don't know where the 0.02% number came from. I looked very hard, and we actually went back and did a second Medline search on endoscopy and harms to try to identify more evidence on this key question and we couldn't find any that was relevant. So, again, this is a low strength of evidence.

So, key question five, then, asked us to look at differential efficacy or safety in subpopulations that you listed for us. We were able to find evidence on some of those subpopulations. There was a good quality systematic review in 2005, which used an individual patient data meta-analysis of five randomized controlled trials looking at age, gender, dominant presenting symptom, and status of H. pylori infection or carrier status. There was a small but statistically significant benefit of endoscopy for symptom relief in patients who were over 50 years of age. There were no other associations with any of those subpopulation breakdowns.

A good quality cohort study from the same year found that on average patients with malignancy are 20 years older than patients without malignancy. A fair quality cohort study from the same year also found that prevalence of malignancy rises with age. There was an economic evaluation model from 2008, which looked at the efficacy of various interventions for upper GI symptoms, and I just note for this key question the relevant finding is that the relative effectiveness of the different interventions, in other words, the listing order of them, is the same in 30 year olds as it is in 60 year olds. There was a poor quality retrospective chart review done actually through the VA system in 2004 trying to correlate significant endoscopic findings with age, gender, race, and NSAID use and found no correlation between any of the findings or any of those subpopulations. So, we rated strength of evidence moderate for age, because there does seem to be an association of differential effectiveness for older-age categories versus younger, but for all others was rated very low.

Finally, key question six asked us to look at cost and cost effectiveness of endoscopy for GERD. I will show you a graph in a couple of slides, but H. pylori test and treat was favored by seven out of the ten economic evaluation studies as being the most cost effective and five of those seven were good quality. So, that gives you an indication that most of the economic evaluation models favored test and treat as the most cost effective strategy. There was one good quality economic evaluation, which looked at 30-year-olds... hypothetical population of 30-year-olds and a hypothetical population of 60-year-olds in the U.S. Incidentally, this is the only economic evaluation done in the U.S. All others were done in a different country, but this one favored empiric proton pump inhibitor over test and treat or endoscopy for 30-year-olds, but for 60-year-olds found that test and treat would be the more cost-effective strategy.

There was a very good quality economic evaluation of data from several studies in Canada that found no one strategy was clearly cost effective but a protocol, which I'll explain in a moment called Candys was the most cost effective at a clinically relevant willingness to pay threshold of \$30,000 to \$70,000 per quality adjusted life year. The Candys protocol for Canadian dyspepsia incorporates empiric PPI for patients who present with predominant heartburn or reflux. If their predominant symptom is not heartburn or reflux, then they get a test and treat strategy. If they test negative, they get the PPI. If they test positive, they get the eradication. So, that's what that protocol, the Candys protocol, that they used in this study. It's kind of a melding of empiric treatment with test and treat. So, moderate strength of evidence that test and treat is the most cost effective strategy.

Just to further explain what I mean by most cost effective strategy at a willingness to pay threshold. This graph puts on the X-axis the amount of Canadian dollars that we are willing to pay for a quality adjusted life year. Then on the Y-axis, the proportion of the population which will have a cost-effective intervention at that threshold. So, you see the peak in the middle, the one that is highest in the center of the graph, which becomes dominant at about \$30,000 Canadian to about \$70,000 Canadian is the Candys omeprazole arm of the study. So, that's what I mean when I say it's the most cost effective at this particular threshold of willingness to pay for a quality adjusted life year.

This is the graph I was mentioning before. I just wanted to... I know the text is very small, and I don't expect you to read it, but just wanted to actually demonstrate the quality of the studies versus what they found to be the most cost effective intervention, and that test and treat really did have the most good quality studies behind it as a cost effective intervention, that the studies that favored empiric PPI tended to be of poorer quality, except for that one U.S. study I mentioned where in 30-year-olds empiric PPI was the most cost effective, and notice that there is no column for endoscopy. It was never the most cost effective option in any of the studies that we found.

So, those were our findings for the evidence. Moving on to just a quick summary of relevant guidelines. These were quality rated by us, as well. The American Gastrointestinal Association in 2008 has a good quality guideline recommending endoscopy for GERD that's unresponsive to treatment and recommends against routine endoscopy for surveillance.

The American Society for Gastrointestinal Endoscopy has three guidelines that you see listed there, two of fair quality and one of poor quality. They recommend endoscopy for screening for Barrett's esophagus or recurrent reflux after surgery and suspected extra esophageal manifestations of GERD. They also recommend endoscopy for patients 45 to 55 years of age with new onset dyspepsia and alarm symptoms, or endoscopy or PPI, basically leaving it up to the provider's discretion, for patients less than 50 years of age who are negative for H. pylori.

The final poor quality guideline is specifically related to modifications for the elderly and basically states that you should only perform endoscopy in elderly patients when the results will influence your clinical management. A quick summary of the relevant policies, as was mentioned by Dr. Hammond, there's an old, nondated national coverage decision for CMS for endoscopy, which allows coverage when reasonable and necessary for the individual patient. There are no applicable LCDs for Washington or CMS region 10.

Aetna does have a clinical policy bulletin criteria from last year, which divides indications for endoscopy and to diagnostic high-

risk screening or surveillance. Diagnostic, as you can see there, is similar to others failed therapy, presence of alarm symptoms, dysphagia specifically, or bleeding. High-risk screening considered to be a patient with greater than five years of GERD symptoms, patient with pernicious anemia, patient with cirrhosis or portal hypertension, and then they recommend surveillance for Barrett's esophagus, adenomatous polyps, or a history of caustic esophageal injury. We also looked for policies at Group Health, Regence Blue Cross/Blue Shield Washington and found no policies.

So, just to wrap up in summary, there's a high level of evidence that upper endoscopy is not more effective for symptom relief than noninvasive strategies for uncomplicated dyspepsia. There's a moderate level of evidence that endoscopy is more beneficial for symptom relief and for detection of malignancy with rise in patient age. There's a moderate level of evidence that alarm symptoms, clinical opinion, and computer-based models are poor predictors of malignancy. There's a low level of evidence that repeat endoscopy for patients with nonmalignant findings does not improve symptom outcomes. There are few data on the harms of endoscopy. There is a moderate level of evidence that H. pylori test and treat is the most cost effective strategy for symptom relief and empiric PPI may be more cost effective in younger patients. In general, the guidelines and policies that exist are rather permissive and rely heavily on clinical judgment of the provider. Any questions or comments from the committee?

Craig Blackmore: Thank you for that presentation. It's Craig Blackmore again, and we have a little procedural glitch. Apparently, we did not unmute the phone appropriately when soliciting comments from people who were on the phone who might want to address the committee, so we're going to try that again and make sure we didn't miss anyone, because this is a public meeting and we want to have people to have the opportunity to address the committee. So, is there anyone on the phone who wanted to provide public comment to the committee on GERD? If so, please identify yourselves. Okay. I think we have ensured that the public has had an opportunity, and so we'll close the public comment phase. Thank you. So, now we'll get back to where we were, which is basically an opportunity for the committee to ask questions

regarding the evidence of the Health Technology Assessment report.

Chris Standaert: I have a few questions. I'll take one and let other people ask some.

Craig Blackmore: Who are you?

Chris Standaert: Oh hi, Chris Standaert. My first question was that you excluded the studies on Asian populations, and looking at census data, over 7% of the Washington State population is Asian-American. Wouldn't that represent a relevant subgroup for us to know about?

Robyn Liu: Thanks for that question. We did look at that and perhaps Dr. Schembre can give some opinion on this. Asian-Americans tend to have cancer rates closer to Americans rather than Asian-Asians, if that makes sense. So, we felt comfortable excluding those studies based on that prevalent data.

Chris Standaert: Studies with Asians performed in Asia.

Robyn Liu: Yeah, we excluded studies of Asians living in Asia.

Chris Standaert: Do we know anything... but we don't know much about the Washington State population. That's Asians who immigrated from Asia versus Asian-Americans who descended from Asians who migrated from Asia.

Craig Blackmore: Dr. Schembre, can you tell us about what happens to the risk of cancer when you're exposed to a Western diet?

Drew Schembre: The data suggests that over certainly two or three generations, the risk of upper GI cancers migrates toward that of an American population, or North American population. I guess the other issue is, certainly in Seattle there are many first and second generation Asians. That population seems to be changing fairly rapidly.

Craig Blackmore: So, it's not a matter of if you live in Asia for a period of time and then you come the U.S. you become more U.S.-like in your risk. It's actually over generations.

- Drew Schembre: Yeah. It's one to two generations.
- Chris Standaert: And how much higher is the risk of cancer in the Asian population? She said seven times? Is that what I heard?
- Drew Schembre: Yeah, and it depends where in Asia, but in Japan early gastric cancer and esophageal cancers are several fold, five to ten times higher to the point where they do surveillance endoscopy.
- Robyn Liu: Korea also.
- Drew Schembre: China, it's unclear what's going on in China, since a lot of people haven't entered the medical arena.
- Craig Blackmore: So, questions on the technology report, itself, from the committee. I have a question about the test and treat strategy. My understanding is that we test for H. pylori, and if it's present treat it. In the absence of a positive noninvasive test for H. pylori, does that imply empiric treatment with PPIs or does that imply...- what's the consequence, the pathway under test and treat?
- Robyn Liu: Yeah, thank you. There were different approaches in some of the studies. The best quality, the Canadian data, those studies would proceed with an empiric PPI in patients who tested negative for H. pylori. Some of the studies... there was one poor quality study where if they tested negative they went straight to endoscopy at that point. So, it kind of depends, but generally by and large the best quality evidence is for empiric PPI if there is a negative test for H. pylori.
- Chris Standaert: Is there data on the duration of treatment with an empiric PPI on those studies? So, let's talk about empiric, so is it they get EGD after six weeks, after 12 weeks, after six months?
- Robyn Liu: Exactly, yes, thank you. Some of the studies use a threshold of six weeks, some use the threshold of 12 weeks. Those are the most common. Six months is a little long. I think most of them would use either between the six to 12-week range. It's not uniform.
- Richard Phillips: Yeah. I had a question regarding the patient classification, I guess. When I looked at your meta-data analyses where you have the five studies, etc. They seem to be based on symptoms that were

related to dyspepsia, whereas when we look at all of the patients that came from the state presentation, we were looking at patients who also had epigastric pain, a little bit more symptoms, which were not necessarily specific to dyspepsia, and one of the problems I'm having is that... is the data that you're presenting really the same category of people who are coming, I mean that we are seeing say come through an ER or through a gastroenterologist's office. It's not clear to me. For example, if somebody comes in with pain, intractable vomiting, I mean you might be ruling out MI, you might have intractable vomiting, gastroparesis, etc., etc., and yet when you get to the meta-analysis, it seems to me you've already weeded those patients out. Is that a fair assessment, or am I missing something?

Robyn Liu: So, if I understand your question, is the meta-analysis excluding patients who may present with more severe symptoms. Is that fair? Yeah, so the answer is yes. They generally do, and again with the PICO that we were given to patients presenting with an initial complaint of upper GI symptoms, these were the studies that we identified as relevant to that population. So, most of them do. If the patient presents with something like vomiting blood or some other alarm symptom, then those were mostly excluded from these studies and the meta-analyses.

Craig Blackmore: So, this is Craig Blackmore again. This is going to get to kind of a procedural issue and that is that our... the question before the committee is for the use of upper endoscopy in people with basically GERD or symptoms that look like GERD. So, our decision will not apply to the use of upper endoscopy for other indications, for which we have not had an evidence report. So, we're going to have to figure out how to sort of phrase that, but the only thing we can make a decision on is what we've been charged, and that's for the constellation of patients in this symptomatology that is potentially GERD, etc. Does that sort of make sense, because that...

Richard Phillips: While I agree with you totally, that's what I'm having problems with, at least from my perspective. And that comes a little bit from Steve's presentation where the category included patients who came in with pain in addition to patients who came in with dyspepsia.

Craig Blackmore: I think it would include pain and dyspepsia, but it would specifically not include people who had already been diagnosed with cancer, people who had known esophageal varices, people who had some known condition that the endoscopy was being used for. It's for those people and their initial presentation for some sort of symptomatology and I think we have some understanding what that symptomatology is. So, you use upper endoscopy, from my understanding, for a lot of different things, and we are only focused on that subgroup, which is an initial presentation for symptoms that might be related to GERD or dyspepsia, and that's what we have the evidence on. So, it's a little... we have to make sure what we're talking about is what we have... the question that we have the ability to answer.

Seth Schwartz: This is Seth Schwartz. I just had a couple questions just for a little clarification about the meta-analysis for key question one. I understand that there's a relative risk for reduction for the early endoscopy group in that patient level data. I'm just trying to understand what outcomes you looked at and how exactly that was calculated. I guess part of what I'm trying to get my head around is that upper endoscopy is not a treatment, and yet we're looking at symptom relief. So, I'm just trying to understand how that works.

Chris Standaert: I was about to ask the same question.

Robyn Liu: Actually, yeah. That's an interesting observation, because for some patients, there's perceived to be a benefit to actually receiving the procedure, that they will feel better if they get the endoscopy versus if they don't and whether that's psychological or, again, Dr. Schembre may have an opinion on this, but the studies do consider that as a therapeutic intervention and look at symptom relief in that they did find that statistically significant, but very small benefit for the patients who actually had had an endoscopy, and there's an extensive discussion, and it's the Cochran review. They give an extensive discussion of why that might be, in terms of why it might make a patient feel better to just have had an endoscopy.

Seth Schwartz: And secondarily, do you know what the raw numbers were, actually, in terms of... because presumably this was a

- dichotomous outcome, improved or not improved, or how was that analyzed?
- Robyn Liu: Can I take a second and look that up for you?
- Seth Schwartz: That's fine.
- Robyn Liu: Thank you.
- Marie Brown: This is Marie-Annette Brown. I'm assuming that then they controlled for people who after a negative endoscopy started PPIs and were willing to do that, as opposed to people who just had the endoscopy and reported fewer symptoms. So, did having just the endoscopy increase PPI use and that's how it improved symptoms, or did it... or are we talking about just symptom improvement from the procedure alone controlling for the fact they may have started on PPIs?
- Robyn Liu: It was controlling for the PPI use and the benefit was to those. So, those who had endoscopy and those who did not have endoscopy had equal likelihood of using PPIs.
- Marie Brown: Okay.
- Robyn Liu: Does that help?
- Mari Brown: Mm-hm.
- Robyn Liu: Okay. Now, the raw numbers for that meta-analysis... were you wanting numbers of patients in that meta-analysis, or...?
- Seth Schwartz: I guess that's kind of what I'm looking for. I mean, it's, you know...
- Robyn Liu: Okay. So, 1,924 patients, 946 in the endoscopy group with a mean age of 40 years, 978 in the test and treat group with a mean age of 41 years.
- Seth Schwartz: And the resolution rates in the two groups were?
- Robyn Liu: With the... let's see... they kind of... they break it down in several ways. Let's see if I can find the overall. So, they're using a

symptom questionnaire and a score. So, I'm not sure how meaningful the number is going to be to you.

Seth Schwartz: Well, that's the part I'm trying to get at.

Robyn Liu: Yeah.

Seth Schwartz: I'm trying to figure out if there's a statistically-significant difference because these are big numbers or if this is a clinically-significant difference.

Robyn Liu: Right. So, it's a small difference in symptomatology.

Seth Schwartz: For instance, are they using an outcome measure that's like a 10-point scale and it was a 0.2% difference in that?

Robyn Liu: It's 0.11% difference.

Seth Schwartz: And do we know on the outcome measure they were looking at, is there a clinically-significant difference that's indicated beforehand? For instance, a lot of outcome measures will say that a one or a two-point change on that scale is a clinically-significant difference. Do we know what that is for the outcome measure?

Robyn Liu: Mm-hm. The reason it's taking me a few minutes to look this up is because the Cochran review meta-analysis was published as a separate study, so I'm going back and forth between the two papers to figure out where the information is that you're looking for.

Seth Schwartz: That's fine.

Craig Blackmore: If I might, while we're... we'll give you a moment to do that. I'd like to ask a question of Dr. Hammond. You gave us some data on how much the state has been paying for EGD, and I wanted to get some clarity on what that mean. Does that mean how much we pay the doctor who does it? Does that include the technical fee? Does that include sedation, nursing, etc.? Or, I mean, what does that mean?

- Steve Hammond: Yeah, again, I'll give my best answer, but I think Margaret can probably augment this. As I recall, what we did was look at all costs, medical costs for the day of the procedure. Is that correct, Margaret?
- Margaret Dennis: This is Margaret. We were not able to do that because the day of procedure also seemed to include a lot of colonoscopies and mammographies. So, we were looking at the facility codes and the professional... the facility and professional charges that came in on the endoscopy code only.
- Seth Schwartz: So, that wouldn't include sedation?
- Margaret Dennis: No sedation. And we did in the report indicate that when we looked at all day of procedures we looked like we were... and evaluated against some sample patients, we were about 20% low. So then I'll ask Dr. Schembre, how often do you use sedation, administer medications, etc. when you're doing upper endoscopy?
- Drew Schembre: Drew Schembre. How often do we...?
- Craig Blackmore: I mean, is that always done?
- Drew Schembre: Virtually always.
- Craig Blackmore: Yeah, thank you. Any other questions for somebody other than the evidence vendor while the evidence vendor team has a chance to drill down?
- David McCulloch: This is David McCulloch. Question for Steve Hammond. You may or may not have this information, Steve. The most troubling thing to me in your presentation was the huge difference in likelihood of repeat endoscopy in PEB patients versus Medicaid patients, which to me suggests that if there was a financial incentive, almost 30% of the time it would get redone, and I believe the evidence suggests that it's very rarely indicated. Do you have enough data to say... can you look at clinical variation between gastroenterologists who bill the state. I mean, I...
- Steve Hammond: I think that might be possible, but we didn't attempt that.

- David McCulloch: Okay.
- Steve Hammond: Margaret, do you want to comment any further?
- Margaret Dennis: I'm not sure I heard the question.
- David McCulloch: I mean I think when looking at unnecessary procedures, or waste, I think there's an increasing trend both nationally through Jack Wennberg's Dartmouth Atlas and even within the state, it's now possible to look at regional and geographic practitioner variation and what's the likelihood if you send somebody to this cardiologist that we'll get this test? I just wonder among these, you know, 8,800 people who got at least one endoscopy, or, among those who got more than one endoscopy, if it's possible to look to see is there a particular gastroenterological group or gastroenterologist that routinely does annual or every three-month endoscopy in follow-up? Just looking at the variation in clinical pattern.
- Margaret Dennis: We do sometimes attempt to do that, but we did not with this data.
- David McCulloch: Okay.
- Seth Schwartz: This is Seth Schwartz. I've actually asked Dr. Schembre that question about what might the indications for repeated endoscopies.
- Drew Schembre: Well, there are actually very few good indications for repeat endoscopy for uncomplicated reflux. Depending on how coding and reviewing data is done, there may be cases of Barrett's esophagus, which are undergoing ablative therapies or something that would require as much as q.3 month endoscopies, but ideally those would be coded differently and would not be in that data set.
- Chris Standaert: So, I guess I'm confused about this too, because in our data from the state, they include Barrett's in here, and the objective diagnosis of 20% of the people getting a scope is Barrett's esophagitis. Another 10 or 15% are stricture, and I want to get back to the evidence vendor when she gets there because the follow-up issue is confusing me a bit, because the follow-up she

talks about is sort of symptomatic. It doesn't change symptoms, but you wouldn't do a follow-up EGD to improve symptoms, I wouldn't think. You'd be doing it because you'd want to monitor something. If somebody has Barrett's, I would assume you'd want to monitor that once in awhile. Something talked in here about surveillance and more of five years of symptoms, people would re-scope, and I don't think we have data on that. I don't think we're... repeat scope for symptoms is very different from repeat scope for some sort of pathology you need to follow, I assume, but we don't have any data on repeat pathology, and if they're counting Barrett's and other things as a reflux symptom, then we're intermingling things, and I'm not sure how much we can say about follow-up. That gets to be my problem.

Craig Blackmore: So, so can I rephrase that as a question for Dr. Hammond? The data you showed us about repeat endoscopies, does that include individuals who have strictures and Barrett's etc., or is that on individuals who are in your sort of more complicated...?

Steve Hammond: Well, it does include all those diagnoses that were thought to be possibly related to GERD and upper GI symptomatology. So, it would include those with Barrett's. We did...

Chris Standaert: It would or would not?

Steve Hammond: Would.

Chris Standaert: Would include those with Barrett's.

Steve Hammond: So, we considered breaking it down further to looking at those diagnoses that were more based on... more likely to be based on objective findings and those that looked more likely to be based strictly on symptoms, but we did not get to that level of analysis.

Chris Standaert: For Dr. Schembre, is there a role for repeat or surveillance EGD in people with objective pathology on an initial scope so they have Barrett's, they have a stricture, they have some [inaudible], they have varices, they have some things that are a legitimate reason to re-scope them?

Drew Schembre: Oh, absolutely.

- Chris Standaert: That's what I would think.
- Seth Schwartz: So, maybe we could dig into this just a little bit. Do we know what the percentage of people in the PEB group were with the Barrett's diagnosis compared to those with a Medicaid group?
- Drew Schembre: It's 22%.
- Chris Standaert: 22.9% for PEB.
- Steve Hammond: So, that would assume that you've got a good percentage, a quarter of the people with the diagnosis of Barrett's that...
- Seth Schwartz: What was it in the Medicaid?
- Chris Standaert: 12.9 for Medicaid.
- Seth Schwartz: 12.9, so that, yeah.
- Steve Hammond: So, you've got...
- Chris Standaert: Although the strictures were higher in Medicaid and strictures were lower in...
- Seth Schwartz: Although interestingly, only 3% of the people in the Medicaid group got follow-up, and yet presumably 12% of them had Barrett's diagnosis. So, that's kind of a discrepancy.
- Chris Standaert: You wonder... that's where the question of sort of, you know, it's pure supposition as to why their rates are different. I wonder the same thing economically. You wonder the same thing about access to care and follow-up and all these other things that affect the Medicaid population that they... maybe they don't come back. I don't know, maybe.
- Craig Blackmore: Or maybe they're more recently enrolled.
- Chris Standaert: Yeah.
- Craig Blackmore: You know, the other thing they have to be on the program for a period...

- Chris Standaert: Yeah, so it's I think we're speculating. I understand the comment, but I think there are probably other reasons that could account for that, which makes it tricky for us.
- Robyn Liu: This is Dr. Liu again. For the earlier question about the symptom score. So, in the meta-analysis, they were dichotomized, because the five studies that they considered in that meta-analysis used four different scales, and so basically they dichotomized those into improved versus not improved and so the relative risk being improved if you had an endoscopy versus if you didn't was... sorry, the relative risk of being not improved if you had an endoscopy was 0.95, as opposed to if you did not have endoscopy. So, statistically significant, but I would venture to say not clinically significant symptom relief in that meta-analysis. So, they... and that was the limitation of the studies that they did have to dichotomize it because of the different scales that were used.
- Chris Standaert: So, a related question on the follow-up thing, your statement about the low level of evidence that endoscopy does not improve symptom outcome, again, we don't... we're not talking about endoscopy really as a treatment. So, in those studies was there diagnostic information and not just sort of symptom outcome but on other things they might have found on repeat endoscopy of these patients or their role for surveillance in them... in that study? Or is it all just sort of on symptoms, because I guess I'm confused to why one would think that repeat endoscopy would improve symptoms in the first place. That may not be the reason for doing it.
- Robyn Liu: That study is not looking at surveillance or repeat endoscopy. That was just looking at endoscopy for an initial presenting complaint, and so, the one that looked at...
- Chris Standaert: But the one on repeat endoscopy?
- Robyn Liu: On repeat endoscopies, which was the 300 patients who underwent an initial study for symptoms and had benign findings, some of them had... about a third of those patients had a repeat endoscopy afterwards within the following nine years and the... just the methodology of the study was limited. It was a telephone survey, and they were just able to determine that the, you know, those who had a repeat endoscopy were just as likely to complain

about their tummies as those who hadn't had a repeat endoscopy. So, it's a low-quality, or it's a low strength of evidence because it's very limited.

Chris Standaert: And there's nothing about the indication for the repeat endoscopy? We don't know if they're being done for symptoms or for Barrett's or for whatever.

Robyn Liu: Yeah. We don't know that, and we don't know what the finding on the repeat endoscopy was either.

Chris Standaert: That limits it a bit, I would think.

Robyn Liu: So, it was... the study was included in our analysis because it did meet our inclusion criteria, but it doesn't give you actually that much good information.

Kevin Walsh: Kevin Walsh. I'm a little confused. The question is that we're being asked to evaluate is upper endoscopy for GERD and upper GI, upper gastrointestinal symptoms, correct?

Craig Blackmore: Yes.

Kevin Walsh: But the information that we have from the state doesn't distinguish between people who have GERD and upper GI symptoms and people who have stricture and Barrett's.

Man: Correct.

Kevin Walsh: So, the presumption that this is a problem is not really validated, is it? Because we don't know of the people who had the repeat studies, we don't know what percentage of them had Barrett's or stricture. In other words, diagnoses that would logically be restudied and what percent just had GERD.

Steve Hammond: Would you like me to comment? I agree, and this is Steve Hammond. I think it would have been of interest to do that extra level of analysis and see the frequency of repeats in those who had a diagnosis based more on objective findings than strictly based on symptoms. What we do have is the interesting discrepancy between the rate of repeat endoscopy in the PEB group and the Medicaid, which I interpreted to mean somewhat

tentatively interpreted to mean that there may be some degree of discretion in repeat endoscopy, but that is speculative.

Man: I would like to ask another question of our evidence vendor. Dr. Liu, I'm looking at your slide 17, and there's a good quality prospective cohort study by Marmo, 2005, and it states on this slide that the diagnostic yield for malignancy of endoscopy increased for males greater than 35 and females greater than 57 years old. I don't know what that means. I'm assuming they didn't have apriority hypothesis that it was going to go up at age 57. Is there a threshold for increased? I mean, did somebody just look at the data and say it kinda went up? What's that mean?

Robyn Liu: Yeah. They were looking specifically at updating the systematic review that's referenced directly above that on the slide. The Vakil systematic review where Vakil concluded that an age of 55 was a logical cutoff, and then the...

Craig Blackmore: So, what does a logical cutoff mean? I'm still sort of struggling with?

Chris Standaert: And for what it's worth, the Vakil Study was published after the Marmo Study, so it couldn't be an update.

Robyn Liu: Yeah, sorry. It's not the...

Chris Standaert: So, you're...

Robyn Liu: I apologize...

Chris Standaert: So, it couldn't have been done that way.

Robyn Liu: Yeah, that was a misstatement. So, let me get the Marmo Study right in front of me again. They did have, the authors did have some apriority assumptions about an age cutoff and let me remember where that had...

Craig Blackmore: Are they looking at a threshold risk? Is that...? I'm just trying to understand what criterion they're using.

Chris Standaert: There's some population differences, because that's sort of a weird dichotomy.

- Robyn Liu: Mm-hm.
- Chris Standaert: You know, and is there a difference in the male and female populations that they're looking at? Is there some other explanation for this other than in...?
- Joann Elmore: Right. This is Joann. This study... I'm glad you asked this question, because I would like our evidence vendor to be real critical in reviewing this study, because I believe there were only 22 patients with cancer out of the 5,000, and if this is our moderate evidence, I think the numbers are very small, and we may be putting more weight in it. In addition, the summary in your conclusion is that only the combination of age and gender together was able to predict upper GI malignancy in patients with uncomplicated dyspepsia. And so, my question is, are we being critical enough in reviewing this binary cut point of age alone? You've given us this summary of the study by Marmo, which is 22 patients, which really in their quotes of what's stated in their article, age itself is inadequate. You need age and gender. Then you also go over another study by Bowery, which had a much higher number, but in that study of the 123 patients with cancer, most of them had the alarming symptoms. Even if they found that age was maybe statistically significantly associated, of those 123 patients in the Bowery study in 2006, almost all of them had alarming symptoms. Only 19 had no alarming symptoms. So, my question for our evidence vendor is, can you please help us understand if we were to consider age alone?
- Robyn Liu: Yeah, it's definitely something to wrestle with, because... so, the Marmo study did have 5,224 patients and 22, and so they were... so you're looking at... the Marmo study is only considering patients without alarm symptoms, and so, 22 of those 5,224 had a malignancy found on endoscopy.
- Man: So, I'm sorry. You're giving me numbers that are different than what's in the slide. The slide says 4,329. I want to make sure we're talking about the same thing here. Maybe we'll take a...
- Robyn Liu: There has been an error on the slide. Oh, no I see. I apologize. Okay. So, here's where that discrepancy falls. The Marmo study ran their simulation... study twice, once on what they called a

training sample and then a split sample to try to evaluate the... to validate their predictions. So, the split sample was 4,329, and that was the outcomes reported on the slide. So, that's why those numbers are different.

Craig Blackmore: So, they did a split sample validation on a population that only had 22 cases of cancer, is that what I'm hearing?

Robyn Liu: They did...

Chris Standaert: Can I ask a question of our expert while she's doing this? It's related. So, just... I'm trying to figure out if this is just a statistical artifact, because the number of cancers are so small. So, for our expert, is there a known difference in the national history in incidents of esophageal cancer by sex... by male versus female? Are they different, or is it not? Is there any reason for us to think they're different? Is this just a fluke of a study with 20 patients?

Drew Schembre: Of the national history is similar. The incidents are significantly different for esophageal cancer with almost a 5:1 difference between male and female in adenocarcinoma of the esophagus. Gastric cancers are about the same, slightly increased male predominance. But, I'm glad you brought this up. One of the things to think... that is missed in a lot of this discussion of incidents of cancer is the incidents of premalignant conditions, Barrett's esophagus, and this is missed in a lot of these studies. Even though the incidents... and some of these studies are older, you know, over five years or more, and just like in the colon, colonoscopy is meant to look for colon cancers but also to look for premalignant polyps. In the esophagus, the equivalent is Barrett's esophagus, and in 2012 there are numerous effective treatments to actually eradicate Barrett's esophagus when it becomes precancerous high-grade dysplasia that are not accounted for and the numbers are relatively small, so it wouldn't be picked up in a lot of these populational studies, but that drives some of the investigation.

Chris Standaert: Hence, the Barrett's driving the need for it... the need or the indication for repeat EGD.

Drew Schembre: Correct. The other part of that is that in some of this coding data, the initial endoscopy would often not be coded as Barrett's until

the biopsies come back. So, you can't... even though it looks like Barrett's, you wouldn't necessarily code it as Barrett's until you had a follow-up endoscopy.

Chris Standaert: You didn't know until they diagnosed. You did the procedure and you billed, you didn't know about Barrett's because you didn't have the pathology back.

Drew Schembre: Yes.

Craig Blackmore: But if one's looking at a test and treat or an empiric PPI treatment strategy, when we're talking about cancer, we delay... it might be... have an outcome effect, but the lay-in diagnosis of weeks or even a few months for a precancerous condition like Barrett's intuitively I wouldn't expect that delay to have outcome implications.

Drew Schembre: Well, actually it does in that a test and treat approach for symptoms related to reflux can mask Barrett's esophagus to the point that it's not investigated. And when it becomes cancer, you have missed that window of intervention.

Chris Standaert: Does that become then... I saw in here somewhere that said... this idea of sort of people with five years of GERD symptoms, regardless of... if they're being treated for five years, I assume you... do you monitor? Is there a guideline or a standard for how long someone would be treated for symptomatic reflux symptoms before they are... guidelines recommend they routinely monitor to look for the presence of Barrett's because they require sustained long-term maintenance?

Drew Schembre: The guidelines from the societies are fairly weak on this, because the data is just not there. There is kind of... the ASGE recommends endoscopy in groups who have, especially males over 50, who have had reflux for five years or who have reflux [inaudible] times a week or on long-term PPI therapy, and of course, the equation is skewed a bit now because patients will often have been on PPI therapy with over-the-counter PPIs well before they're seen by any health care professional.

Craig Blackmore: So, we're due for a break. It's midmorning. So, why don't we take 15 minutes and give the team a chance to play with...

Robyn Liu: I can answer one question about the Marmo Study that was posed earlier, which is that the training... the validating... the split sample validation was a separate population of patients. So, the training sample was 2001 and then from January to October consecutive patients presenting in 2002 was the validation sample. So, it's separate. It's not a subgroup.

Craig Blackmore: Okay. So, we'll reconvene, as I said, in 15 minutes. Thank you.

Time to call the meeting back to order and ask the committee to rejoin at the table here. We have a quorum. We're back in session. On our agenda, we have basically sort of informally transitioned from the period where we hear from our various presentations and direct our questions to the presenters now to the more general discussion among the committee members still using our resources, but among ourselves as we work towards some decision making. Now, that being said, do we have follow-up on the question on the Marmo Study? Maybe we need to wait for... okay. She'll be back. See, we gave everybody else a break, but we don't give the vendor team a break. All right. What other points of discussion. We'll just open it to the committee at this point for any questions or general points, as we nibble on our midmorning snacks.

Seth Schwartz: I guess I wanted a little more clarity about on the... oh yeah, back to key question one on slide 16, we talk about there being cohort studies with six different tests for GERD, and I'm curious, I mean, we're kind of talking about GERD as a screening strategy, or sorry, endoscopy as kind of a screening strategy for GERD. So, I'm just trying to understand better what the alternatives are and, you've commented on the sensitivity of these two strategies, the 24-hour pH probe and, well actually there's no comment on exactly what the sensitivity is on that. I just think it's good, and then this sequential strategy including endoscopy, which is 100%. I'm curious what the other options are what... that did not include GERD, what the sensitivities were for those, and then again, also what the specificity was of those different screen regimens.

Robyn Liu: Sure, absolutely. So, that's the Maiden Study from 2005, and the six tests that were looked at were upper gastrointestinal endoscopy, they considered histology or biopsy as a separate test

from endoscopy, which was a little bit possibly fishy, because you wouldn't necessarily be able to do a histology without the endoscopy first. They looked at omeprazole challenge test, barium swallow with fluoroscopy, radionuclide scintigraphy or a nuclear medicine scan, and 24-hour pH monitoring. So, those were the studies that were considered.

So, they established a gold standard of a concordance of three tests. So, all the patients in the sample were submitted to all six tests, and if three of the tests agreed on a diagnosis of GERD, that was considered the gold standard. This patient has gastroesophageal reflux disease. So, considering that as the gold standard, the omeprazole challenge test had a sensitivity of 84.4%, a specificity of 56%. Endoscopy had a sensitivity of 64.4% and a specificity of 84%. Histology had a sensitivity of 82.2% and a specificity of 60%. Barium swallow had a sensitivity of 26% with a specificity of 92%. Scintigraphy had a sensitivity of 15% with a specificity of 96%, and pH monitoring, which was considered the sort of best of individual study, was a sensitivity of 77.7% and a specificity of 92%. Then when you looked at the three together for a step-wise diagnosis, they found that if you took the omeprazole challenge test plus endoscopy plus histology, and compared that sequence to the gold standard in the study that there was a sensitivity of 100%.

Carson Odegard: I have a follow-up question on that. Carson Odegard. When we look at these sensitivities and specificities on these, when you drive at a J-value... okay, some of them have J-values, some don't. Is that because it wasn't... I noticed... how is that J-value derived? What is the importance of that? I mean, I assume it's the combination of sensitivity and specificity.

Robyn Liu: Mm-hm.

Carson Odegard: Giving you some kind of value for those together.

Robyn Liu: Right. So, yeah... so the J-value is a... I don't know the formula for that, but it's the sort of combined sensitivity-specificity and so, table two of the study does give all of those, and the highest J-value is the pH monitoring, which is 0.69. Endoscopy alone is 0.48. Histology alone is 0.42. Omeprazole challenge is 0.4.

- Barium swallow and scintigraphy are both quite low, 0.18 and 0.11.
- Carson Odegard: Wow. Okay.
- Craig Blackmore: So, I also have a sort of related question. So, you're giving us accuracy data for the diagnosis of GERD.
- Robyn Liu: Mm-hm.
- Craig Blackmore: But, on one hand you're trying to diagnose GERD, but on the other hand you're trying to make sure it isn't something else, and that something else might be Barrett's or cancer or whatever. Do we know the sensitivity and specificity of these tests for sort of the more ominous conditions? I'm sort of assuming these people have GERD and, you know, it's not... it's something you treat symptomatically, but we want to see if they have something else.
- Robyn Liu: Yeah. So, this particular study was specifically looking at diagnosis of GERD. It did exclude patients with alarm symptoms. There were four patients in the sample that had a finding of Barrett's esophagus, and I don't think any patients had a finding of malignancy in this study. So, again, this was a fairly small study basically just trying to determine the...
- Chris Standaert: How many patients in this study?
- Drew Schembre: 70 patients I think.
- Chris Standaert: 70?
- Drew Schembre: Yeah.
- Robyn Liu: Yeah, 70.
- Chris Standaert: So, 4 or 5% had Barrett's?
- Man: Yeah.
- Carson Odegard: So, was the point of putting this in your presentation, was it to point out the fact that those combinations are the gold standard

for... to get the highest sensitivity or was it to point out that the highest sensitivity was the test and treat test out of all of them?

Robyn Liu: I guess the point in including it was the study does meet our inclusion criteria and was looking for the question addressed the evidence of effectiveness of EGD. So, we did include this study, but being as small as it was, the strength of evidence from this particular study would be... we would consider very low because of fewer than 100 patients. So, this one by itself would be a very low strength of evidence.

Chris Standaert: I have one more unrelated question. We didn't talk very much about risks and harms, and I assume... I saw in the data in the report and stuff that there wasn't much in the way of harms of the procedure. I assume when you biopsy people, things go bad every now and then. So, there must be some risk to doing the procedure, and there's some risk to sedation, and what I don't know is, is there a risk to sort of doing a scope that finds things that really aren't relevant? So like, I think MRI'ing everybody with low back pain who is 50 actually creates problems because a lot of them just have problems because they're 50. They're not clinically significant and they're not going to be. Is that a situation that occurs with endoscopy where you find things that really are meaningless but lead to more tests and more things and more risk and more exposure? I don't know. I didn't see that referenced in here somewhere. It's either for you or the expert, whoever.

Robyn Liu: Yeah, we assume so. I mean, we know the risk of those things is not zero, and as I said we made some pretty Herculean efforts to find literature to answer that exact question and found none. You know, I'm sure the risk is very small, but again, it isn't zero. So, the evidence search was basically unable to answer your question, and we really wanted to.

Chris Standaert: So, for the expert, the risks of the procedure, do you have any sense of the scope of that, and also again there's a risk of over diagnosis essentially leading to sort of unnecessary things, the sort of [inaudible] disease creation from scoping people? Is that our concern, or no?

Drew Schembre: Sure. Drew Schembre. The risk, as was mentioned, the risk of the procedure itself is very, very low but it's not zero. It's probably

somewhere around 1:10,000 with a significant event, and that's usually sedation related and in a rare, rare case perforation or bleeding, but the kind of incidentaloma identified at endoscopy and then pursued either surgically or other imaging is uncommon but not vanishingly rare. In fact, we do a lot of endoscopic ultrasound. We're sent lots of these lumps and bumps that were kind of detected at endoscopy and then once they're identified, just like on cross-sectional imaging, you have to essentially follow it up and prove what it is or what it isn't. I couldn't tell you how often that happens, because it's a large denominator, but it does happen occasionally.

Chris Standaert: But no real good data on that anywhere.

Drew Schembre: Correct.

Craig Blackmore: The vendor is shaking her head.

Robyn Liu: Yeah. We tried.

Chris Standaert: Okay.

Craig Blackmore: Any other questions at this point?

Joann Elmore: This is Joann Elmore. I'm wondering if our evidence vendor has had time to review the issue of the binary cut point of age and whether it's potentially confounded by the presence of symptoms, and whether you would really rate the data as moderate quality.

Robyn Liu: Yeah, thank you. So, I did review the Marmo study in detail during the break and the age cutoff that they started with, their apriority assumption, was based on the old AGA and ASGE guidelines from 1998 and 2001 respectively, which did recommend, in the guidelines, an age cutoff of 45, and so that was their... that was their assumption. The aim of their study was to identify risk factors in patients with uncomplicated dyspepsia and so, again, they're looking specifically at patients without alarm symptoms, and trying to determine whether that age cutoff is valid. So, there was a training sample and a split sample. In the uncomplicated dyspepsia group, 5,224 in the training sample, 3,684 in the split sample with uncomplicated, and so there was an

error in my slide, because the 4,329 number is the total split sample, and then there were a number of patients with alarm symptoms or comorbidities that were then excluded. So, the uncomplicated dyspepsia split sample was 3,684, and that's the number that should have been on the slide. So, I apologize. They used a fifth percentile rule to derive age cutoffs in that sample, and for the training sample was 35 years for males and 57 years for females, with 15 out of 16 and 6 out of 6 cancers detected over those thresholds respectively.

Craig Blackmore: So, I'm sorry. I don't understand what a fifth percentile rule... what does that mean?

Robyn Liu: Sure. So, looking for... so, where you'll miss... where you'll catch 95% of malignancies. So, making the cutoff where 95% of the malignancies fall above it.

Chris Standaert: And so in the... you said in the women they had six cancers and so 57 just represents the youngest person who had cancer, so it's a post-hoc.

Robyn Liu: In this sample, yeah. So...

Chris Standaert: So, that's put... but that wouldn't... but that doesn't... so, if you post-hoc go back and say, well our youngest patient had a cancer at 57. Therefore, 57 is a good cutoff. You can't do that. You're not testing the assumption that 57 will find them and then going to look. You're just sort of saying the youngest person we saw in our sample is 57, so we'll start there, which seems like, and you only have six people. So, that seems fairly poor in terms of statistical relevance.

Robyn Liu: Right, so yeah. So, as to the question of is this a moderate strength of evidence. The moderate strength of evidence designation was given to age in general. There is more malignancy, as you get older. It was not intended to be a moderate strength of evidence that there should be a cutoff of 35 for males and 56 or 57 for females. So, I apologize if that wasn't clear. There's a moderate strength of evidence that malignancy is more common and an endoscopy will therefore be a better yield, as the patients are older, but not to give you a very clear recommendation about what that age cutoff should be.

- Joann Elmore: Or if there even should be an age cutoff.
- Robyn Liu: Yeah. Or if there should be an age cutoff, specifically, yeah. So, yeah. I mean, you're looking at a study of, you know, 3,000 people with uncomplicated dyspepsia without alarm symptoms, and yes, a small number of them have malignant findings and so if you're looking at that specific population, you know, the study is suggesting, I would say with a moderate strength of evidence, that you're safe in that population to consider age and gender together, but I... the slide and the suggesting that age has a moderate strength of evidence for differential effectiveness, that was not intended to reflect [inaudible] for this particular study. This is just the one study.
- Michelle Simon: Okay. Thank you. This is Michelle Simon. I want to actually expand on that a little bit. So, on that same slide, the study above, which is the 2006 Bechtold study and it's a 17 cohort study.
- Robyn Liu: Mm-hm.
- Michelle Simon: Systematic review, I'm wondering about the studies that are included there and what the ends are of those studies.
- Robyn Liu: Sure.
- Michelle Simon: What kind of sizes of populations are they looking at?
- Robyn Liu: Yeah, I can... that's all in the... we actually have all of those studies in the table in appendix C. Overall, the end was over 57,000.
- Michelle Simon: It is? Okay.
- Robyn Liu: In the 17 studies. I could give you the end of each of the 17, but...
- Michelle Simon: No. I'm just wondering...
- Robyn Liu: Over 57,000 patients in total.
- Michelle Simon: I just wanted to hear that number, yeah.

Robyn Liu: Mm-hm. Yep.

Craig Blackmore: Any other questions at this point? So, I guess at this point I'd like to get a sense of where the committee is. We've heard a lot of information. Before we do that, I want to get back to the clarifying what we're deciding and not deciding. So, you know, our choices are cover, cover with conditions, and not cover, but we have to recognize that that decision we will be making is limited in scope to the specific population and the specific question that is before us. So, we are not looking at the use of endoscopy in people with cancer, known stricture, known Barrett's esophagitis. We are looking at people who are presenting with a symptom complex that might be GERD, might be... but have not been evaluated for that. So, within those confines, I'd like to get the feel from the committee about where we are, what we think we know, what we think the sort of gray areas are at this point, and then we'll use that sense to move on. So, does somebody want to... I'm gonna kinda go around and get some different perspectives, but does somebody want to start that process for me?

Chris Standaert: I'll give it a go. It's a bit... I think our data is a bit of a jumble, because we have different things tumbled together in here, and I think that like what you just said, the only thing we can really talk about is sort of the role of endoscopy and essentially the acute management of somebody presenting with initial symptoms of... or initial presentation of relatively uncomplicated GERD, because we don't really talk about the other sort of more extreme stuff, and in that population, you know, the question is do you do an initial endoscopy and treat or do you do an initial empiric either H. pylori test or PPI and treat and then at what point after that does it become reasonable to do a scope? So, is that... do you treat somebody for six weeks and they are all happy and they're off their drugs and they're all well, you don't do it? Is it that you treat them for six weeks and they still stay on the drug but they're happy and symptom free but you still have to go monitor? Is it... and then the monitoring... the trouble is what you brought up before also, this issue of you're not necessarily doing... if somebody has symptoms for six weeks and either responded well transiently to a PPI or didn't respond, you're not really scoping to diagnose GERD. You're scoping to diagnose something else, and we don't have great data on that, but that's the reason you're

doing the scope, and that actually does change clinical management, and our numbers that the state has are pretty high levels of finding things that aren't simple GERD. So, about 30% have strictures or varices. It's confusing. I also don't see in the literature, in the stuff we have from the state, I don't... the issue of overutilization of rapid escalation and utilization, the issue of excessive... I don't see data that tells me that this is being used inappropriately by the providers in the state as it is. I don't see a suggestion of that really in the data. So, I'm sort of bouncing around in those ideas.

Richard Phillips: I would have to agree. I, you know, it's hard to make a decision on something that you don't see in the data and you don't see the management sequence here, as you're describing. We don't see what takes place in what sequence and what timeframes at all, and the other thing with... I mean, the agency data is good, but it just gets muddied by the things that are in there. Barrett's esophagus is, you know, 22.9% when you add the Asian factor in there too, which could muddy it up even more, and then some of these other diagnoses. It's really hard to make a decision on, I mean using that data. So, I, you know, I have to agree.

Joann Elmore: I thought Chris did a great job articulating our summary, and you used a word that's important clinically, which is acute, and I don't know that I heard our evidence vendors talk about whether any of the symptoms in any of the studies were acute... the acute management.

Chris Standaert: Mm-hm. I corrected myself... I corrected myself and changed it to initial, because I used acute and realized that... it's like wait a second. It's actually the [inaudible] presentation. Usually, people have had symptoms for five or ten years before they come in.

Joann Elmore: Right.

Robyn Liu: Yeah. So, the evidence is looking at initial presenting complaints but doesn't necessarily quantify how long that complaint's been present at the time they present to medical care.

David McCulloch: This is David McCulloch. As I look at the data the state presented, I don't see an alarming trend. It looks like between 7 to 10% of

the time an upper endoscopy is done, only 10% of those with a diagnosis of GERD were done. So, I...

Craig Blackmore: Well, I don't know that that's true. That's per year. So, that means out of the population of people who have GERD each year, 7 to 10% of them are getting endoscopy. It doesn't mean they don't all get one in their presenting year and then not five years after.

David McCulloch: Okay. And, well let me go on. And as I said, the only... I don't know if this is a problem, and if the state feels like there's discrimination in whose getting follow-up, then there are different mechanisms to deal with that, you know. Doing chart audits and looking at unreasonable variation in clinical practice. As I look at the evidence, it... I mean, I'm not a gastroenterologist, but it seems to me there clearly are situations... I mean a lot of simple GERD and upper GI symptoms can be empirical treatment or test and treat, but there are quite reasonable circumstances that I don't think we should be trying to pass out and can get specific about when an upper GI endoscopy is a worthwhile thing to do. I'm... that's where I'm sitting right now.

Seth Schwartz: I guess I'm trying to figure out a little bit better how endoscopy is actually used, because I think what we're seeing here is that there's no compelling evidence that endoscopy is better than these test and treat strategies or other less invasive, likely less expensive, options for diagnosing GERD, but it's not clear to me that's the way that this is actually clinically used. I think what we're seeing is that this is a test that's used to make sure nothing else bad is going on. So, the point at which that becomes necessary, I don't think we have the data to really say that and part of what I'm struggling with is that there are no, we're hearing at least from the data, is that there's no good alternative way to identify a high or an at-risk patient other than possibly age and possibly gender, possibly. So, as far as use in initial diagnosis, I'm starting to feel pretty comfortable to say that that's not... that there's no evidence to support that, but I'm not really sure that that's the really right question to be answering here, yet, that's what we're kind of charged with answering. So, that's what... I'm seeing a role for endoscopy, and I'm trying to structurally get in my head the idea of when, you know, under what circumstances

that's indicated, or do we even need to talk about that, I guess is the question for you, or for the committee.

Craig Blackmore: So, I guess we have three choices, right? We have cover, not cover, and cover with conditions, and a no cover decision would mean you're never allowed to use endoscopy in patients who don't have cancer or some other condition, and, you know, personally, I'm not going to be able to do that, because how would you know? And then a cover with unconditional cover would mean, you know, it's up to the individual providers to do this when and as often as they like. And a cover with conditions might be you need to have a trial of PPI or in certain age groups or not, and you need to have a test and treat approach first for some period of time, and that's sort of the decision we have before us.

David McCulloch: Is... is... I'm sorry. Can I...

Craig Blackmore: Yeah, please.

David McCulloch: I need a point of clarification, please. So, key question one is what is the evidence of effectiveness for early treatment strategies that include upper endoscopy compared with empiric medical management? So, are we really... and if, if we vote no, don't cover, we're just voting not to cover its use in that situation, aren't we?

Craig Blackmore: I mean, I... so I guess what I'm hearing from you is that we don't really have the authority to say you can never use endoscopy.

Chris Standaert: We don't have that authority.

David McCulloch: That's not what's being asked.

Craig Blackmore: We wouldn't say that anyway, I don't think, but I think the question before us is here's the initial presentation and is it appropriate to allow the use of endoscopy in that initial presentation or should there be some other approach, and I don't know if we want to specify what that approach is, but presumably we do define, on some level, what initial presentation means, and so...

David McCulloch: Okay.

- Craig Blackmore: And we might define that as a period of time or failure of a treatment of some sort or some other pathway.
- Chris Standaert: And we have to define what sort of simpler, uncomplicated presentation is. They kept using this word alarm symptoms, which is sort of weird to me, because that's... it's like it pops up all over the place like everybody know what that means, you now?
- Craig Blackmore: Defined in here somewhere.
- Chris Standaert: It... it... but it's defined, it's like, you know, e.g. for example, you know? Whereas if we say this, we have to be very specific as to what we're talking about or use language that lets people sort of express themselves.
- Craig Blackmore: And there... and there's sort of two approaches to that, which I think depends on the actual question we're being asked. So, I guess we need to clarify. One approach is to have that as a condition, and the other approach is to have it outside of the scope of the decision, and I think we... I think the question being asked of us includes that population, so I think it is incumbent on us to say, should we choose to cover with conditions, it's incumbent upon us to say and we think in this group early might be appropriate.
- Chris Standaert: Mm-hm.
- Craig Blackmore: If, you know, again, I'm not trying to push the committee in a certain direction but, you know, we have to define those.
- Chris Standaert: Right.
- David McCulloch: Also, it just seems to me that those... that while I would agree that I think we need to address that population, because I think excluding them does them a disservice, but I think that clinically that it... it's going to have a different look. If a patient comes to your office saying my stomach hurts, I get full early, that's very different than a patient saying I've been vomiting blood, and I think that as a clinician you're going to... you're going to downplay the importance of the GERD symptoms and up-measure the importance of those other symptoms, and I think it would be very

difficult not to consider endoscopy even though the data is a little bit equivocal on that, because the implications are more significant, and as we talked about using endoscopy to rule out other things, probably those other things might be... you may be more worried about the risk of those other things, so. And yes, I think we should comment upon them, but I think they're probably going to come out as exclusions.

Craig Blackmore: So, so I think... I think what... where we're headed is making a decision about two distinct clinical scenarios and... and we need to somehow define those in more concrete terms, but one is the alarm symptoms, however they're defined, and the other is the absence of alarm symptoms, and we might treat them the same or differently, but I think we need to at least discuss them separately. Does that resonate with the committee?

David McCulloch: Well, if you look at key question three, we're being asked even more than that, aren't we? 'Cause it's asking specifically about for what diagnoses and within what timeframes is repeat endoscopy indicated? So we, I... I agree with you about what we're being asked initially, but aren't we being asked more than that?

Chris Standaert: I think our data's very tricky on that, though, 'cause we don't have data on surveillance. We don't have data on the need for repeat endoscopy for Barrett's.

Craig Blackmore: But again, we're only looking at the patients who don't have Barrett's. So, if we make a ruling on repeat, it's on patients who do not have cancer, Barrett's, stricture, etc.

Joann Elmore: And we do have evidence on that.

Man: You figure on Barrett's, if you have an endoscopy it's a recursive problem.

Chris Standaert: I guess the issue is the people who get...

Man: Isn't that true?

Craig Blackmore: But one... so, we're looking at initial presentation and if you... and then we're... I'm talking about breaking that down until we've got these alarm symptoms or we don't, and then we've been asked

also to look at repeat but not in the people who have something bad on their initial endoscopy, bad meaning Barrett's or stricture or cancer, but the people who are diagnosed with GERD, uncomplicated, and do they... do we feel it's appropriate that they get repeat and can we define some interval at which it might be appropriate? I'm not saying we can, I'm just saying that's what's being asked.

Chris Standaert: Funny, this... I mean this is where we ask the question, there's a question on the follow-up data that they gave us, because I guess you could break... just like you did with the first two. So, if you do, say you say it's a six-week or 12-week window, you treat with PPI, it doesn't work or they're not cured or whatever, and then you can do an EGD, and you see nothing, or you see something, right? So, you see something that warrants medical follow-up. You see Barrett's, you see a stricture, they become a different category. You see benign-appearing reflux, however that could be defined, and then the question is in those... in the people who have pathology that warrants follow-up, at first we have no data. We can't even talk about them. We shouldn't be making a comment at all.

Craig Blackmore: We're not. We're not making a decision on them.

Chris Standaert: I know... I know. We shouldn't even comment on them at all. For people who have a benign EGD, again, however we choose to define it, or if we could define it, the question is, at some point is it... do you do a repeat EGD? And it's curious. The data we have is for symptom management. So, we did a repeat EGD at two years and it didn't make any difference in their symptom management, as opposed to we did... if you have... I mean if you have a benign... somebody with new onset reflux, you do an EGD, it's benign, but they've had symptoms for five years, should you repeat it to see if they're developing some more significant pathology? But that's not what the studies talk about. They talk about symptom relief, which is, again, that's not why you're doing it. You're doing it as a diagnostic test, and this is where that diagnostic versus therapeutic part of the follow-up data really threw me off, because that doesn't help me, because you wouldn't... you wouldn't do it two years later or three years later or four years later thinking that you're just going to make them feel better. You

do it because you're worried about some sort of pathology, I assume.

Craig Blackmore: So, so... I'll ask the vendor, although I think I know the answer. Is there any data on the diagnostic yield of repeat endoscopy in individuals with symptoms refractory to treatment?

Robyn Liu: So...

Craig Blackmore: I think that's the question.

Chris Standaert: Yeah. Yeah, that's a good way of putting it, yeah.

Robyn Liu: Yeah. And what you're getting at in your discussion is a little bit of a disconnect between the key questions and the PICO, because... and so, the population intervention comparator and outcome of interest that were defined at the beginning of the question, the population was defined as initial presenting complaint and so we excluded studies of people that were done not with the initial presenting complaint, which left us with very little to go on looking at key question three. So, that's where you're running into this... into this trouble.

Chris Standaert: Wasn't a PICO table set up to answer key question three, then?

Robyn Liu: Not separately, no. So... so, we assumed in our review that when, as you have said when they go under their initial endoscopy, if there's something there, if they have Barrett's or they have cancer or they have a disease finding that they then left our population. So, that did leave us with not very much to go on for helping you answer key question three, because we didn't feel that was... that we were being asked to make a summary of evidence for follow-up of Barrett's and follow-up of erosions and follow-up of ulcers and follow-up of polyps...

Craig Blackmore: But... but, that's not...

Robyn Liu: ...and follow-up of whatever else might have been found.

Craig Blackmore: That's not the question I'm asking. The question I'm asking is, individuals who have continued symptoms, what's the diag... so, you had your EGD and it was negative, but you still have

symptoms. It was negative for Barrett's or some of these other more...

Robyn Liu: Right.

Craig Blackmore: ...but yet your symptoms persist for five years.

Robyn Liu: Mm-hm.

Craig Blackmore: Did your research include identifying any literature on what the yield of a follow-up EGD on patients with continued or recurrent symptoms is?

Robyn Liu: We were not able to identify any studies addressing that particular...

Craig Blackmore: But, did you try? Was that included in the?

Robin Liu: Yeah.

Craig Blackmore: Okay. So, we have the information to answer that question such as it is.

Robyn Liu: Such as it is.

Craig Blackmore: Okay, thank you.

Woman: What we don't have, though, it seems like, is the same kind of information that they seem to have about like colonoscopy. You repeat colonoscopy if you have... every 10 years, because they assume then that pathology doesn't change. If it's a clear colonoscopy that the growth of the tumor would be slow enough that you could pick it up once every ten years. Is there any of that kind of information about endoscopy? I mean, if you were to do it once and you had repeat symptoms, what would be your risk in five years for having Barrett's? And it wasn't identified on the first one.

Robyn Liu: It's not a perfect comparison, because screening colonoscopies are done in all persons over the age of 50 to identify asymptomatic premalignant lesions and endoscopies are not routinely done in anybody... in people without symptoms, and so

the comparison isn't really valid between upper endoscopy and colonoscopy. I think Dr. Schembre has something to add.

Drew Schembre: This is Dr. Schembre. Most Barrett's esophagus develops in younger people. So, it's very unlikely that if somebody has an index endoscopy... if somebody has an index endoscopy, they are unlikely to develop Barrett's if they haven't had it at the index endoscopy, even after 10, 20 years.

Marie Brown: So, repeated exposure to GERD symptoms wouldn't increase the risk of developing Barrett's after five years or ten years?

Drew Schembre: No. It seems to be there's a genetic predisposition for making Barrett's esophagus, as opposed to ulcer... kind of a different story, and the vast majority of people who would be presenting for an index endoscopy would have had significant symptoms over some amount of time that would have put them at risk for developing Barrett's, and in the vast majority of cases, if they haven't developed Barrett's by the time they have an index endoscopy they are not going to then develop Barrett's subsequently.

Chris Standaert: So, is there a recognized indication for an individual who has persisting reflux symptoms and a history of a benign endoscopy to have another endoscopy at some point in their life for the same symptoms? Is there is a clinical indication for that, or is that commented upon again in guidelines or some other form that would help us?

Drew Schembre: It is generally recommended only if there is a significant change in symptoms, new alarm symptoms, such as dysphagia or weight loss or bleeding or anticipating a different medical therapy. Say somebody is now failing an acid suppressant medication and anticipating an antireflux surgery, there would, theoretically, be an indication to take a look really as a preoperative evaluation rather than to diagnose anything... any new precancerous lesion or something else.

Robyn Liu: You asked about any other guidance. The policy from Aetna that's included in our report specifically excludes coverage for repeat EGD if a prior normal EGD and symptoms remain unchanged, and then under their category of high risk screening, they note that

after a negative... so, persons with chronic five years or more of GERD at risk for Barrett's, are eligible, but after a negative screening EGD, a further screening EGD is not indicated in those persons. So, Aetna specifically excludes a repeat EGD if the first one was benign.

Chris Standaert: If symptoms are unchanged.

Carson Odegard: Excuse me, Carson Odegard. Also, Aetna really spells out what the alarm symptoms are, and they don't go into alarm symptoms. In the report, we see that these are the alarm symptoms. So, I think, you know, it would be good to know exactly what the... what the alarm systems are, whether we go by the guidelines, the Aetna guidelines, or what the parentheses are of alarm symptoms.

Robyn Liu: As I was... this is Robyn Liu again. As I was writing this report, I made exactly the same comment that Dr. Standaert made, which is everybody talks about alarm symptoms like we should all know what they are, and that's the case in the guidelines and much of the literature. So, different individual studies will spell out different... they'll encompass some subset of the same ten or so symptoms, but not all will encompass all of them. So, some of them will have specifically dysphagia, weight loss, abdominal mass. Some of them will leave out dysphagia but include pernicious anemia. So, it's not... in the literature, it's not a cut and dried group. Aetna's policy, as you said, does spell out specifically what they mean.

Carson Odegard: Mm-hm. Thank you.

Craig Blackmore: Any other comments? Okay. So, I think we've got this structured around looking at sort of two groups in the initial presentation. The first is the group with alarm symptoms, whatever they are, and the second is the group without alarm symptoms, and I don't want to... I want to start the discussion by targeting the initial presentation for GERD symptoms without any of the alarm symptoms and then at this point I don't want to dig too deeply into what constitutes an alarm symptom, but I want to see where we are specifically in that initial group that doesn't have any red flags, if you will, and my question to the committee in sort of an informal discussive sort of manner is do you think we're in a place

of unlimited coverage or are we in a place of coverage with conditions, conditions might meaning some age or might meaning some trial of some other treatment, and I want to get a feel for where we are in that. I'm excluding no coverage, because no coverage I think would mean, the way I frame this, would mean never, and I don't think anybody's in the never group. So, I think...

Joann Elmore: It sounds like we're discussing coverage with conditions.

Craig Blackmore: Well we're either... we're either talking about... and that's what I'm sort of getting at. Are we at coverage with conditions or are we at cover because for whatever reason? So, I want a sense. David, where are you?

David McCulloch: I would hate us go down the path of trying to parse out what exactly constitutes an alarm symptom. My impression of this whole field is, if you are a well-trained, ethical gastroenterologist, the majority of the time you would either empirically treat or test and treat, but some percentage of the time, 5-10%, you have some clinical index of suspicion that there's something else going on, and that's absolutely what a gastroenterologist should be asked to do. It'll be rare, but we should absolutely be allowing that to be something that should be done. I don't have any evidence that gastroenterologists are mistreating the state, and they're not... I mean, I don't think we've evidence that the current state isn't perfectly reasonable. So, I don't see any reason why we should be trying to say, you know, parse out all the different possibilities of alarm symptoms and how much weight loss over what period of time. I just think that's a... that's a mess to go down. That's my advice.

Craig Blackmore: So, what I'm hearing from you is that basically an argument for coverage without conditions. Leave it at the judgment of the gastroenterologist.

David McCulloch: Yeah.

Craig Blackmore: Okay. Are there other thoughts around the table?

Chris Standaert: I would guess that most of the time people get treated by their primary care provider, and if they don't respond they go to a gastroenterologist who then decides to do an EGD or not. I doubt

many people show up in a gastroenterologist with nobody else ever having seen them for their reflux symptoms and never having tried a PPI. Maybe, but I... it seems like that is a minority, and there clearly... the data clearly suggests that the initial diagnosis of somebody with reflux with a scope is a bit excessive, right? But, you don't have to do that. That somebody with just an initial presentation you can treat them and diagnose them some other way. If that doesn't work, maybe you scope them. But like David says, I don't have any evidence that that isn't actually what's happening, and so we can either say... we can reiterate what already appropriate care, but we have to be very careful with our words that we don't hamstring somebody from what they're doing, and we have to define alarm symptoms, which are... we may be able to do, but we may not be able to do. Maybe that's just a long walk for a short jump that we don't really know that this isn't being done correctly as it is and the indications seem pretty clear, and the guidelines are pretty consistent, and most people probably follow the guidelines and do we... is it worth the process of going through that? That's my question.

Craig Blackmore: So that's basically two similar voices.

Chris Standaert: Yeah.

Craig Blackmore: Are there other perspectives around the table that differ?

Michelle Simon: I guess I differ a little bit. I think that there's some evidence that test and treat seems fairly equivalent to strategies for this and I think that the costs, if you take them as equal, there's not more harm from either of those. Take those... all those other things equal, then the cost is a little more for endoscopy. So, that's something to consider there. I wouldn't be happy with defining alarm symptoms at all, because we really don't have any evidence about that, and we would just be making it up, and I'm not comfortable with that at all. But, what we could say is for uncomplicated presentations of dyspepsia or GERD, and I think that kind of rules out anything else that's going on. We could just say, in this case test and treat instead of saying in this case do something else. I'd rather not do that part.

Craig Blackmore: Kevin?

- Kevin Walsh: Two points. One, I guess Dave, I'm going to disagree with you. The issue is not whether the people are doing it appropriately or not. That should have been asked... that should have been answered before we ever got all this stuff. We're just left with the stuff. So, we have to deal with the stuff. I mean, I think your point's appropriate, but I think it's not relevant in this situation, unfortunately. The second point is to reiterate what Chris said, and that is what we're really doing is giving indications here to people like me, you know, the family physician, not to the gastroenterologist, because I can guarantee you that if I send a patient for an EGD, they don't get a cons... they don't need a consult first unless I ask for one. I can just get the EGD. So, I can send them for an EGD because or I can send them to an EGD following a guideline, and so I think that's how we have to imagine... that's the audience that we're talking to. We're not talking to gastroenterologists here. I don't think. So, I think there is a place for a guideline and whether it's... whether EGD is currently being used or not, unfortunately, is not... we don't get to discuss that. What we just have to do is look at the evidence and I think Michelle put it as well as I could. I would support that wording.
- Chris Standaert: I'd be comfortable with what Michelle said, as well.
- Marie Brown: I would too.
- Craig Blackmore: I'm uncomfortable sending the message back to the medical agency director saying you didn't prove this was a problem, so we're not going to decide on it. I mean, I agree with your criticism of sort of... criticism maybe isn't the right word, but I mean, I agree we don't have the kind of data we would like to understand the magnitude of the problem, but we have been asked to make a decision, and I think we have to do that. Okay, other thoughts around the table? Joann?
- Joann Elmore: I think I'm hearing that the presumptive standard of good quality clinical care, given the level of existing evidence, is that we should not jump to perform EGDs in patients quickly and that in a patient that has an alarming sign or symptom, it might be appropriate, or in a patient who fails medical management it might be appropriate, and I think that's what I'm hearing. I'm also hearing

that we don't know if it's currently a problem, yes or no, and we don't know if clinicians in the community, they may already be following this appropriate community standard.

Craig Blackmore: Carson?

Carson Odegard: I just want a clarification what Kevin said. So, you have a patient come into your office and you have some suspicion, you can order, without the consultation, you can order the EGD, right?

Marie Brown: Yes.

Carson Odegard: So, you can just go out and just order that and get the results back.

Marie Brown: Yes, right.

Carson Odegard: Okay. Without going through any other tests. The patient won't be looked at again going okay, what's the history of it... of your medication?

Marie Brown: Well, you'll look at the... I mean, we'll look at them as the primary care provider.

Kevin Walsh: Once the EGD is done, obviously if there's pathology found, then they go down a different arm, but in order to get into the room to get the scope done, they don't need a consultation.

Carson Odegard: Yeah.

Kevin Walsh: I mean you can order an MRI without a consultation. I can order an echocardiogram or a stress test without a consultation if I choose.

Carson Odegard: Right.

Kevin Walsh: So, it's possible to do all those things, sure.

Carson Odegard: Okay, yeah. All right.

David McCulloch: Craig, I...

- Craig Blackmore: Would you like to comment further?
- David McCulloch: Well, I just... I can't see is going down the path of trying to parse out. So, you may not get reimbursed for doing an endoscopy by the state unless you prove to us this patient has had a therapeutic trial that failed of what for how long. Has alarm symptoms that we'll have a big long list for, or has dysphagia or... I mean, I would find...
- Joann Elmore: We don't need a list.
- Carson Odegard: No.
- Kevin Walsh: I would agree. I don't think we need a list. I think there is some clinical judgment here in terms of what constitutes alarm symptoms, but I think we don't have any evidence to suspect that people are misinterpreting what alarm symptoms are. I mean, it could be... it leaves it open a little bit. I acknowledge that it leaves it open a little bit, but, particularly since we're not too concerned about over abuse here based on the data we've seen, I'd be quite comfortable saying alarm symptoms and letting the clinicians figure that one out.
- David McCulloch: On failed therapy we've upped them as well. So, I don't see how that helps either us or the state to say, we're now gonna put a roadblock in. You need to... before they'll pay for it, you need to come to us and see I need an EGD because this patient has failed therapy, has alarm symptoms in my opinion, has dysphagia or is bleeding.
- Joann Elmore: As a primary care provider, I think it would be helpful, and I agree with Kevin that that is the population that you're speaking more commonly to, because anytime a patient is sent to a gastroenterologist, there is usually a sense that as a PCP we can't... that what we're doing to manage them has not been adequately effective, and we're concerned about whether there would be alarm symptoms or something that we would miss.
- Kevin Walsh: Dave, look, go back and look at the recommendation that they said they would be comfortable with.
- Craig Blackmore: Slide 22 from the...

- Kevin Walsh: On page 11.
- Craig Blackmore: ...state agencies. And I guess... so, I mean, I'll read it. It's right here. In the state agencies recommendation, our job is not to follow the state agencies recommendation, but what they say is their recommendation is to cover with conditions, which is failure of trial of treatment to improve or resolve symptoms or presence of alarm symptoms or advanced age.
- Marie Brown: Right.
- Craig Blackmore: Or objective findings of serious upper GI pathology. So, that may not seem like it is that valuable to us in this context, but clearly they perceive that... it may seem to us like that's overly simplistic, but to them that would address the concerns that they have.
- Chris Standaert: And, we'd have to specify. That's for people with us... whatever this un-word, uncomplicated. You say four people with uncomplicated symptoms of gastroesophageal reflux. That's to whom that applies.
- Craig Blackmore: Which would be the objective findings of serious upper GI pathology, I assume.
- Chris Standaert: Well, we need to define the population we're talking about. So, we... this is our coverage for this population. That's all I'm saying.
- Craig Blackmore: Yeah, well I think that's fair.
- Chris Standaert: Yeah. And you get to do all that stuff you can do, which is sort of what Michelle did, and you can sort of imply the alarm stuff by just saying for patients with uncomplicated presenting symptoms of whatever and let the state define uncomplicated, whatever that is. Then you get into these vagueries. I see David shaking his head as to sort of what is the point of that, because we're not really defining anything anyway, and we're letting him define it, and it's all... it becomes a big jum... you know? I understand what he's saying. I'm comfortable with Michelle's language, but it's...

- Joann Elmore: Well the conditions specify what the compli... in a sense, with the complications when you say without alarm systems... symptoms I mean.
- Chris Standaert: Right.
- Kevin Walsh: I think if you... if you go back to the data, I mean, I think what we're seeing is that it's not better than... for diagnosing GERD... it's not better than a trial of PPIs or a trial of antibiotics for H. pylori, and all these circumstances we don't know. So, what we're basically saying with this type of, we're kind of, I think, swirling around, is that if we put that constriction on that it shouldn't be used because in the absence of other things it shouldn't be used. That's enough.
- Craig Blackmore: I mean, I guess to... my response would be two parts. One is that we've got information that it might be enough from our state quoters over here, and we can even ask them, and the second is I don't think we can go much further than that anyway. So, you know, I think we're either... my personal opinion would be we're either saying cover without conditions or we're saying cover in these vague terms, and I think given that we've seen evidence that these other conservative less-expensive strategies are equally effective in that opening setting, I think we're obligated to put those on as a condition. Again, that's an opinion and that's where I am.
- Marie Brown: I agree with that.
- Kevin Walsh: Me too.
- Craig Blackmore: Joann is chomping at the bit.
- Joann Elmore: Hmm?
- Craig Blackmore: Did you have something, Joann? You look like you're...
- Joann Elmore: Well, I'll make a proposal then...
- Craig Blackmore: Okay.

- Joann Elmore: ...for our group to consider. Looking on page 11, the state agencies recommendations, I would propose the following edits to this. Cover with conditions. The first would be failure of trial of medical treatment to improve or resolve symptoms. Now, I don't know whether we need to add the word medical, but that's one suggestion. For the second bullet, I would recommend editing it to presence of alarming signs or symptoms, period. I would not recommend the binary age cutoff, and I added in the signs, because that would cover the third bullet, which is all these objective upper GI pathology, which I don't think we had adequate evidence from our vendor to review at today's meeting, and I think that if we leave it as presence of alarming signs or symptoms, this leaves it to the clinician's expertise.
- Chris Standaert: That third category only unless people who have had an EGD.
- Joann Elmore: Right.
- Craig Blackmore: So, we're gonna...
- Chris Standaert: So that doesn't make sense in an initial presentation because you don't know any of that.
- Craig Blackmore: ...we're going to frame our decision as inpatients, which is however it says in the beginning. Inpatients with an initial presentation complaint of upper GI symptoms and/or GERD, which would exclude these people here anyway.
- Joann Elmore: Mm-hm.
- Chris Standaert: Mm-hm.
- Craig Blackmore: Okay.
- Joann Elmore: But I would... I would want it alarming signs or symptoms, because a patient could have lost 20% of their body weight and not have any complaints, but I could be very worried about them, so.
- Chris Standaert: Mm-hm.

- Craig Blackmore: So, where we are is we're hovering around what conditions might look like if we vote for coverage with conditions. Is there further input on what Joann is suggesting here around what these conditions are?
- Chris Standaert: Should there be a time for medical treatment? Six weeks, 12 weeks?
- Carson Odegard: No.
- Marie Brown: We don't have evidence.
- Joann Elmore: ...for a time.
- Chris Standaert: But then they're going to define it.
- Joann Elmore: That's right. They will.
- Kevin Walsh: Joann, I think you're making a proposal for initial EGD.
- Chris Standaert: Mm-hm.
- Kevin Walsh: Correct?
- Chris Standaert: Mm-hm.
- Kevin Walsh: But if you look at the wording because they add the third thing in, it covers repeat.
- Joann Elmore: Exactly. That's why I didn't know what to do with it.
- Kevin Walsh: No, so why not leave it in? Because so, take the patient who's had an initial EGD because they met the criteria and there's nothing found, and they're saying unless the patient has... unless the signs or symptoms have progressed, or there was an initial finding, which is what the third one states, then there's no basis for a repeat. So, what I'm saying is that this... if you looked at all three statements, it covers both the initial and the repeat scenarios.
- Joann Elmore: So, you would eliminate key question three, then, and we wouldn't need to answer key question three.

- Chris Standaert: He's saying this would answer key question three.
- Joann Elmore: This would, yeah, right.
- Chris Standaert: The other choice would be the separate statement saying...
- Joann Elmore: Right.
- Chris Standaert: ...repeat endoscopy is not covered for those with a benign... with no serious pathology identified on initial endoscopy and stable symptoms over time.
- Michelle Simon: And Kevin, I was sort of agreeing with the state agencies recommendations but wanting to simplify it and put it more in the clinician's hands, because I don't feel that we went over all of the evidence about all the GI pathology and repeat endoscopies today. So, that's why I said presence of alarming signs or symptoms so that an alarming sign could be objective findings of serious upper GI pathology in the past.
- Kevin Walsh: Okay.
- Michelle Simon: But then I also heard Craig say, well what about the... this is in the initial presentation. So, what is the stem of our coverage with conditions? What are the... what is the patient population that we're dealing with here? Adult patients with symptoms suggestive of GERD, sort of as a blanket, with acute symptoms suggestive of GERD? Or initial presentation? All right.
- Craig Blackmore: The initial...
- Woman: The initial PICO question says adults with initial presenting complaint of upper GI symptoms and/or GERD.
- Craig Blackmore: Okay, can I just stop for one second. Margaret, can I get your or Christine, or somebody to throw a slide up there that has the words on it so we can review it and we have a record?
- Kevin Walsh: While they're doing that, can I... there's just one group that I think we've not covered adequately in this discussion so far, and those are the patients that present with GERD, respond to PPIs but then

stay on PPIs for a long time, say two years, three years down the road. Their symptoms are the same. They're controlled with PPIs, but is there some role for endoscopy in those patients, or do we not need to worry about those patients?

Chris Standaert: So, this is such a... this is the trouble... this is what David brought up the trouble... the language. Do you say failure of trial to improve or resolve symptoms? So, if somebody stays on PPIs for three years, did they fail your trial, or did they do well with your trial? I mean, I don't treat this. I don't know. So, if somebody stays on PPIs for three years, is that a treatment success or is that a failure, because the problem never went away?

Kevin Walsh: Yeah, my understanding is that's a success. I mean, if their symptoms go away with treatment, even if you keep them on treatment, that's a... well, I guess I don't know for sure, but I mean, do you consider that a failure?

Joann Elmore: Yes.

Chris Standaert: See, he's shaking his head.

Drew Schembre: I consider it a failure.

Joann Elmore: I do too.

Kevin Walsh: Okay, a failure.

Joann Elmore: Because if you look at the indications for those drugs, they say they're not for prolonged use.

Kevin Walsh: Okay.

Joann Elmore: Although, when people do their own trials and they go off of them and then their symptoms come right back, they may go back on them. So, that's the most common scenario I've seen in primary care.

Carson Odegard: That's probably the reason for the five years. Probably, they're getting off of them and then going back.

- Chris Standaert: And then we're... but then we're hoping the state agency defines failure the same way that all of you just did as a clinician saying somebody who stays on it for two years is really failing PPI therapy. I mean, there's something else you're worried about.
- Carson Odegard: Mm-hm.
- Chris Standaert: This is not a successful treatment.
- Man: But the wording here says failure of a trial of treatment to improve or resolve symptoms.
- Kevin Walsh: Yeah, well, so if you do it and it improves it... is that...
- Chris Standaert: But they never come off.
- Kevin Walsh: But they never come off. Or even if they come off and then they come back, but that was still a success. I mean, they responded to the treatment. It's just vague. There's vagueries here that I think are.
- Joann Elmore: Sure.
- Kevin Walsh: I mean, I don't know... I don't think we... I don't know what the answer is. I just think that's there's a vaguery here about these patients that we don't know what happens, and if they are going on and off these treatments for a long period of time, could that be masking something else or not? I mean is it adequate to say...
- Joann Elmore: Well, that's what we asked the clinical expert, and according to him, there's... the risk for developing something serious like...
- Kevin Walsh: In the... in the presence of an EGD that was normal the first time.
- Marie Brown: Right.
- Kevin Walsh: But the question is, these are people who have never had one.
- Marie Brown: That's right. Okay.

- Chris Standaert: The people going off them, they do respond to them, but they come off then they get their symptoms again, they respond again, and they come off and they have an EGD.
- Seth Schwartz: Right, so they responded to treatment...
- Chris Standaert: It sounds like they should have an EGD.
- Craig Blackmore: So, I'm going to propose that we treat the initial separate from the... well no, never mind. Never mind.
- Seth Schwartz: I just think we need to come up with language to handle these patients is what it comes down to.
- Man: But the question, Seth, is when you say... when this says treatment...
- Seth Schwartz: Mm-hm.
- Man: It's not like putting someone on a beta-blocker, and it makes their hypertension better, so they stay on the beta-blocker forever. These drugs aren't meant to be used forever. So, if... if you improve over the course of two months on the medication and then we stop it and your symptoms recur, then the question is, is that... is it just EGD? Because it's not... the drugs aren't meant to be used forever.
- Seth Schwartz: Mm-hm.
- Kevin Walsh: Well, I think that's a reasonable statement, but then, but if you're cons... so, would you consider that a failure of treatment if they respond to treatment, you take the treatment away, and then their symptoms recur. Is that a failure? I just... like to me that's a success if they respond to treatment, so I just don't know. I mean, and again, this isn't something I treat regularly, so I'm just trying to...
- Chris Standaert: And you're assuming the state is defining it the same way you are, which makes it... which makes me a little concerned that...
- Craig Blackmore: So, give me words.

- David McCulloch: Craig, I don't think there are word. This is the most... I mean, these are, we're going through this academic exercise of parsing out words, and these are no conditions. I mean, failure of a trial of treatment, what TUMS? Yeah, I've been taking TUMS for about two weeks, it's no better. Okay, you can have an EGD, or do we need to define what needs to be either ranitidine at this dose for this amount or a PPI? I mean, I just think there's no way we can do that.
- Craig Blackmore: But there's an implementation process here. You know, it's not our job to say 15 versus one.
- David McCulloch: I'm trying to save the state from themselves, I guess.
- Craig Blackmore: That's not our job. That is not our job.
- David McCulloch: Other than you say, we would cover an upper GI endoscopy unless you call and justify it to somebody... 1-800 number because in treatment... to improve... well how much improvement? Well what do you think Mrs. Hernandez? Resolved well? It's... I mean, I just think it's so vague.
- Chris Standaert: If we don't define their reasons, we'll define it or the state will define it, and that becomes our... this is always our dilemma. So, our language, the better we define it, I mean, we seem to know what we think we want to say, but can we say that in a way that really translates so that when the state or the regions, whoever defines this, they're really capturing what we're trying to say here. I mean, that's our dilemma, and that's where ... does the language trap us more than help us?
- Kevin Walsh: I mean, there's two risks we run. One is that the payers define it too loosely so a couple of days of TUMS and doesn't get better is enough to clarify. I think more than likely the burden's gonna be the other way. That they might have a very stringent requirement for what that equates to, and I think from what I'm seeing in the data I don't have any problem with that. I think it can be as stringent as it needs to be.
- Michelle Simon: I think we do have a suggestion for what it is. It's the test and treat. Test for H. pylori and then do a PPI trial. No one's talking

about TUMS in the research that we've seen, so far. So, I think we can be fairly specific if we want to be.

Joann Elmore: I'll recommend words.

Craig Blackmore: Thank you.

Joann Elmore: The stem at the beginning, I would get rid of the word initial. I would propose...

Craig Blackmore: Yeah, you can't get rid of... well...

Michelle Simon: Mm-mm.

Joann Elmore: Well, among adults with presenting complaints of upper GI symptoms and/or GERD.

Craig Blackmore: Okay.

Joann Elmore: That would be among adults with presenting complaints of upper GI symptoms and/or GERD.

Chris Standaert: Well, yeah, you can't get rid of initial because then you have this problem of recurrence. So, if somebody comes back and they've had multiple symptoms, they had multiple courses of treatment, they'll keep responding to the PPIs, and they can be cut out, because they're presenting with it, and you treat them, and they get better.

Marie Brown: Or they go to a different provider.

Chris Standaert: But then they present next year with the same thing.

Joann Elmore: But then that's an alarming sign or symptom, and you leave it... I would rather leave this in the clinician's hand, and so then the two that I would recommend are cover with conditions, failure of trial of medical treatment to improve or resolve symptoms, or presence of alarming signs or symptoms.

Marie Brown: I don't know. There's something that makes it more... that makes it clear to have initial in there.

- Joann Elmore: How do we deal with the...?
- Marie Brown: Because, they'll repeat... is just such a... repeat symptoms is just a different...
- Man: [inaudible].
- Marie Brown: Yes. Different.
- Craig Blackmore: So one could add at the first bullet failure of trial of medical treatment to improve or resolve symptoms or continued symptoms. I don't know.
- Joann Elmore: I like having initial, but then you can't have the third bullet.
- Marie Brown: Right.
- Joann Elmore: And then we also need to have a separate addressing key question three, this bit about repeat endoscopy if you want to... and I think adding initial is helpful here, and having those two bullets, but then we have not... we will need to separately address key question three.
- Marie Brown: Right.
- Kevin Walsh: The other thing you do is under that failure of trialed medical treatment to improve or resolve symptoms, you could put a parenthetic... parenthetical statement, which simply says recurrence of symptoms after cessation of treatment indicates treatment failure, or something like that.
- Marie Brown: That's an interesting idea.
- Kevin Walsh: I mean that's...
- Craig Blackmore: So, let's ask the agency directors, since they're here, what are your thoughts on the ability to implement a decision that we're sort of working around here?
- Steve Hammond: This is Steve Hammond. I will comment very briefly and then maybe invite Dr. Nobuhara to comment, if she wishes to. I think there would be some value in setting some guidelines on when

upper endoscopy is appropriate and warranted and covered, and leaving most of the details of implementation to the agencies. I don't think we should assume that if there are conditions for coverage that it would necessarily require a full prior authorization process and, in fact, with the volume of these being done, that would be a serious challenge to agency resources. But, there can be an expedited prior authorization process, for example, that simply sets standards. I do think, and I just looked at our recommendations, and it really was not... did not specifically address repeat endoscopies, and I think that some comment addressing that could be helpful, but since this is a much larger issue for Medicaid, I'll ask Dr. Nobuhara if she would like to comment.

- Kerilyn Nobuhara: Yeah, Kerilyn Nobuhara from Washington Medicaid. I agree with Dr. Hammond that we could probably implement this via an EPA process. My one concern is that PPIs are not the preferred drug for treatment of GERD for our clients. It's actually the H2 blockers, and we do have a pharmacy policy that limits PPI use to 90 days. So, we would prefer that any specific pharmacy intervention be left to agency discretion.
- Craig Blackmore: Yeah, it's worth pointing out that the state has a separate committee that deals with issues of drugs and...
- Marie Brown: Which drugs?
- Craig Blackmore: ...pharmacy, and our process is focused on technology. Obviously, things get muddled, but we should try to leave that to the pharmacy committee.
- Marie Brown: Which is, medical management does that... using the word medical management does that.
- Seth Schwartz: Just one comment on the last sentence we have up there... findings of serious upper GI pathology. What... I think serious is kind of a vague word, and I'm not sure what is meant by it.
- Craig Blackmore: Well, if you just say upper GI pathology, that means GERD.
- Marie Brown: Right.

Craig Blackmore: Doesn't it? I mean, this is all vague. This is all... it's going to be a process of implementation that we're not going to get into the details of.

Seth Schwartz: But could serious just mean bad GERD?

David McCulloch: Maybe we should say really serious. And do we need to put in the word adequate failure of an adequate trial of medical treatment?

Chris Standaert: I mean, it's... I'm sort of... I don't usually go this way, because I like language, but I'm sort of agreeing with David here that trying to define this. I don't treat this, so I'm trying to define this, and I'm trying to read what you're trying to say in this and how this would be translated, and I have difficulty, because the studies really talk about six or 12 weeks of treatment, but we don't mention time, and we probably should. Recurrent symptoms, different presentations, alarm signs and symptoms, a very vague phrase. I don't really know what that means. Objective serious upper GI pathology. I don't really know what that means. So, you have three criteria that are very vague and ill-defined. Again, if we are vague in our language, someone is going to define it, and I am not totally convinced that it will be defined the way that we, as clinicians, want it to be defined if somebody's defining it for us. Although I totally agree that clearly this is not a good approach. There's no indication for doing a GERD for the initial presentation... somebody walks in with reflux, there's no reason to scope them that day. Clearly, you should try something else. The literature clearly says that, and I totally agree, but I really wonder whether we're helping or hurting by trying to sort of parse this out, personally. Because, I'm just, actually I'm trying to read the language you're writing, and I read it, and I really don't know what you're saying. I understand what you're trying to say, you know what I mean?

Craig Blackmore: I think, I guess I would say if the intent is there, then the implementation will reflect that intent, and I'm willing to give them the benefit of the doubt on that, personally. And I don't think, you know, I'm stuck in this place. I can't vote for coverage without conditions, because we know that... we have data. You shouldn't just do this on everybody, and at the same time I don't think it's... I don't think we're going to get anywhere trying to be really precise on these conditions. So, although this is not

satisfying in some ways, I think it kind of... I think it's where we end up.

Michelle Simon: I want to say two things. One, I don't think we can say that if the intent is there the implementation will follow, because I think we just... we know from past experience that isn't always the case. You know, lumbar fusion for example. We know that the usage of that went up and that was not our intent. So, I would say we need to be as clear as we want to be on this topic. But that said, I would rather be, like I said before, instead of defining the conditions, say for initial presentation of uncomplicated dyspepsia or GERD... period. That's kind of how I feel.

Chris Standaert: It's easier.

Craig Blackmore: Without the bullet points at all?

Michelle Simon: Yeah, without them.

Chris Standaert: She's doing the out... like the inverse of this is what she's trying to say. That rather than define the conditions say, you know, she's doing the... sort of the inverse of this, a mirror of what this is, which is simpler.

Joann Elmore: It's using a vague word in the stem.

Michelle Simon: Right.

Chris Standaert: For what it is... for what is not concerning rather than a lot of words for what is concerning. She's trying to find what... use a vague word for what is not concerning.

Kevin Walsh: So that would be a no coverage, right?

Marie Brown: No, it would be coverage.

Craig Blackmore: No, with conditions. You still use...

Kevin Walsh: In initial patients with uncomplicated GI, you don't cover it. Or with uncomplicated GERD, we're not going to cover it. That's what you're saying, right?

- Michelle Simon: No.
- Carson Odegard: Are you eliminating the...
- Michelle Simon: It's covering for that.
- Carson Odegard: ...for the bullet points. She's just changing the wording of the sentence.
- Joann Elmore: Maybe we have to keep them then.
- Kevin Walsh: Is your point that those bullet points define complicated?
- Michelle Simon: No. I'm saying get rid of the bullet points.
- Kevin Walsh: That's what I'm saying. So, you're saying get rid of the bullet points. Then, the point... then the statement would read among adults with initial presentation of uncomplicated GERD, it's not covered.
- Michelle Simon: It is covered. That is the one condition.
- Kevin Walsh: Uncomplicated. Then you're giving it to everybody. It would be complicated.
- Carson Odegard: Right.
- Chris Standaert: Well, that's our condition, that it's not covered in these. Our condition is it's not covered in patients who have uncomplicated symptoms.
- Joann Elmore: But then you have to define...
- Chris Standaert: No. She's just saying leave it there and let them... let whoever wants to define uncomplicated.
- Michelle Simon: I'm saying let them define it.
- Chris Standaert: Because you're trying to define complicated.
- Michelle Simon: We're trying to define what complicated is.

- Chris Standaert: Right.
- Michelle Simon: And I think that's a bigger nut to crack then...
- Carson Odegard: Yeah, because otherwise you're going to go down the Aetna route and you don't want to go there, because that would take you forever.
- Chris Standaert: Part of the trouble with the Aetna route is we don't have the data to disagree with the Aetna policy. We didn't look at surveillance and things they looked at. We don't have data on that, so we can't just follow them.
- Craig Blackmore: Okay.
- Steve Hammond: Dr. Blackmore, can I make one comment on behalf of the agencies?
- Craig Blackmore: Yes.
- Steve Hammond: Okay. Looking at the proposed language, I don't see that the question of repeat endoscopies is really directly addressed. Are you seeing that as outside the scope of the decision you've been asked to make or can we address that?
- Marie Brown: Isn't that key question three. It's key question three.
- Craig Blackmore: We haven't addressed that yet.
- Seth Schwartz: We're developing language for initial, not repeat.
- Marie Brown: Right.
- Seth Schwartz: And I think we've accepted the fact that we're going to have to now develop language for repeat.
- Craig Blackmore: I don't...
- Joann Elmore: This may be the difference in which one has the less harm with it, to put uncomplicated in the stem, which is vague, or to have two vague, or three vague, bullet points underneath it. But they do,

the bullet points do point in the right direction, and it is a little more specificity than the word uncomplicated.

Seth Schwartz: Think about it this way. What if the first statement was speaking to the initial... to a first time EGD, okay? And then the...

Kevin Walsh: The first bullet or the first line?

Seth Schwartz: The first two lines. The first statement is meant to address initial EGD. The next three could, with a little tweaking, be used to cover repeat. In other words, in order to have a repeat EGD, you would have to have, and then we could say development of alarming signs or symptoms or previous objective findings of GI pathology on EGD.

Kevin Walsh: I think that's a different situation. I think what we've heard about repeat is one that there's virtually no evidence. Two, there's certainly no evidence to support doing it if the initial one is normal. So, I think in terms of repeat, the way I'm seeing it, would be something to the effect of it's... repeat endoscopy is only indicated if the initial endoscopy was abnormal or new concerning signs or symptoms have developed.

Seth Schwartz: That's what I was trying to say.

Marie Brown: Yes.

Seth Schwartz: I agree with you.

Craig Blackmore: So, to get back to this, I think we have to remove the word uncomplicated from the stem, because the question that's presented to us is not limited to uncomplicated. So, we have to kind of address the bigger group and then narrow it. We can't only address the narrower group.

Marie Brown: Right.

Craig Blackmore: I think, because, you know, we're given the population of adults with initial presenting complaint of upper GI symptoms. We're not given the population of adults with an initial presenting complaint of uncomplicated. So, I think we have to render some sort of decision on complicated. Now, we can have a separate

statement that says it's covered for complicated, but we have to, on some level, address that.

Seth Schwartz: No, you don't. No. If you just say, I mean if you want to say it the way they say it, you say unless the patient has complicated symptoms.

Craig Blackmore: Well, we can say that instead of the three bullet points. That's another approach, but I think in the stem we have to say... the stem has to address the bigger group, and then we have to pull out the complicated versus the uncomplicated, and we can either do that by saying complicated or we can do by saying three bullet points, or we can do it by saying 50 bullet points that define symptoms.

Joann Elmore: And it seems like in the evidence we saw, the language of alarm signs or symptoms is more often used than the word uncomplicated or complicated. I think we have, even though it's not defined as well.

Kevin Walsh: I tend to agree with that. I think that alarm symptoms, while it's vague, is at least a commonly used term. I would argue that we could get... if we're going to have a separate statement about repeat, we could get rid of the third bullet point, because I think it really only refers to those patients.

Marie Brown: Right.

Kevin Walsh: And I think to address David's concerns, it would make sense, although it's equally vague to say, failure of adequate trial of medical treatment, because that, at least, puts some hedge on taking a couple of TUMS.

Michelle Simon: Right. Good, adequate.

Joann Elmore: I agree, yeah.

Michelle Simon: So, put the word adequate before trial. Failure of adequate trial.

Craig Blackmore: First bullet point, failure of adequate trial.

- Joann Elmore: And while she's typing, I have a question for the group in hopes that you can fix a grammatical issue in the stem that has bothered me. GERD is a diagnostic term. Patients don't usually present with complaints of GERD.
- Craig Blackmore: Complaints of upper GI symptoms or consistent with GERD is how you have to put.
- Joann Elmore: Thank you. Okay. Or symptoms consistent with GERD. So, in front of GERD put or symptoms consistent with. Thank you.
- Seth Schwartz: What's upper gastrointestinal symptoms, then?
- Craig Blackmore: It's the population we're studying.
- Seth Schwartz: Could we just say complaints?
- Chris Standaert: Could we say presenting complaints consistent with GERD? Is that... are we talking about GERD patients? Is that all we're talking about?
- Craig Blackmore: I don't think that's all we're... we're also talking about, you know, heartburn or...
- Joann Elmore: Dyspepsia, heartburn, silent reflux.
- Chris Standaert: But isn't heartburn a symptom of GERD?
- Craig Blackmore: Uh, sure.
- Joann Elmore: Once you differentiate it's GERD from cardiovascular.
- Craig Blackmore: It's not all [inaudible]. Okay, so for adults with a previous space... that might read previous endoscopy, I guess.
- Marie Brown: Yes.
- Craig Blackmore: Upper endoscopy?
- Marie Brown: Mm-hm.

- Craig Blackmore: Okay. So, we're all, I think, trying to get to the same place, and we have some philosophical differences around how much responsibility we leave to the agencies and how much we take on ourselves and how much we leave to the gastroenterologist and how much we leave to the primary care doctors, but I think philosophically we're converging, and so, though we may not be 100% on agreement in the level of specificity conciseness we used to define these conditions, can I get a feeling from the committee that this is reasonable? I think there's probably ten different perspectives on how they would phrase it, but is a reasonable capture of where we want to be?
- Seth Schwartz: What's written up here?
- Craig Blackmore: Yes.
- Seth Schwartz: Well, don't you want to say for adults with a previous normal upper endoscopy?
- Craig Blackmore: No. If they had one and it showed something, they can have another one.
- Chris Standaert: And [inaudible] change of symptoms on that last one too, because changing symptoms is a prior indication for a repeat upper endoscopy.
- Seth Schwartz: That's my whole point. If they didn't have a normal endoscopy, we're not addressing them.
- Craig Blackmore: Oh, so this is backwards.
- Seth Schwartz: We're addressing people who had a normal upper endoscopy the first time. Is there... and what we're being asked is, is there a place for them to have a repeat.
- Craig Blackmore: So, that bottom line should be... so the bottom line is the repeat.
- Chris Standaert: Adults with a previous normal upper endoscopy is covered when there is a concerning change in symptoms or something like that, because that's our indication, yes?

- Seth Schwartz: Well, if that's the wording that has to follow, but we're not... what I'm saying is we're trying to distinguish the group of people who had pathology on the initial endoscopy from the people who didn't.
- Craig Blackmore: But isn't objective findings of serious upper GI pathology? So, it's only covered... if you've already had one you only get another one if you've got serious upper GI pathology.
- Marie Brown: Yeah, so it would be and. You'd put and after endoscopy for adults previous upper endoscopy and objective findings of serious GI pathology.
- Craig Blackmore: No. I think it would...
- Seth Schwartz: Wouldn't it read for adults with a previous endoscopy, repeat endoscopy is covered with the condition of objective findings of serious pathology or new concerning signs or symptoms was the other one we talked about.
- Chris Standaert: So, for adults with an upper endoscopy for signs and symptoms of GERD? Because, I think what they're saying is you're talking about two different populations, because we're only supposed to be talking about the population of people who presented with reflux symptoms. Yes?
- Seth Schwartz: Oh, I see.
- Chris Standaert: And now we're talking about anybody with a previous upper GI, which is different than our initial population. Isn't that what you're saying?
- Craig Blackmore: So, this is of the patients who initially presented with GERD and they've already had a previous, can they get an endoscopy, and the answer is only under the conditions of an objective finding of serious upper GI pathology, and now I'm hearing a change in symptoms.
- Chris Standaert: But we can just put in a bullet point saying repeat endoscopy is only then covered for those with an abnormal initial endoscopy or...

- Craig Blackmore: I don't want to say abnormal, because abnormal can mean, you know...
- Gary Franklin: I'm sorry, it's Gary. I think all you need to do is repeat the terms that you used in the first statement above. So, for adults with a previous upper endoscopy for an initial presenting... for initial presenting complaints of upper GI signs or symptoms. Otherwise, you'd want the same population. So, you want to repeat those words down below.
- Craig Blackmore: Can you make it so, Margaret?
- Gary Franklin: So, after endoscopy add that there.
- Marie Brown: How can you have initial presenting complaints and?
- Craig Blackmore: That's historic. That's how they initially present.
- Seth Schwartz: Well, patients with a prior endoscopy or those...
- Chris Standaert: You could just put a bullet saying repeat endoscopy for these patients is only covered in... so get rid of that whole thing and put a bullet point saying repeat endoscopy in this population is only covered for those and then define that.
- Joann Elmore: What evidence are we using for this repeat? The evidence vendor gave us a single reference... Westbrook 2005 N of 302. I'm a little unclear what we're basing this on.
- Craig Blackmore: So, we...
- Joann Elmore: It's sort of common sense, but...
- Craig Blackmore: We understand from the evidence vendor that we have the evidence. Now there may not be any of it, but we have it, and so we're making a decision based on that. I don't think anybody... well, I don't know.
- Seth Schwartz: And to further... to further complicate...
- Joann Elmore: I'm just trying to say we have inadequate evidence to make a comment on repeat.

- Chris Standaert: The choices are either... the choice is either the lack of evidence tells us there's no evidence to support the use of it or the lack of evidence tells us we shouldn't really comment, because we don't really know.
- Joann Elmore: I think we shouldn't comment.
- Chris Standaert: You have to pick one of those two.
- Craig Blackmore: We are asked to comment. We are asked to look at the evidence and make the best determination we can. If there's no evidence, then we can look to expert opinion or whatever, but we're asked to answer this question. We can make a decision that we will not place limits on it. We can say repeat endoscopy is covered regardless of... under any circumstances, but we have to make a decision.
- Joanne Elmore: Can't our decision be that there is inadequate evidence for us to make any specific comments?
- Chris Standaert: You could say at the discretion of... I think what Craig is saying is that you have say something. So, you could say we won't limit or do it at the discretion of the treating physician, or something like that. We could not regulate.
- Craig Blackmore: We can cover, cover with conditions, or not cover.
- Michelle Simon: I'm not sure we have inadequate evidence. Could I ask the evidence vendor to speak to that, about the repeat endoscopy? Is it just that one Westbrook study or, I thought there was another one?
- Robyn Liu: That one Westbrook study was the only one that we found to address key question three specifically using our PICO exclusion criteria.
- Chris Standaert: But this is...
- Joann Elmore: But, criteria is limited to the articles related to this topic.
- Chris Standaert: Right.

- Robyn Liu: Related to right repeat endoscopy. So...
- Chris Standaert: This is one of our problems, that the PICO table sort of didn't cover our question very well, and maybe there's no evidence, but maybe we didn't look.
- Craig Blackmore: Again, you...
- Robyn Liu: So, I don't know. The clinical expert may have knowledge of other studies.
- Craig Blackmore: No. I want...
- Robyn Liu: We've already weighed in on that.
- Craig Blackmore: I want... I want to hear again, because I thought I heard before that you looked for every article on repeat endoscopy in people who do not have Barrett's, cancer, etc. So, among the people with uncomplicated, if you will, absent alarm symptoms, whatever, among that group of patients you have given us all the data.
- Robyn Liu: I have given you the one study that our search strategy turned up, yes.
- Craig Blackmore: So, there's data out there on repeat endoscopy for Barrett's, but we don't care. That's not our question.
- Michelle Simon: That's not our question.
- Marie Brown: Right.
- Chris Standaert: No. She just said she gave you all the data for which their search strategy showed papers. That didn't answer your question, to my satisfaction personally, because I thought your question was excellent. Do we have the data to answer that question, and if our PICO table didn't lead us to the data, didn't create an appropriate search strategy to get to that question then we have a problem.
- Craig Blackmore: Then we'll ask it again. So, Dr. Liu, we're still struggling.

- Robyn Liu: Okay. Yeah, so... so, Heidi has clarified for me the search strategy excluded studies of... so if this study was done on... if the population identified for this study was people who had already had an endoscopy, we did not look at those studies.
- Joann Elmore: So, that's why I'm saying we should not address key question three, because we don't have the evidence.
- Craig Blackmore: So, that's a different scenario. I thought we had the evidence, in which case we have to render an opinion. If we... if that evidence has been excluded from the search, then we can't render an opinion on it.
- Joann Elmore: Thank you.
- Robyn Liu: So, yeah. So the study we had was people with an initial presenting complaint before they'd had an endoscopy who were then followed along and may or may not have had a repeat. But if the population in the study at the start of the study had already had endoscopies, that was excluded under the PICO.
- Craig Blackmore: Okay. So, therefore, we cannot make an evidence-based decision on repeat endoscopy. We don't have the evidence. So, we can delete the bottom bullet... the bottom paragraph.
- Joann Elmore: The stem.
- Man: Yeah. And then just put the objective.
- Craig Blackmore: And then...
- Chris Standaert: So, you'll have to add at the top of the stem upper endoscopy is covered for... is covered under the following conditions after the stem. Yeah.
- Marie Brown: That's good. That helps.
- Chris Standaert: And alarm signs... didn't you say alarming?
- Joann Elmore: I said alarming.

- Chris Standaert: Alarm is the word they keep using, but they talk about alarm symptoms not alarm signs. So, alarm symptoms or other concerning signs? Because you're adding the signs in, Joann. That wasn't in... the papers talk about alarm symptoms.
- Craig Blackmore: We can leave signs.
- David McCulloch: No, it... no, alarming sign is a 30-pound weight loss in the past...
- Chris Standaert: So, alarming signs or symptoms?
- David McCulloch: Alarming signs or symptoms.
- Joann Elmore: So, change alarm to alarming.
- Richard Phillips: Or you could put high risk, but that opens up a whole other.
- Michelle Simons: Can I ask the clinical expert if that makes sense?
- Drew Schembre: [inaudible] I had in this discussion, but thank you for asking me. They... with the words, they use alarm symptoms. That's a term to encompass dysphagia, weight loss, bleeding. So, I think for that portion of it, alarm symptoms is the proper verbiage, but if I can take two minutes to just completely back up. The incidents of reflux is growing with the growing population. So, some of this data with increasing use of endoscopy mirrors the increasing size of our population. Not just size, but size. So, some of that's not surprising. In addition to this, there has been a kind of a medicalization of heartburn as a condition. It's no longer just heartburn, it's a disease. So, the population is increasingly aware of complications of reflux, dyspepsia, for better or worse. You throw in a couple of celebrity diagnoses, and then everybody's concerned about esophageal cancer. That said, esophageal cancer is one of the most rapidly rising cancer in incidents in the United States depending on how you read the data, up to five-fold increase, since the 70s. Now, some of that is probably artifact of endoscopy, but it is rapidly rising, and there's growing awareness of this. In addition to that, up to 30 or 40% of people who have Barrett's esophagus have no alarm or alarming symptoms, which skews the indications to do an index endoscopy toward being more cautious rather than less cautious. So, with all of these concerns about what might be going on, plus increased patient

awareness and the relatively low risk associated with endoscopy, it strikes me as a bit excessive to put a lot of restrictions on a procedure that is, for the most part, being used appropriately, but that's not the purview of, or the questions being asked of the committee. But, I would strongly caution against some of the restrictions that might be put in and misinterpreted and deny kind of access to the population that's actually who needs these screening procedures or these endoscopies most, which is some of these Medicaid patients who nobody wants to do endoscopy on anyway, because they're most of the gastroenterologists are losing money to do that endoscopy in the first place. So, you make it more difficult, they're not going to get, they're not going to get the procedures.

Craig Blackmore: Thank you for your opinion. Okay. So, we've removed the repeat endoscopy from the table, because we don't have the ability to comment on that. Further discussion of the list?

Chris Standaert: That should probably go to alarm symptoms or...

Marie Brown: Alarm, yes.

Chris Standaert: Alarm symptoms or... so would the clinicians help me with... concerning signs? I mean, are you looking for physical... physical signs that are... that trigger you at whatever word you think would work for that.

Joann Elmore: It seems like symptoms would be adequate... would adequately cover.

Craig Blackmore: Yeah. I think the intent is clear whether we say signs and symptoms and concern.

Joann Elmore: Yeah.

Craig Blackmore: Okay. So, I want to get to our decision tool, which is in the packet. All right. So, we turn to the HTCC Coverage and Reimbursement Determination Analytic Tool, and this is a tool used to help us work through the process of decision making. The first part of the tool outlines our responsibilities and the basic determination... the basic principle that our determinations are evidence-based, and they're based on the questions of is it safe, is it effective, and

does it provide value? Is it cost effective? And, the tool also includes relevant Medicare and other coverage decisions. We'll note that there is a Medicare national coverage decision, which is undated, which we've talked about. The staff goes through and pre-populates this document for us with outcomes that are potentially of concern, and so at this point in the process we look at the list of outcomes and determine if the list is comprehensive to include those that are relevant from the standpoint of the committee. For safety outcomes, the one listed here is perforation. Are there other safety outcomes we might add? I think probably...

Marie Brown: Anesthesia.

Craig Blackmore: ...anesthesia and aspiration and some of the associated risks associated with sedation. Any other outcomes related to safety that the committee thinks may be relevant? Next are the outcomes with respect to effectiveness and again, we have accuracy listed here, sensitivity and specificity. We have the effect on treatment planning, diagnostic yield, detection of cancer, and I would probably add cancer and precancerous conditions including Barrett's esophagus and cancer prevention. Are there other outcomes that are relevant to the committee that we haven't included on the index? Considerations of special populations. We've discussed gender and age. We've discussed... well other comorbidities that are potentials here are comorbidities, things like BMI and then under costs the relevant outcomes.

Chris Standaert: We didn't get much into the Asian origin issue as a risk factor. So, that's a special population.

Craig Blackmore: We didn't get much into the Asian origin issue.

Chris Standaert: It seems to represent a distinct population...

Marie Brown: Right.

Chris Standaert: ...for the incidents of concerning disease in people with upper GI symptoms.

Marie Brown: Right.

- Woman: That could be the presence of an alarm symptom [inaudible].
- Chris Standaert: No, I'm just saying we... in going through our tool we have to recognize that as a special population that is...
- Joann Elmore: Or you'd have a higher index of suspicion. So, it may be asymptomatic. So, leaving it to symptoms doesn't always.
- Craig Blackmore: So, presence of alarm symptoms or high-risk group? Is that relevant? It's not a sign.
- Carson Odegard: We don't have any evidence.
- Seth Schwartz: We don't have the evidence.
- Marie Brown: Yeah, that's true.
- Craig Blackmore: It didn't... they excluded the studies on the population.
- Marie Brown: Right.
- Michelle Simon: It sounds like it may be only first or second generation.
- Carson Odegard: Yeah.
- Craig Blackmore: Okay. There's a separate issue of screening for cancer in Asian populations, which is clearly not the question that we're addressing today. So, I think we can safely pass that by. Okay, I'm going to get to the first voting question. These are nonbinding votes, and we will use our... what color cards do we have? Yellow cards, and this is the committee is giving their perspective on the question of is the technology effective, safe, and cost effective, and it will be the technology being endoscopy and the comparator would be treatment with medical management, whether it's test and treat or PPIs or H2 blockers or whatever. So, the first question is, is the... is upper endoscopy of unproven equivalent, less, or more effectiveness compared to the comparators?
- Chris Standaert: In terms of diagnosis we're talking about, or in terms of clinical evidence?

- Craig Blackmore: We're talking about in terms of clinical outcomes for individuals in their initial presentation with the signs and symptoms of GERD or however we phrased it up here.
- David McCulloch: I'm sorry, Craig. Among adults initially presenting with GERD.
- Craig Blackmore: Among adults initially presenting with presenting complaints of upper GI symptoms or symptoms consistent with GERD, upper endoscopy is equivalent more or less or unproven benefit compared to medical therapy.
- Josh Morse: I see ten equivalent... nine equivalent, one unproven.
- Joann Elmore: Two unproven.
- Josh Morse: Sorry. I'm sorry.
- Craig Blackmore: Safety.
- Chris Standaert: There are only ten... so that's eight.
- Craig Blackmore: There are ten of us.
- Josh Morse: Thank you.
- Craig Blackmore: So in terms of safety, same question.
- Chris Standaert: Can some... again with safety of medical management are the complications to the drugs?
- Woman: Yes.
- Chris Standaert: I don't know. To me, I don't know the safety of the alternative treatment, myself, and we didn't talk about that.
- Marie Brown: That's right, we didn't.
- Chris Standaert: So can...
- Craig Blackmore: Which is why I'm going for unproven.
- Marie Brown: Unproven.

- Chris Standaert: Okay.
- Marie Brown: Yeah.
- Josh Morse: Well, everybody's unproven. Ten unproven.
- Craig Blackmore: And then we get to the question of cost effectiveness. Actually, I want to go with that. Go with this.
- Josh Morse: Unprovens. One, two, three, four proven. Thank you. Four unprovens, six less.
- Craig Blackmore: Okay. So, is there further discussion, at this point, based on what we now understand of the committee's perspective on these issues, or shall we proceed directly to the coverage vote.
- Joann Elmore: I think we can proceed.
- Craig Blackmore: All right. We're gonna proceed. So, there are three choices. The first choice is that we will cover upper endoscopy unconditionally among adults with initial presenting complaints of upper GI symptoms or symptoms consistent with GERD. The second choice is that we will never cover... or not cover... patients in that clinical scenario with GERD, and the third choice is that we will cover with conditions and through our discussion we have pre-specified the conditions to be as stated on the slide, failure of adequate trial of medical treatment to improve or resolve symptoms, recurrence of symptoms after initial treatment indicates treatment failure, or presence of alarm symptoms. So, now we will take the binding vote on the coverage decision.
- Josh Morse: One, two, three... nine cover with conditions, one cover.
- Craig Blackmore: So, by... according to the terms of our statute, we are required to either agree with Medicare national coverage decisions or specify why we disagree, and in this case there is a national coverage decision, which we've heard about, which is undated and questions were raised about whether it was an evidence-based decision. We do not agree with it. It's... I'm sort of reading it. It says "covered when reasonable and necessary for the individual

patient." I would suggest that we have done a comprehensive review of the evidence, much of which is presumably subsequent to this decision and are understanding of the evidence dictates that we differ from this Medicare coverage policy. Any comments on that from the committee?

Marie Brown: I think you could say that that previous statement was not specific, adequately specific, not that we have great lots of specificity ourselves, but you could say that there's adequate data to be able to give more specifics, like alarm symptoms.

Craig Blackmore: Okay. Any other comments?

David McCulloch: Let me just comment, Craig, since I am [inaudible] coverage with these conditions and [inaudible] have sort of flip-flopped, and I think, as I read that note, that's a very nice positive statement, which is in the spirit of what the evidence that we now have tells us. That's... a good ethical doctor would be doing an upper GI endoscopy under those circumstances, and stating that, if that gives the state then something they can fall back on and challenge discrepancies from good clinical practice, I'm fine with that.

Craig Blackmore: Okay. Okay, we... lunch is here. We will adjourn for lunch. It's now 12:05, and we are basically on schedule. We will reconvene at 12:45.

Joann Elmore: To start our second topic.

Craig Blackmore: To start the second topic. Thank you.

Well good afternoon everyone. It's quarter of one, so I'm going to call the session... call the meeting back into session. We have a quorum of the committee members. The next item on the agenda is our discussion of robotic-assisted surgery and the first part of that discussion will be for scheduled open public comments. We have had a number of individuals request time before the committee in advance. In addition, we have had a sign-up sheet outside. If there was anybody who showed up at the meeting that didn't let us know ahead of time, there's still the opportunity for you to speak to the committee. If there's anybody who had desired to address the committee but had neither signed up outside or notified us in advance, now is your

opportunity to get on the sign-up sheet that Josh has. Not seeing anybody else, we'll go with our list.

Okay. So, we're going to start off with the individuals who notified us in advance that they would like to speak to the committee. The format for this, if you could please identify yourself and tell us if you're representing an organization, a society, or a company or whatever and also tell us financial conflicts of interest. So, do you work for a company that has an interest, as somebody... do you receive any sort of money or compensation, or has somebody paid for your travel expenses, etc. Then, each of the presenters, we've got a 30-minute time allocation to make sure everybody has an opportunity, we're going to have to limit all the presentations to 3 minutes. If you had slides for us ahead of time, they should be preloaded. So, first individual identified is Kathryn Barry. Is she here?

Kathryn Barry: Yes, sir.

Craig Blackmore: There you are. Okay.

Kathryn Barry: Thank you.

Craig Blackmore: And we have Margaret... will it be Margaret? Somebody... or Christine has a sign for letting people know when they have a minute left or something. So we're going to have a sign or some sort of note to wave that you have a minute left so we can keep people on schedule. So, please.

Kathryn Barry: Thank you. My name is Kathryn Barry. I am the health policy consultant to Intuitive Surgical, and I have been since 2004. I am a reimbursement consultant in the medical device industry with a specific interest and expertise in minimally-invasive surgery, since the early 1990s with laparoscopic cholecystectomy. As Intuitive's consultant, I am paid a fee to provide on a daily basis accurate information and education to providers, payers, and patients about the health policy decisions that I have worked with AMA and CMS, as well as to be aware of policy decisions, as they are posted by leading payers across the county. I do not have an equity position with any of my device client companies.

I submitted a detailed comment to HTA on March 31st, but unfortunately, most of my comments are not fully reported in your final evidence report regarding codes, coverage, and reimbursement. So, I've left cold and chilly Connecticut to come to equally cold and chilly Seattle this morning in order to highlight for you information on the decision that was made by the AMA in 2007 to use existing laparoscopic CPT codes. Medicare's decision to create a new family of ICD-9 procedure codes for robotic-assistance in 2008, and most importantly what I find most compelling for my reason for being here today is to highlight to this panel the plethora of robotic-assisted payer policies that have been published, since 2005.

Contrary to your final evidence report, I would like to raise this panel's awareness to the widespread acknowledgement and acceptance of robotic assistance as integral... integral to the primary procedure, and I would like to leave for this panel a summary of payer policies so that you can flip through these pages and make a decision that impacts your beneficiary's access to advanced laparoscopic surgery here in the state of Washington. In brief, the following health policy decisions have been made, as summarized in this slide on the bottom. Number one: Per the AMA, the primary surgical procedure remains a laparoscopic procedure. Per leading payers, specifically Blue Cross/Blue Shield, plans all over the country, Cigna, United Healthcare, robotic assistance is integral to the base procedure, just like the trocar and straight-stick laparoscopic instruments, these are all tools that are not separately reimbursed. As a result, coding and coverage should be based upon the payer's established laparoscopic procedures.

There are specifics that I would like to share with you about the AMA. I'm certainly available after this meeting for full discussion and disclosure with regards to the AMA robotics workgroup. After two years of deliberate deliberations by the AUA and ACOG, it was determined that the primary procedure was a laparoscopic procedure and CPT codes that exist in the laparoscopic CPT sections of every surgical specialty should be used. I would also like to point out that numerous surveys have been done by the AUA, since the time of 2007, and as a result, in 2011 an editorial revision to bundle robotic assistance when performed was made to the laparoscopic radical prostatectomy CPT code.

After this decision in 2007, CMS in 2008 issued an ICD-9 procedure family for robotic assistance. In 2004, this silly code...

Craig Blackmore: Can I get you to sum up, please. We're going over time.

Kathryn Barry: Yes, sir. In 2004, this silly code of S2900 was issued by a local carrier, as a local carrier code to increase the reimbursement for laparoscopic radical prostatectomy. This was preceding the 2007 decision by AMA. Since 2007, all the leading payers have considered that robotic is incidental to the primary surgical procedure. I would highlight to this panel that this is just a sample list of payers who have issued payer policies and contrary to appendix I, page 350 in your final evidence report, I have a three-page summary table of payers that do identify robotic assistance, and they all say the same thing, as quoted here on the bottom of this slide. Any additional charges for robotic-assisted surgery...

Craig Blackmore: Okay, I'm sorry. We're trying to be fair here. We have to keep people on schedule. We explained that to you, and I'm going to have to move on.

Kathryn Barry: I appreciate that, sir, and I am available on this final slide for the panel to review.

Craig Blackmore: The next speaker I have is Douglas Sutherland. Is he here?

Mark Shelmire: I'm representing him today.

Craig Blackmore: Okay. Then please tell us who you are your conflicts, as we described.

Mark Shelmire: My name is Mark Shelmire. I'm an administrator at Multicare Health System based in Tacoma, Washington. Unfortunately, Dr. Sutherland is unable to attend today. He was on call and was pulled into surgery. So, in his words, thank you for holding this meeting. It is refreshing to witness an attempt to control the costs of health care based on evidence.

I do not plan to go through slides that hold data that, no doubt, you have already read. Rather, I will make four critical points. First, it is a complete fallacy that the robot is an unnecessary and

costly adjunct to straight laparoscopy. Most of the procedures I perform with the robot could only be accomplished via an open approach, and if attempted laparoscopically, the quality of the results would be greatly compromised. Therefore, this panel is really deciding between robotic and open surgery for complex surgeries.

Second, robotic surgery results in fewer complications compared to open surgery when performed by competent surgeons. There is no level one evidence to support this claim, and it is unreasonable to wait for level one evidence. We live in a society where the patients get to choose the modality of surgery they have. Therefore, level one data represented of the American practice will not come. Nevertheless, based on the best complications data this panel has to consider, you are making a decision between a high-quality approach in robotic surgery versus a low-quality approach in open surgery.

Third, adding a robot to the surgery does not automatically improve the quality of the results. Robotic surgery cannot be learned on the fly. It requires dedicated training with grueling oversight by expert robotic surgeons in consistent practice, no different than any other surgical practice. The promised results associated with robotic surgery requires high-quality surgical training.

Lastly, the robot is being overused. There is no question that several surgeries being performed now do not require the robot for quality results. These include cholecystectomy, ovarian cystectomy, and radical nephrectomy to name a few. However, refusing to pay for all robotic surgeries in response of this reality would be a blunt, ignorant response to cost cutting, in my opinion. In many cases, robotic surgery is the reference standard of surgical care. Reviewing individual procedures and determining the necessity of the robot a priority and verifying the ability of the surgeons, again, determined a priority, would result in both cost savings and would maintain the standard of care. Thank you.

Craig Blackmore: Thank you. Next on the list is Dr. Shah.

Chirag Shah: All right. So, I'd like to thank the committee for the opportunity to present my thoughts on what I think is a very important

decision. I'm a practicing G1 oncologist in a group of six G1 oncologists that provide the most comprehensive complex gynecologic and gynecologic oncology care to women in this state. We trained on the robot.

Craig Blackmore: Sorry. Conflicts of interest?

Chirag Shah: Oh sorry. I have no financial disclosures or conflicts of interest. I apologize for not bringing that up, sorry. I just wanted to present a recent publication that we have from our experience from our first thousand surgeries and highlight a quick kind of synopsis of why I think this is a relevant issue. This first slide just gives you a breakdown of the various numbers of diseases that we were able to treat with the use of the robotic system. The one disease site that we treat the most is endometrial cancer, which is the most common GYN cancer in women.

As you can see here, I think this slide most clearly illustrates some of the points that Dr. Sutherland just made in his discussions through his proxy here, but essentially, a year before we began robotic surgery highlighted in 2005 and 2006, less than 10% of our procedures were performed minimally invasively. By 2008 and 2009, this had increased to 36%, and we are in the process of collating these numbers... don't have them, but we think that's only increased. So, I think this really illustrates how traditional straight stick laparoscopy has been around for many, many, many years, and we were not able to apply it to our practice without this technology. This slide just illustrates two major complications... or two major areas where the robot improves outcomes, less blood loss, shorter hospitalization, which are highlighted there. The overall complication rate is illustrated here; 20% in an open historical cohort to 6% major complications in the robotic cohort, which is highly statistically significant. There are four other publications in robotic surgeries comparing them to the other option for endometrial cancer staging in this state in our group, which would be laparotomy. You can see a clear difference in the complication rates between open surgery versus robotics, and as I illustrated earlier, without robotics we were not able to get into the realm of minimally-invasive surgery.

So, in summary, the technological advantage allowed because of the robot allowed for widespread integration into our practice,

which did not occur with standard laparoscopy. As compared to traditional laparotomy, robotic surgery in complex gynecology and oncology leads to improved clinical outcomes. Fewer major complications, decreased hospital length of stay, and decreased blood loss. Thank you.

Craig Blackmore: Thank you. Next, Dr. Jim Porter.

Jim Porter: Thank you for inviting me to speak today. I'm director of robotic surgery at Swedish Medical Center. My relationship with Intuitive is as a trainer and proctor, and I am reimbursed for training. First slide, thanks. So, this is basically to show you that I did a lot of laparoscopic surgery prior to the robot, before my transition to robotic surgery, and had performed over 1,600 robotic procedures to date, and we are also a training center for robotic surgery.

I want to talk to you briefly about our data in our IRB-approved database from our first 1,200 robotic prostatectomy patients, and these are all my patients, a single-surgeon experience. The mean OR time, and this is including patients from the very beginning to the very end, is three hours, and I would tell you now, we're an hour and a half to two hours on average. One of the major advantages you've seen already with other procedures is lack of blood loss. So, our average blood loss is 187 cc. We have transfused a total of 11 patients, which is remarkable compared to the open operation. Patients go home quickly, as well; 95% of our patients are going home in less than 24 hours. This is a major savings for our hospital and for the patient. The catheter that is placed after prostatectomy historically stays two to three weeks. This is routinely removed in one week with the robot. Our positive margin rate, this is very comparable and actually better than open, and I've actually included a comparison slide to a physician, a very experienced open surgeon presenting a series in 2001 of 1,000 patients, and here's the comparison data between our series and theirs. So, length of stay improved, blood loss better. Transfusion rate better, and positive margin rate. So, we're able to do a good cancer operation, as well. Functional outcomes for prostatectomy are very important, and we use validated questionnaires both before and after surgery for these results. As you can see, our continence rate in our last 400 patients compared to the first is 91%. That means no pads

whatsoever. Our overall potency rate, comparing both bilateral and unilateral [inaudible] is 81%. How do these compare? Well, here's an open series from Memorial Sloan Kettering, as well as a laparoscopic series from the person who invented the operation, and you can see these are the results: blood loss, transfusion rate, continence, and potency all improved with the robot.

I also want to move onto partial nephrectomy, because this is a key operation, and this is removing the tumor and sparing the kidney, which has major implications for patient's survival. We know patients who have more kidney tissue into the future live longer. Laparoscopic partial nephrectomy was something I did and is a very challenging procedure, and this is exemplified by the best laparoscopic surgeon in the world presenting its first 800 procedures. His mean warm ischemia time was 565 in his first 565 patients with 31 minutes. We had a similar experience in our first 91 patients at the University of Washington. Our mean warm ischemia time was 35 minutes. This is the time the kidney is clamped during partial nephrectomy. So, we brought on the robot and what we found was almost an immediate decline in our warm ischemia time. So, our mean warm ischemia time now at 182 patients is just under 20 minutes, and for our last 20 cases, it's 15 minutes, almost half of what we saw with laparoscopic surgery. Again, improvements in blood loss and transfusion, our complication rate is very low, and we presented all these results as part of a multi-institutional study of robotic partial nephrectomy in European Urology in 2010.

So, comparing our results to those of Dr. Gill, you see the complication rate, transfusion rate, blood loss, and warm ischemia time are all improved with the robot. So, in conclusion, robotic prostatectomy offers clearly less blood loss, shorter hospital stay, and improved functional outcomes, and robotic partial nephrectomy is enhanced with shorter warm ischemia time and fewer complications. Thank you.

Craig Blackmore: Thank you, Dr. Porter. Next on our list is Dr. Curet. Sorry if I don't have it pronounced correctly.

Myriam Curet: Thank you. Yes, it's Dr. Curet. I'm the chief medical advisor at Intuitive Surgical who manufactures the da Vinci surgical robot. As such, I am employed by them and also hold equity in the

company. What I wanted to talk about today is the fact that you can't just take a snapshot of robotic surgery. It is a movie picture, and it's an ongoing phenomenon that's changing. You will see that adoption of the procedure of the use of this tool occurs procedure by procedure and different procedures adopt at different rates, and published data clearly lags the adoption.

I'd like to reinforce what Kathryn Barry said, which is the da Vinci surgical system is a surgical tool, a sophisticated tool, but a surgical tool. It's not a new form of therapy or a new surgical procedure, and there is no separate or incremental billing for robotics. I wanted to just show you over the past seven years what's happened with adoption. The blue circle here is prostatectomy. You can see adoption growing and now you can start to see cancer operations, hysterectomies. Coming up there, benign hysterectomies, sacral colpopexy is the light green and myomectomy. So, what we have most recently is showing it's adopted over time. So, you can't just at one point in time say this is where we are and now understand that it's an evolution, and that's the same thing that's happening with the data that's out there. These are all the procedures that have been done by the da Vinci surgical system.

The ones in red are the one where there was very low penetration of minimally-invasive surgical procedures before that, because they were complex, difficult operations to perform. So, the da Vinci surgical tool has enabled patients to have a minimally-invasive approach when otherwise they would have had an open approach. The point that I was trying to make about the literature is just in the last few months, since the cutoff date for the literature review for this health technology assessment, there has been a number of [inaudible] there that I wanted to summarize for you. This one by Dr. Lao, et al., in obstetrics and gynecology looked at cancer operations with the robot versus a historical control of open and laparoscopic. You can see that there was a 27-minute increase in OR time, but despite that, complication rates, blood loss, hospital stay, and short-term cancer recurrence rates were all better with the system. Likewise, cost both with or without amortization of the acquisition costs were lower for the robot because of the decreased hospital stay associated with the procedure. Dr. Siddiqui, et al., in the American Journal of OB/GYN looked at one-year outcomes after robotic and abdominal sacral

colpopexy, functional outcomes as identified by symptomatic and anatomic failures were equivalent between the two groups, but you can see here, again, less blood loss, less wound problems, less fever postop, and less ileus postoperatively associated with the robotic cohort.

A meta-analysis recently published in European Urology did propensity scoring and compared open laparoscopic and robotic prostatectomy. Again, you can see a lower positive surgical margin rate for the robotic group, lower blood loss, lower intraoperative and perioperative complications, and a shorter length of stay in this meta-analysis and propensity scoring. Another article... I'm sorry... this didn't move forward... that looked at the nationwide inpatient sample that had approximately 40,000 patients in it did propensity scoring on these groups and, again, with the robotic less blood loss, less transfusions, lower rate of intraoperative complications, and overall postoperative complications, as well as lower cardiac and respiratory complications, and a shorter length of stay in the robotic group.

And then, one final study looking at 100% Medicare sample rate looking at patients who had open or a minimally-invasive prostatectomy, the majority of which were done robotically, lower blood transfusion rates, lower intraoperative and perioperative complications both overall, as well as for each individual complication, and I think very significantly a three-fold higher rate of mortality if you have an open prostatectomy than if you have a minimally-invasive prostatectomy. Long-term complications followed the same pattern with anastomotic strictures, ureteral complications, and lymphoceles being less common in the robotic group.

So, in conclusion, I want to say that robotic surgery has been adopted across numerous surgical procedures, and the standard of care is already robotic surgery for many urologic and gynecology procedures. The data is lagging behind the procedures, but as you can see, there has already been a number of high-quality publications just in the last few months demonstrating the value of robotic surgery. Thank you.

Craig Blackmore: Thank you. Next on our list is Dr. Lenihan.

John Lenihan: Thank you. To the committee, I'm John Lenihan. I'm an OB/GYN. I'm the medical director of robotics and minimally-invasive surgery for Multicare Health Systems. I do proctor and teach for Intuitive Surgical for which I get paid. I wanted to briefly, everybody's shown you data... I just want to explain to the people here what robotics has meant to not only myself and surgeons like me but to our patients in Tacoma.

Robotic surgery has been described as disruptive technology. Disruptive technology is a term that was coined by an economist in an article in 1995 called *Catching the Wave*, and it describes new procedures or new technologies that totally disrupt the way things are happening. For example, gun powder disrupted the technology of bows and arrows and changed warfare. Cars disrupted the technology of horses and changed transportation. Chloroform is a medical anesthetic device that disrupted medical treatments so now we could people to sleep, and robotic surgery is a similarly disruptive technology.

Its growth has taken off like smart phones and cell phones have, which have replaced our old phones. Clear benefits you've heard today from the other speakers, the lower blood loss, shorter hospital stays. The women who fill out surveys to look at what they want out of medical treatments, Harris polls, Gallop polls, consistently the number one thing that women want from their therapy is to be cured and the number two things is to return to normal faster. Robots, as you've seen from the other data, certainly meet this. Benefits to the surgeon are also important, because surgeons now can have all this computer enhancement that enables them to do surgeries in an easier way. There's choices for surgeons. Surgeons do not get paid more for doing a robotic procedure. As a matter of fact, if I was to do an abdominal procedure, I'm going to get paid more, because the RVUs are covering me for all my rounds and postop care, so I'll make about 30% more for doing a robotic procedure.

So, I have a choice as a good surgeon of offering my patients an open procedure, a laparoscopic procedure, a vaginal procedure, or a robotic procedure. My practice is now almost 99.9% robotic. In our hospital system, we have about 45 OB/GYNs. Of them, 23 are trained on the robot. Those 23 OB/GYNs can offer their patients surgery with any of the techniques I just mentioned.

Guess what, those robotic surgeons offer robotic surgery to those patients, over 96% of the time. So, they have abandoned laparoscopic and vaginal and open surgeries, why? Because of better outcomes. They see that their patients are doing better. They see how they recover. They see how they get back to normal.

This is... one of our plans in our hospital was to try to lower the abdominal incision rate for hysterectomies across our three-hospital system. You can see when the robot was introduced in 2005, second and third robots came in 2007 and 2009. We've dropped our abdominal incision rate to under 10% for three hospital systems. Around the rest of the country, including south King County and Oregon and other places, the abdominal incision rate's still 60-70%. So, the patients in Tacoma now can have more minimally-invasive therapies. The future of robotic surgery is basically... it's a computer so the visualization things that are coming in the future are amazing. We can see around corners. We can see in the dark. We can see through walls with fluorescent imaging, with infrared imaging. We can see things that open surgeons just can't see. So, this is clearly disruptive technology. It's here to stay. It's better for our patients, the surgeons like it better, and the surgeons who can choose, choose to do robotics. Thank you.

Craig Blackmore: Thank you. Next, Dr. Jarris... sorry.

Ray Jarris: Hello. My name is Ray Jarris. I am an emergency physician at Swedish Medical Center, and I'm speaking to you today as a patient, and I'm going to have read quickly if I may. I have no conflicts of interest other than I work at Swedish Medical Center. Members of the committee, my story is very personal and one of a prostate cancer patient who is also a physician. Like many, if not most men, the thought of prostate cancer evokes fear and unfortunately leads to denial and avoidance of the fact that one in six of us will be diagnosed with this disease. Despite being a physician and understanding the surgery for prostate cancer has progressed significantly in the past 30 years, since graduating medical school, my fear of incontinence and impotence was still overwhelmingly very real. I had chosen to follow the U.S. Preventive Services Taskforce Guidelines for my care and had personally not participated in PSA screening.

In 1995, I was reviewing hundreds of health screening results annually for different groups of firefighters. Not thinking much of it personally, I had a PSA added to my cholesterol screen and was shocked when I was advised from my internist of the results. After hearing 9.7, which is far above normal, I collected myself in the middle of a busy emergency department shift and contacted a trusted urologist for follow-up post-haste. The results of the evaluation were reassuring and denial, again, became my preferred fear-based strategy.

Fast forward to just before Christmas 2010. My brother calls. Paul's two years younger than I. Not only is he a family physician, but he is also the former commissioner of health for the State of Vermont and presently the executive director for the Association of State and Territorial Health Officers in D.C. Paul has espoused and personally followed the findings of the U.S. Preventive Services Taskforce, as well. However, his life insurance company did not. After an insurance exam, he was advised that he had an elevated PSA. He sought out the esteemed Dr. Patrick Walsh at John Hopkins. You may recognize the name as in the neurovascular bundle of Walsh, delineation of which marked a critical advancement in the modern approaches to nerve-sparing radical prostatectomy. Paul's biopsies were positive for prostate cancer. My risk of prostate cancer was very real and no longer was denial a viable strategy for me. The fear of loss of intimacy, continence, and a sense of good health came to the forefront of my days and disrupted my sleep.

I believe in the rigor of medical science and the advancement of technology. Reassurance is offered from colleagues in the know, and a friend I had referred to Swedish for robotic radical prostatectomy several years ago. His life is good. His recovery was quick and easy. His wife has a broad smile on her Facebook postings of their adventures in the backcountry of Alaska. Paul's surgery was successful. He spent one night in the hospital and two in a nearby hotel for follow-up. His blood loss was substantial. He takes four weeks off work and is challenged by the pain and management of his abdominal incision. He wears a catheter for two weeks.

March 3 arrives. It's my turn. The day to be the patient is surreal. I let it go and followed the process. It is not quite possible for me to grip that this is for real. This is my cancer, and this is my life. In the recovery room, my first question to my friend and anesthesiologist was, "Did they spare the nerves?" And he chuckled nervously while seemingly to fear for his own manliness and kindly said, yes.

Vaguely remembering the next few hours, I recall a visit by Dr. Porter with good news, and the remaining possibility of returning to surgery the next day should the pathology report suggest extension of the cancer beyond the capsule. The opportunity to return to the operating room the next day is an important benefit of robotic prostatectomy that doesn't exist with open procedures, as I understand it. Dr. Porter and the nurses had been warned that I would not likely stay in the hospital overnight if I had any option to depart. He conceded this would be a first in his experience, but should I feel able, he wouldn't object, although I do think he doubted my resolve.

My abdominal muscles were stiff from the surgery, my head a bit cloudy from anesthesia, but I was good to go, and we were gone that evening. I spent that night at home with relative comfort and only had one pain pill and required a second on the second night. Dr. Porter called the next day and advised me I didn't need to return to the operating room. I was able to run the quarterly medical staff meeting the next day. I was on the treadmill in two days. I went on a four-mile hike three or four days later, although I will admit the catheter was quite annoying. I'd like to state in my clear belief that the evolving robotic technology and today's technical skill of our surgeons offers hope and tangible benefit to men with prostate cancer. It is my firm belief that to hinder the availability of this technology will delay the advancement of treatment and cure of this and other potentially life-altering cancers. Thank you.

Craig Blackmore: Thank you. Next is Dr. Siwek.

Leland Siwek: Hi, it's Leland Siwek from Providence Sacred Heart in Spokane. I do training for Intuitive, and my only other conflict of interest is that patients come seeking me out for robotic heart surgery. I'm a cardiac surgeon. I'd like to talk a little bit about why we do

robotic cardiac surgery. Basically, our hope is to reduce the morbidity of open heart surgery and allow more rapid return to normal function. After conventional surgery with a sternotomy, patients can't drive for a month, can't do any lifting, and have restricted activities for two to three months. With the robotic approach, we don't restrict our patient's activities at all and, in fact, they can return to whatever activities their comfort allows, and that includes either personal or work-related physical activities.

What we're talking about really here is the difference between a midline sternotomy and totally endoscopic procedure that is done in a closed chest. One of the reasons that we're very interested in robotic surgery is that we know that early mitral valve repair, even often before the onset of symptoms, provides the best long-term outcome and survival. Unfortunately, patients are often reluctant to take that advice, because they're feeling well and they're worried about the morbidity and recovery involved with conventional open-heart surgery. Robotic surgery allows an option that is sufficiently acceptable to patients, that they're more likely to choose the therapy that's most appropriate for them. I like this slide, because it shows what patients think about surgery. Patients are interested in the efficacy of surgery, but they're also quite interested in the invasiveness, and we all know that patients will frequently choose a procedure that is only moderately effective if they know that it's less invasive. They don't always choose the best if it's more invasive. Surgeons, on the other hand, have traditionally been trained to provide the most effective procedure regardless of how invasive it is, and we need to move it more into the patient's comfort zone, and robotic procedure allows us to provide a highly effective procedure that's much less invasive.

Now, we wouldn't really be interested, or at least I wouldn't be interested if the outcomes were not at least as good, if not better, than with conventional surgery. There is clear evidence, and certainly our experience has been that for closure of atrioseptal defects, mitral valve replacement, removal of intracardiac tumors, the results are at least as good as conventional surgery, the advantages being the avoidance of sternotomy and reduction of complications and rapid return to normal function. I'm personally convinced, and so are many of my colleagues, that for mitral valve

repair, which is one of the most commonly performed procedures with the robot, the results are actually superior to conventional sternotomy approach. I was going to show some video but don't have enough time, so I just included a few pictures to show the sort of view that a surgeon has. Now, you're not getting the full effect, because the surgeon sees this in 3-D, but a very magnified view of a valve allows us to do even very complicated repairs, in this case a bileaflet repair, artificial chordae, all these things can be done. This shows our experience.

I'll slip by this, but we've done well over 600 open-heart procedures. Our mitral valve success has been greater than 99% with only one conversion to a replacement, two conversions to sternotomy, and only one death in an elderly patient with an aortic dissection. I think you have these in your papers, so I'll skip this, since we're short on time, but some more current publications.

This is the Mayo Clinic and included their initial learning curve and makes the point that this should be compared, as the gold standard against which minimally invasive, for instance catheter-based procedures, should be compared. Quality of life was better than with conventional sternotomy surgery, and cost effectiveness of minimally invasive coronary revascularization was demonstrated in this paper.

Craig Blackmore: Can I get you to sum up, please.

Leland Siwek: I will skip to the end. I had a couple letters that were sent to you, as well, but in summary, robotic surgery, while requiring specialized training and experience, is safe. It's highly effective, provides more rapid return to normal function, is far more acceptable to patients allowing them to comfortably proceed with life-saving surgery and should not be denied to the citizens of Washington, especially the working poor who have the most to gain from rapid return to physical activities and work. Thank you.

Craig Blackmore: Thank you. That's... those are all the individuals who contacted us in advance, and then there are three more who we've heard from just here today, but the procedure is the same. Please identify yourself and your conflicts, etc. First is Eric Lehr.

Eric Lehr: I'm Eric Lehr. I'm a robotic cardiac surgeon at Swedish Medical Center. I have no conflicts to discuss. I would like to thank the authority for the privilege of discussing robotic cardiac surgery. I agree with the comments that Dr. Siwek presented. I'll begin my comments by emphasizing that totally endoscopic coronary artery bypass grafting can only be performed with robotic assistance. There is no open alternative. I will refer to this procedure as TECAB.

The final evidence report refers to the National Institute of Health Clinical Evidence reference 2008C, totally endoscopic robotically-assisted coronary artery bypass grafting and was retrieved on 03/12/2002. The final evidence report by the HCA erroneously summarizes the Nease document four times on pages 22, 125, 126, and 128 going so far as to state that the Nease document provides an active recommendation against robotic CABG. Nowhere in the Nease document is there such recommendation against TECAB.

On page 333, the final evidence report accurately quotes the Nease document, which suggests, "When TECAB is to be used, there should be special arrangements for consent and for audit or research. This is not a recommendation that TECAB should not be done."

In addition, the final evidence report rates the Nease 2008c reference document as fair evidence base quality, and the Nease document should only be considered as poor quality evidence that is only of historical interest. Although dated 2008, the Nease document was issued in 2005 based on evidence considered in August, 2004. This four small case series supporting the Nease assessment of TECAB were published between 2000 and 2002, which is really early experimental results and are of poor quality.

The Nease advisory committee points out, in fact, that for one series it is not clear which patients underwent TECAB and for another series, operative survival rates were not analyzed separately for TECAB, and a third series they point out of the four had heterogeneous patient cohort making generalization of these findings difficult. Moreover, these series used either the first generation da Vinci robot with only three arms and without a

stabilizer or the Zeus system, which is no longer available or supported in clinical practice.

TECAB performed today using the current four-armed robotic device is a completely different procedure with superior outcomes. In 2011, we published a review of TECAB in circulation, which is not considered for this HT analysis. This manuscript summarizes 850 patients from 14 modern case series. There was no perioperative mortality. The incidents of perioperative stroke and renal failure was only 0.5% and 0.7% respectively, very good results. Our paper published by Tschochner et al. in 2011, survival at one, three, and five years is 98%, 97%, and 97% respectively while freedom from major adverse cardiac and cerebral events at one year was 16% and 19% at five years.

While these outcomes were not directly compared to open procedures, and there are no data that does this currently available, these outcomes are comparable to the outcomes for survival and freedom from major adverse events and current major studies, including the recent syntax trial and the Arts II trial, and therefore at least demonstrates safety for TECAB in the current era and similar results to open procedures. In summary, I suggest that the Nease document regarding TECAB should not be included in this HTA unless the committee is willing to accept better quality case series of TECAB that also supersede the early case series supporting the Nease document. Thank you.

Craig Blackmore: Thank you. Next, I have Kathryn Williams.

Kathryn Williams: Hi. My name is Kathryn Williams, and I am a patient. I have no conflicts of interest, and I'm a patient here, and I just wanted to testify today of the benefits that robotic surgery gave to me. I have one child and in 2009 he graduated from high school. Before this, I've had problems with infertility, and so I was trying to preserve my uterus.

So, I've had open myomectomies and/or one major myomectomy, and I was down for awhile. So, we couldn't get pregnant, so we needed to... I was having very bad anemia, and so my doctor, Dr. Lenihan, performed robotic surgery on me, and at the end of May, 2009, my son was going to his prom and I had my surgery on a Wednesday. On that Saturday, I was following my son around. I

wasn't driving, but I was following my son around getting pictures of his prom. And then a couple weeks later he graduated from high school and, of course, I was able to attend that. So, I just wanted to testify that the benefits of the robotic surgery versus an open surgery... I'm hoping that they will continue to let robotic surgery play a part in people's lives. It's a wonderful benefit. I was back at work within a couple weeks, so I just want to testify and share that with you.

Craig Blackmore: Thank you. Finally, I have Mary Rance.

Mary Rance: My name is Mary Rance. I have no conflict of interest. Like Kathryn, this is a personal story. I, too, am a patient of Dr. Lenihan's. He suggested a number of years ago I consider having a hysterectomy and a prolapsed bladder lifted. I'd heard so many horror stories from friends who had hysterectomies at the time that I delayed having the surgery until I was retired, and I had the surgery five weeks ago, and I'm back gardening. I'm back playing tennis. I'm hiking, and I remember waking up in the recovery room thinking to myself, oh my gosh, there's no pain. Something's wrong, and then as I got awake a little bit more, I realized no, I did have some pain, but it was really nothing. I have had invasive surgery. I had a hip replacement two years ago, so I can tell you that I'm aware of recoveries and this was a snap. After two weeks, I couldn't remember why I was sitting and doing crossword puzzles all day, and then I remembered, oh yeah, I'm not supposed to do anything for three. So, this is anecdotal, but I'm glad it's my anecdote. Thank you.

Craig Blackmore: Thank you. So, that closes the scheduled and open public comment period. Next on the agenda is the agency utilization and outcomes. Right. It's been pointed out that I did not check the phone. Christine, can I get you to help me. We have a phone call-in, and sometimes there are individuals on the phone who also wish to address the committee. This is the Health Technology Clinical Committee meeting. Are there any listeners on the phone who had desired to address the committee at this time? Okay. Thank you, Christine, and we will proceed with the agency utilization outcome.

Kerilyn Nobuhara: My name's Kerilyn Nobuhara, and I work in utilization benefits for Washington Medicaid. My clinical background is as a pediatric

surgeon. I was trained to use the robot. I do not use it in clinical practice because of the size limitations of my patient population, but again here today to help the clinical committee make a coverage decision about robotic technology. Next slide.

I think I'm going to spend a little bit of time describing what the robot actually is. Here's the robotic tower, and basically what you have are three or four articulating arms that are basically mimicking the motions of the surgeon who is sitting at a console either in an adjacent room or nearby. The advantages of the robotic technology are one is that the surgeon is sitting, so it's ergonomically advantageous to the surgeon. Secondly, they are visualizing the surgery in three dimensions, as opposed to standard laparoscopic procedures where the visualization is in two dimensions. The third major advantage is that the arms do articulate for robotic procedures, as opposed to standard laparoscopic procedures where those instruments are all stiff and basically are very limited in terms of their direction and motion.

There's a specific reason why you heard from urologists, GYN, and CT surgeons this afternoon. It's because the additional range of motion actually serves an advantage to them when they're operating in very limited spaces. So, spaces such as the pelvis and the chest, and that's why you've heard from these surgical specialties this afternoon. The utilization in Washington State and nationally has been an upward trend, and we do know that there are costs associated with this technology. There are fixed costs for the robotic system itself, and those run in the 1 to 2.5 million range. There's also an annual maintenance fee. This fee is running in the \$140,000... \$150,000/year range. There's also associated variable costs. The instruments that are used with the robotic system are single-use instruments. So, while they are beautiful articulating arms, they are also single-use arms, and so they cannot be used patient to patient, which also drives up the cost for robotic procedures. There is some additional operating and learning curve time associated with the robotic surgeries that probably do decrease over time, and we'll hear from our vendors about that. Next slide.

When the agency medical directors first considered robotic surgery, the sentinel event was an outlier claim that was received from the Department of Corrections. However, the medical

directors later came up with these primary ranking criteria for safety, effectiveness, and cost all as medium rankings. You may wonder as members of the committee why we are looking at this technology at this point in time? Remember that we do have responsibilities for safety and effectiveness determinations in our coverage decisions, and this technology selection really wasn't based on cost at this point. Next slide.

To review the state agency policies, L&I has hit picks 2900 as a noncovered code. You heard earlier from Kathryn Barry that this is actually a nonactivated code in many third party payer systems. There is also no specific policy addressing robotic-assisted surgeries. In PEBB, there is no additional reimbursement for robotic procedures. The coverage or reimbursement is based on the primary surgical procedure, and at Medicaid hit picks S2900 is on PA. We also provide no additional reimbursement for robotic procedures, and the coverage and reimbursement is dictated by the primary surgical procedure. So, again, the medical directors decided that at this point safety is a medium concern for the agencies. The final criteria, which were selected, were morbidity, mortality, reoperation rates, intraoperative blood loss, and postoperative stays, which you'll hear about from the vendors, but there are also some other safety concerns and perhaps in the bigger picture of considering robotic-assisted technology, these concerns might also come into play, and those include how our clinician's technologists and facilities train and certified in the use of the robotic system, and how is robotic-assisted surgery competency established for the different surgical specialties, and at present there's no answer to those questions, but they should be kept in mind. Next slide.

Effectiveness, again the medical directors rated effectiveness as a medium concern at this point. Some of the questions include, what are the appropriate comparators for robotic-assisted surgery. I think it does get confusing, as you go through the vendor report. Sometimes, open surgery is compared with robotic surgeries. Sometimes laparoscopic surgery is compared with robotic surgery. I am very grateful for all the surgeons that are present today. They can probably answer your questions and give you input about the best choices for comparators, but you can see where the outcome measures get very cloudy when you're comparing to very, very different surgical approaches.

Second question, what is the evidence supporting clinically, meaningful short- and long-term outcomes for robotic-assisted surgical procedures? We've lived through disruptive technology before for many of us in the room, we actually were trained in the era of transition from open to laparoscopic surgery, and in that era, in the late 80s and early 90s, there was a rapid dissemination of technology without any evidence to really clearly support its clinical benefit, but you can actually see what happened in that the experience was rapidly disseminated. There was clear benefit to the client, yet that proceeded without real evidence to support any kind of coverage decision from the peer standpoint. Robotic surgery is also a disruptive technology. It is at the same rate of dissemination as the laparoscopic cholecystectomy, perhaps slowed somewhat because of the very high initial costs that are required for purchase of the equipment, but again, another consideration for the committee.

The third point, can robotic-assisted technology be judged separately from the experience of the operating surgeon. My only comment to the committee this afternoon is that you've heard from the best of the best. These are the most experienced surgeons in robotic-assisted surgery that are in the room today. However, any coverage decision which is made will apply to any surgeon operating in the state of Washington. So, I would also caution you to remember that the outcomes are very much dictated by the operating surgeon. Next slide.

Third point, costs. Again the agency medical directors decided that cost at this point is a medium concern. The question is what is the evidence supporting cost effectiveness of robotic-assisted surgery compared with laparoscopic and/or open approaches? We know that there's a cost to the system because of the initial investment from facilities to purchase the robotic equipment. However, we don't know the costs offsets in terms of decreased length of hospital stay and improved clinical outcomes for patients. Next slide.

So, when the agencies looked for data regarding robotic-assisted surgery, it is a challenging data search, because again, there are no unique CPT codes to identify robotic procedures. So, there were two ways in which the data was culled. One is to use the hit

picks code, S2900, which is still active in the Medicaid system, and the other was to use the inpatient ICD-9 procedure codes. So, that's how the data was gathered from the PEBB and the Medicaid populations.

So, here's the PEBB data, and this represents 2007 to 2010. You can see that there is an upward trend in the number of patients who underwent robotic-assisted procedures. You can see the expenditures associated with those increased numbers. We just report an overall average payment for PEBB. This similar trend was seen in Medicaid where there is an upward trend over the last few years in terms of the number of Medicaid clients receiving robotic-assisted procedures and an average payment that went out associated with those procedures. For L&I, there were only two reported cases, and you can see those there. So, across all agencies, an average payment of \$14,500. Again, that represents a mix of all of the different types of surgical procedures. Broken down by procedure type for PEBB, the most common procedures were for prostate, GYN, and the urinary tract. Again, as I explained earlier, the reason for that is because of the technical advantage provided by the robot. Those applications are actually intuitively obvious to the surgeons. You can see the minimal and maximal associated payments. These are all the surgeries grouped together. These aren't broken down by any other specific surgical code. Same for the Medicaid population. Remember that Medicaid becomes a secondary payer for older clients and that's why prostate has dropped to the bottom of the list with GYN. Other includes a number of pediatric cases, and a few cardiac cases in the next in terms of the procedures. You can see the minimum and maximum payments that were paid out for Medicaid. Next slide.

We did pull the counts and the payments over time. I think the main point to recognize from this slide is that there is an upward trend in all of the different categories of procedures over time, and the same trend is also noted in the Medicaid population where over the past few years you can see that the number of procedures and the number of... and the amount of payment has gone up over time. I did realize that it would be most helpful for you to have information comparing a robotic-assisted prostatectomy to a laparoscopic prostatectomy to an open prostatectomy, and I did attempt to pull that claim data when I

went back to the office yesterday but remembered that we have an administrative database, so I can't do any risk assessment and compare equally risked populations. So, I didn't feel that offering up that comparator would be a responsible reporting of data.

I think we can hear a little bit from our vendors about national claims data to kind of get an impression about the difference in robotic-assisted versus open versus laparoscopic procedures, possibly for prostate and possibly for hysterectomy procedures. But otherwise, we haven't been able to do any kind of claims analysis to say exactly what Medicaid at least is paying out. Next slide. To look at the other centers, agencies, and HTA decisions, there is no NCD or LCD for Medicare. Again, a hit picks code S2900 was released in July of 2005. It remains on the list of not reimbursable codes. Hayes has done a number of technology assessments by procedure. You can see many of them are a little dated, from 2008 and onward. Basically, Hayes has rated the technology as a C meaning that there's insufficient evidence to make any kind of final recommendation about the technology in that particular surgical application. The D ratings are technologies which would be considered investigation or experimental. Next slide.

The other payer policies, as we heard earlier, Aetna, Cigna, Group Health, HealthNet have a mix of either no specific policy addressing the use of robotic-assisted technology or reimbursement policies stating that this is not a separate service and robotic-assisted surgery does not receive any additional reimbursement for the technology use itself. So, a summary of the risks from the agency viewpoint, those include the escalation of costs with increased utilization. The incentives are probably towards the facilities that are trying to offset their costs for the initial capital outlay for purchase of the robotic system itself. Other risks include that the robot may bias cure decisions ultimately towards a surgical approach without any necessary supporting comparative effectiveness evidence. There has been widespread adoption of the technology without evidence to support equivalent or superior outcomes. I think that applies more so to certain procedures than to others at this point in time. There's also a lack of externally regulated certification and determination of clinician, technician, and facility competency, and that may be a responsibility ultimately of the peers.

Benefits... benefits are actually pretty obvious, particularly if you're a patient who has received this technology and benefited from it. It enables a minimally invasive approach, which otherwise may not be technically feasible. To summarize, to date there is a lack of high-quality medical evidence addressing the impact of robotic-assisted technology and clinically meaningful surgical outcomes. Robotic-assisted surgery is a method of performing the procedure and is not a separate service. It is a matter of choice of the surgeon. Third is the determination of medical necessity based upon the surgical procedure and not the technology with reimbursement also based upon the surgical procedure.

Just to briefly summarize again about safety, effectiveness, and cost, the evidence on safety is not robust, particularly with respect to reoperation rate, intraoperative blood loss, and postoperative stay. Again, that is procedure specific, better for some procedures than for others, and I think you'll see the vendor report will organize the evidence by procedure, which hopefully will help you in your final coverage decision-making. The evidence and effectiveness for clinically-meaningful outcomes is limited, and third for cost, there is substantial provider costs. There are costs to the system. Right now, they seem to be embedded within the system as the peers aren't necessarily providing additional reimbursement for the technology. However, it is known that there are additional costs associated with the use of robotic technology. So, the final recommendations... the evidence is not compelling, and there may be some added safety risks with robotic-assisted surgery. If a coverage decision is made, we would recommend that this is limited to conditions where added benefit is clearly proven or to where situations occur where the surgical procedure could not otherwise be performed. We would also recommend to leave the authority to determine any additional payment to agency discretion.

Craig Blackmore: Thank you. Are there any questions from the committee related to the agency presentation?

Kevin Walsh: I had a question regarding the utilization rates. We've been told that this is basically a different tool for doing the same thing, and

what you're showing us is increased rates of robotic surgery but have you seen a subsequent decrease in rates of open surgery?

Kerilyn Nobuhara: We didn't look. We could easily find that data, but we didn't look.

Kevin Walsh: Okay.

Chris Standaert: I mean, I think that's the whole question here. I'm troubled by this whole thing. So, sure you show numbers that are going up and it's increased utilization, but that's just replacing another procedure that you'd be paying for anyway. It's a zero-sum game. And you don't pay any more for somebody using the robot than you do somebody who doesn't use the robot. I get the hospitals that put a lot of money in, because they're going to get that. They're going to get that somewhere, and they're making that calculation, but they make the same calculation when they make a nice waiting room, make a single-patient room on a floor. They make the same calculations. They'll get their money back somehow, but we don't regulate that, and it seems like the procedure is a laparoscopic procedure, for which there are existing codes and existing indications for laparoscopic procedures, and this is a tool with which they use them, but we don't talk about which retractor somebody uses, which trocar somebody uses, which stitch they use. We don't talk about that typically. So, this seems to me like we're trying to regulate like a retractor. I don't totally... I'm struggling with how... it's like saying that you can't use this retractor because we don't have good data on that retractor versus another retractor, but somebody really likes that retractor, and the surgeon really prefers it and they like it, and they feel like they do a better job, and there's no data that retractor is dangerous.

I mean, we'll have to talk about that, but if there's no data, then, you know? It's like we're regulating a tool. We're not regulating a procedure for which there are medical indications for which we talk about, you know?

Kerilyn Nobuhara: I think...

Chris Standaert: I mean... can you help me with that? I'm... I don't understand.

- Kerilyn Nobuhara: Yes and no. I think I agree with you completely. Remember that as the directors debated about the choice and selection of this topic, that safety and effectiveness are also responsibilities that we can request help for from the committee to address. So, while costs may or may not be an issue at present, there may very well be development of new CPT codes, which address robotic surgery itself, as stand-alone codes. We actually have the expert in the room. We can ask her how that process is going, and if that is the case, then ultimately will the agencies also be responsible for recognizing additional reimbursement for the use of the technology.
- Chris Standaert: Okay.
- Craig Blackmore: So, I guess what I'm hearing is that we don't know if it's a zero-sum game, right? Because you can't provide that data. So, we don't know if there's been an increase in the performance of procedures, as a consequence of this technology and if that is appropriate or inappropriate, if people might be benefiting from this or might be benefiting from something else.
- Kerilyn Nobuhara: Yes.
- Kevin Walsh: The other question I would have about the cost data. Is that... one of the things that we've seen in the vendor report... that we'll see in the vendor report and that we've seen is that one of the big offsets of the cost of this is the decrease in length of stay from hospitals. So, on the data that you're providing us, this is just the cost of the procedure, or is that hospital... total hospital charge encapsulated in some way?
- Kerilyn Nobuhara: I think Margaret can answer that question.
- Margaret Dennis: Margaret. Most of the costs that we captured were DRG. So, yes, they are full hospital charges.
- Chris Standaert: Just going back to you made a comment about sort of in the future you may come up with codes for this. So, I'm just trying to... I'm still trying to understand the whole thing. So, if, you know, if someone were to look at the way we make codes and the way hospitals get paid, it's based on sort of predicted work and time and all that sort of stuff. So, if what this does is people have

shorter hospital stays and the hospital makes more money because they can make more on the DRG, they'll eventually get... somebody will revalue the code at some point. You would think somebody would revalue the laparoscopy code, because they figure out that people are getting out of the hospital faster and that would be revalued.

Kerilyn Nobuhara: Yes.

Chris Standaert: So, that's not up to us. That isn't up to you. That's up to AMA... that's up to CMS ultimately to sort of revalue that. So, that would drop the payment for this concordantly, if the hospital stay went down, one would think. So if the cost, you know?

Man: Can you give me an example of another situation like that?

Chris Standaert: Yeah. There are a lot of procedures. When CPT decides to reevaluate code, they tend to bundle things in. So, again, you know, they tend to bundle... they'll bundle their fluoroscopy into injection codes, and what they essentially do is they wipe out the separate code for fluoroscopy. So, they're billing for the procedure under fluoroscopy. You bill for the procedure but you no longer bill for the fluoroscopy, because it's considered an integral part of that procedure. So, when things are... the way CPT works, if things are used more than 75% of the time, I think is the number, what they give in procedure, it should be considered integral to that procedure and part of the CPT code.

Man: We bundled the fluoroscopy with the injection [inaudible] total price went down?

Chris Standaert: It went down. Yes. The reimbursement went down.

Kerilyn Nobuhara: Can we have like Dr. Barry answer that question?

Craig Blackmore: I'm sorry, the public comment portion is closed.

Chris Standaert: I'm just... I'm just running it up... basically I'm just trying to run the math in my head a little bit of what you were saying and playing down the road what might happen, but the truth is we don't really know what's going to happen. We know what we have now and we don't really know what's going to happen.

Craig Blackmore: Richard?

Richard Phillips: I have a question. I saw where the Labor and Industry does not cover it. Why does... do they not cover it? There's no additional for it.

Man: Correct.

Kerilyn Nobuhara: No. They only don't cover the hit pick S2900 codes.

Richard Phillips: Oh, okay.

Kerilyn Nobuhara: Which is only, again, as Ms. Barry had explained earlier that code is inactivated in most systems. It's still active in Medicaid under PA.

Richard Phillips: Oh, okay. So, they do cover. They just don't for that particular code. Is there... is there a cost associated with that code?

Kerilyn Nobuhara: No, because it's not covered.

Richard Phillips: Oh. So, they really don't cover them at all, because the code exists and the reason is, is because they don't think it's as... the reasons for this...

Kerilyn Nobuhara: There's no additional reimbursement provided for robotic assistance by L&I.

Richard Phillips: Okay. One question I have, and this is, and Craig you can tell me if this is appropriate or not, but the one problem I have in looking at this procedure is why it came to us as opposed to say certificate of need kind of process. As an example, we have in this state interventional cardiologists who are regulated by the number of cases they have to do. You know, that's set up on them. In addition, you have cath labs that are established, because they are expensive, and we know that these kind of machines cost 1 and a half million dollars plus or minus, a half million dollars, and we've done this with cath labs in the past, and we've regulated them that way within the state. In many respects, it's similar to the situation we have right here where we have probably what 5% of all the surgeons in the state actually do robotic surgery? I

don't know what percent of gynecologists, etc., but yeah, there is an issue there of regulation and credentialing, but we don't get into that. You know, at least traditionally we haven't gotten into that in this committee, and yet these are the kind of questions that are just being posed to us, and I'm trying to figure out why it came to us, as opposed to say going to a different route.

Craig Blackmore: I think we... we don't need to sort of rehash why it came to us. At this point, our reality is it did for better or worse. So, there it is.

Richard Phillips: So, we just accept it as it is.

Craig Blackmore: We have been asked to address this topic. We have been... gone through a process...

Richard Phillips: I understand, and I'm not asking for you to... hoping you can make magic. I'm trying to get an understanding.

Craig Blackmore: We are certainly welcome to provide input to the agency directors on topics and yes or no and how to frame them, and we do that on a regular basis, but for the purposes of today's discussion, here we are.

Richard Phillips: Okay. I got you.

Craig Blackmore: Other questions for the agencies?

Carson Odegard: I just have one question, Carson Odegard. Could you give us just a general kind of feeling of the counts versus payments? I mean, it looks to me like, as the counts go up the payments go up accordingly, but then you look at a couple of other categories and it looks like payments go down. Can you just give us kind of a general idea? Are these trends consistent with the... are the payments consistent with the counts, or are they?

Kerilyn Nobuhara: I'm not sure I understand your question, honestly.

Kevin Walsh: Carson, are you asking if the... for the same procedure, are the charges or costs changing?

Carson Odegard: Right.

- Kerilyn Nobuhara: No, because we didn't separate it by procedure. These are just total charges associated with either that V code or that hit pick S2900 code, and the reason why we couldn't do that... well, there's a myriad of reasons, but one of the primary reasons is that there are so many different laparoscopic codes associated say with a hysterectomy, even with a prostatectomy or lymph node dissections. So, there are a number of codes that were included. So, we couldn't break it down like specific procedure.
- Carson Odegard: Okay. Thank you.
- Craig Blackmore: Anybody else? Joann is that?
- Joann Elmore: Yeah, I'm just... this is Joann Elmore. I'm just wondering about the utilization data given the fact that the ICD-9 codes, there's no extra payment whether it's robotic-assisted versus not, how confident are we that it's being adequately used, the 17.4 codes, so that you're capturing what is actually happening in the state of Washington? Because I don't see any incentive for the surgeons and their staff to be using these specific codes, since they're paid the same amount.
- Kerilyn Nobuhara: Yeah, I agree. The only way we would be able to do that would be by a chart audit to look at the ICD-9 procedure codes, and we did not do that.
- Seth Schwartz: Which, when you think about, raises an interesting question about how's it going to be governed if you can't even tell when it's being done.
- Chris Standaert: I assume they don't have an obligation to report that they use this code. There's no requirement that you check one of these codes if you use it, I assume.
- Kerilyn Nobuhara: You are... there are rules by which coding should be reported, and they should be reported if the robot is used.
- Chris Standaert: They should be.
- Joann Elmore: Do they have to?

Craig Blackmore: I'm sorry. So, I'm going to just stop here. We have a... the charge of the committee is to act based on the best available evidence, and the evidence vendor is the primary source of that evidence. The evidence vendor produces a technology report based on the key questions. That report is then vetted publicly and goes through a period of peer review and comments on that report also go through the peer review process, and we strongly discourage the attempt to introduce evidence and other material that is outside of that process.

So, we have a public comment period and we certainly welcome that input, and we really welcome input from the public during each stage of the process. There are, I believe, six different times when that occurs, and we don't routinely turn to other sources of information here, and I know you're new to the agency, so that's something that probably isn't clear, but that is the process of evidence distillation and vetting and balancing, so.

Any other questions? Okay. So, the next item on the agenda is the vendor report, the technology assessment, but before we do that I want to introduce our clinical expert who serves as another resource for the committee. In this case, the role of the clinical expert is to provide clinical context and to answer the technical questions that may arise about the procedure. Many or most of us on the committee don't necessarily do this particular procedure, and so we have somebody participating in the meeting who can help us to understand the technical details.

So, Dr. Jeffery LaRochelle has agreed to join us, and he's a urologist, so his specific expertise is around the urological applications of the technology. Dr. LaRochelle if you could just introduce yourself and if I could ask you to go through the same exercise of telling us if you have any conflicts of interest and representation.

Jeffery LaRochelle: There we go. My name is Jeffery LaRochelle. I'm an assistant professor of urology at OHSU. I have a focus on urologic oncology, so I do cancer surgery of the kidney, bladder, and prostate and testis. I have certainly had robotic training as part of my oncology fellowship training. I was trained on the robot. I do open standard laparoscopic and robotic-assisted laparoscopic surgeries. I look at it as a tool, of course, with appropriate

application. So, I'm happy to answer any questions, of course. Thank you.

Craig Blackmore: Thank you. It's an important role, and we appreciate you being here and technical questions will come up in the course of the discussion, which we'll direct your way.

Michelle Simon: Just for the record, do you have anything to disclose?

Craig Blackmore: Thank you.

Jeffery LaRochelle: No. No disclosures whatsoever, thanks.

Craig Blackmore: Thank you. So, let's proceed with our Health Technology Assessment report.

Ken Gleitsmann: Thank you.

Craig Blackmore: Thank you.

Ken Gleitsmann: My name's Ken Gleitsmann, and I'm here with my colleague, Kendra Bunker. We'll be presenting the evidence report on robot-assisted surgery today, and we're also accompanied by other members of our center, Valerie King and Heidi Krizh, and they'll be resources for us during this evidence presentation. So, robotic-assisted surgery... first, we'll take you through a very brief background.

The PICO methods and key questions were developed in concert with the Washington HTA process. Followed by that, we'll present the results of our evidence, research, and a brief mention of guidelines and policy followed by an overall summary. So, in background, robotic surgical systems assist surgeons in performing minimally-invasive procedures and the da Vinci was approved by the FDA in 2000 for general laparoscopic surgery. In the year 2010, almost 300,000 da Vinci procedures were performed in the U.S. representing a 35% increase from the year prior and a 30% year increase was expected in the following year of 2011 for the da Vinci procedures. So, this is the robot piece.

This one happens to show a four-armed robot, and this is a typical operating room setup with the robot in what is called the docking

position at the patient's bedside. There is a skilled assistant shown opposite the robot, and that assistant can be a surgeon, but not necessarily. That surgeon helps to exchange instrumentation, helps with suction and visualization and retraction. The surgeon is remote from the surgery seated at the side cab arrangement that is in the bottom right of this photo, and he is working with the help of a 3-D visualization device inside that console.

So, the PICO developed with the Washington HTA was a population of adults who had planned surgery to be performed with this robotic-assisted device. Intervention was this surgery with robotic control, and the comparators were surgeries that were done without the robot, either open or laparoscopic.

The various outcomes were length of stay, utilization, recovery of activities of daily living, a quality of life overall and disease-specific mortality or survival, cancer recurrence, adverse events and healing time costs and cost effectiveness. The methods, I'm going to spend just a minute here on methods along with the Washington HTA, again, there was a technological assessment done by the Canadian Agency for Drugs and Technology, which we'll refer to heretofore as CADTH published in 2011, which discussed four basic surgeries, which were high volume in Canada and that is prostatectomy, hysterectomy, nephrectomy and cardiac surgeries. In addition to that, a best evidence systematic review methodology by procedures was done. So, we identified recent good quality systematic reviews and also did a Medline search for subsequently published individual studies. If neither a systematic review or subsequent studies were found, we went back to a 10-year Medline search for individual studies in that case. Quality assessment was done.

This is a relatively more complicated slide than it looks. I'm going to spend just a minute here. So, the quality assessment was done for methodology in terms of the systematic reviews and the individual studies using a tool developed, or modified, by the center and based on the sign and nice tools, using the scale of good, fair, and poor, because CADTH uses a slightly different scale in terms of the number of levels, you'll notice that in the CADTH studies there are two extra levels referred to for the majority of the procedures in CADTH and those were good, fair, and fair to

poor. I'll make one exception coming up, and I'll mention that. In addition to the methodology and quality assessments, there was the grade system used to rate the overall strength of evidence, and we're using a key here in red that you'll see goes from high to very low and you can, the key is that there are more x's in the circles for the high than the very low. So, overall, there were 644 citations reviewed, 59 of which met the inclusion criteria including five systematic reviews, and these systematic reviews, one I just mentioned was the CADTH. All were rated with our tool as good quality, and just briefly the other four systematic reviews were related to the anatomic procedures. So, there was an abdominal systematic review, one on esophageal and gastric resection, one on gynecologic procedures, and one on urologic procedures.

Most studies of the 54 individual studies that supplemented these reviews were retrospective cohorts. In addition to the 644 citations that we reviewed, 200 citations, actually more like 230, were submitted during the public comment period, of which 20 studies met our inclusion criteria. So, the key questions, the obvious first two are efficacy and adverse events. I'm sorry, not just efficacy but cost effect... or clinical effectiveness. Question three concerns subpopulations and in addition to the routine subpopulations of gender and age and comorbidities such as diabetes, in this particular evidence base, we looked especially at surgical experience and for... we identified a population of high BMI patients that were pertinent to this review. The last key question number four about costs and cost effectiveness.

So, I wanted to mention how we're going to organize this presentation, since it represents such a broad waterfront of 28 procedures, and this was mentioned by one of the committee members and that is we're going to talk about the strength of evidence and that's the way the rest of this presentation is organized.

So, first we're going to take those procedures that had moderate strength of evidence starting with the CADTH procedures and then following the other procedures just for key questions numbers one and two. Following that, we'll look at the strength of evidence that is low and very low in an aggregate presentation for the same key questions of one and two. Following that, I'm going to turn the presentation over to my colleague, Kendra

Bunker, and she will talk about key questions three and four and those findings also presented in aggregate. So, we'll get started and, again, just orienting you to the slide.

This is a slide that discussed robotic prostatectomy. The indication is next to the procedure and that is for prostatic cancer. The next box below the blue box is a box that discusses the number of studies and the quality ratings of the studies. So, there were 55 studies; 51 of these were in CADTH, and the others were individual studies, and they were quality rated from high to poor. I just want to point out that there was one high rating in the CADTH, in the entire CADTH technology assessment and that was a study about robotic prostatectomy versus open and that's why we didn't put that on the other slide, just for sort of clarity.

So, we'll, from now on, be seeing CADTH quality ratings that only have a four-step, or a five-step scale, sorry. So, again, robotic prostatectomy up top and the comparators on the left side of the slide. The first comparator is laparoscopic. So, this is robotic versus laparoscopic prostatectomy, and again following the red key, the entire slide is referencing those procedures that have a moderate strength of evidence. So, for key question one, there was decreased operative time between robotic and laparoscopic, decreased length of stay, decreased estimated blood loss, and decreased transfusion risk and similar positive margin rates.

For key question two, the complication rate was similar in the two comparators... or in the comparator. Changing comparators on the left hand side of the slide now, between robotic prostatectomy and open, we find that key question number one for efficacy... no, say reduced length of stay. Estimated blood loss, transfusion risk, and positive margin rates. This was only noted in patients with PT2 cancers. On the other hand, that comparator notes an increased operative time, increased urinary continence at 12 months, and increased sexual function return at 12 months. Again, a similar complication rate. This should look like a familiar slide now in terms of orienting.

Again, the procedure is on top. This is for robotic hysterectomy for the indication of endometrial or early-stage cervical cancer, and the number of studies in this case were 34. That breaks down to 28 in the CADTH review and 8 subsequent studies, and the

quality ratings were here from good to poor. Again, incorporating the CADTH and the center's quality rating scales. So, between robotic and laparoscopic for a moderate strength of evidence, there was a decreased length of stay and blood loss, similar operative times, and a decreased complication rate in the laparoscopic comparator. However, when compared to the open procedure, there was decreased length of stay, decreased blood loss and transfusion risk and an increased operative time. The harms or adverse effects were noted to be decreased in the complication rate in the open group.

This slide looks a little different. Still, the procedure, and this is not a CADTH procedure, was covered by another systematic review, but this was robotic radical cystectomy for the indication of bladder cancer. So, the... and the left side looks like a little different because there was not a comparator of laparoscopic that showed a moderate strength of evidence. So, once again, just to emphasize to the committee, we are first looking at those procedures where the outcomes had moderate strength of evidence. So, again, a number of studies here. One systematic review and that was the Venusaur Urologic Review and five subsequent studies. This is robotic versus open, and there's moderate strength of evidence that there is decreased blood loss and length of stay and elevated operated times, similar complications rates in this comparator. If you're wondering where the laparoscopic is, I'll just mention again, this is moderate strength of evidence. There was evidence versus the comparator of laparoscopy, but that evidence, as you'll see later in the presentation, was very low, because of the number of studies.

There was a single study that discussed that comparator. Again, a slight difference in the look of the slide, but again, the procedure is at the top of the slide. This is... or the comparator in this case is at the top of the slide. This is a summary slide. Again, for moderate strength of evidence, all of these were discussed in one good quality review by [inaudible], and in fundoplication procedures there was... the one review had nine studies, no subsequent studies, and they showed moderate strength of evidence for similar length of stays, operative times, and risks of complications. Colorectal procedures, on the other hand, for robotic versus laparoscopic procedures were covered by that same systematic review in seven studies.

There were seven subsequent studies that the center rated as poor quality, and in this case there was moderate strength of evidence for decreased blood loss and length of stay, similar bowel function return, and return to oral diet, and in Roux-en-Y procedures for morbid obesity, again moderate strength of evidence from the same systematic review of abdominal procedures that showed four studies and two subsequent studies that we rated at the center as poor quality and in this case there was moderate strength of evidence showing similar operative times and an increased odds of conversion. In this case, it was conversion to another procedure, usually open.

So, we're through the moderate strength of evidence for key questions number one and two, and we're moving to the other procedures, and the other procedures are listed in the blue box, and in these procedures, the low and very low strength of evidence for these key questions is rated as such because of the high risk of bias and limited findings in these procedures... for these procedures. The details of the procedures are in a tool I'd like to tell the committee about in the report that's in appendix D. We have provided you with two summary tables. The first table in appendix D is a summary of comparators, procedures, and outcomes just listed. Table two in appendix D takes that information and gives you some directionality. So what is operative time as an outcome, increased or decreased, and that should be an easy way to look in summary at these other procedures, actually, all the procedures in this report. So, some of the commonly found statistical findings in this blue box of procedures were, and this is a very general statement, longer operative times, shorter length of stay, decreased blood loss, and similar complication rates. For example, gastrectomy is in this list, and gastrectomy in this particular evidence base was reported robotic versus laparoscopic and also robotic versus open, and in the... in both comparators noted increased operative times at a low strength of evidence and decreased blood loss in the robot versus open.

So, there are different comparators, different interventions all represented by low and very low strength of evidence. Another example would be the trachelectomy procedure, and that was robot versus open procedures, and their only study noted

decreased blood loss and decreased length of stay. So, that was rated as a very low strength of evidence. So, those are just two examples. Now, I'm going to turn the presentation over to Kendra Bunker who will take us through key questions number three and four.

Kendra Bunker:

Great. Thank you, Ken. So, with key question... could I have? Thank you. With key question three, you asked us to assess whether there was differential efficacy or harms in subpopulations, and the subgroups you asked us to look at included age, gender, comorbidities, patient characteristics, such as BMI, and also provider characteristics. So, out of all these subgroups, the only evidence we identified that included actual subgroup analyses pertained to surgeon experience and those with high BMI. So, beginning with surgeon experience, we did find moderate strength of evidence that surgeons experienced in robotic prostatectomy had improvements for most clinical outcomes.

These included improvements in operative time, length of stay, complications, and positive surgical margin rates. So, for example, in the less-experienced surgeon group, you might have a benefit over the open procedure in terms of length of stay of 1.5 days whereas in the experienced surgeon group, the benefit increases to a two-day decrease in length of stay. The exception of this was estimated blood loss, which was unchanged with experience.

Now, we go down to evidence that was low or very low strength of evidence, and we identified evidence regarding surgeon experience for a few other procedures indicating that robotic proficiency did influence outcomes for these procedures. These included colorectal resection, hilar myotomy, lobectomy, thyroidectomy, cholecystectomy, hysterectomy, and mitral valve repair. Moving on to the subgroup of individuals with high BMI, we identified low-strength of evidence across three procedures. These included hysterectomy with a robotic procedure being compared to the open procedure. The robotic procedure did have significantly longer operative times but also significantly decreased estimated blood loss, length of stay, complication rate, and complication severity. These are the same sorts of relationships you find in the broader population but among the

population of individuals with high BMI the differences are of a greater amplitude.

With the Roux-en-Y gastric bypass procedure, when the robotic procedure is compared to laparoscopic you also somewhat counter-intuitively see that operative times decreased as the degree of obesity increased. Additionally, with adjustable gastric band when the robotic procedure compared to the laparoscopic procedure in the broader population the two procedures have similar operative times, but when you get into the subgroup of individuals with BMIs greater than 50, the operative time is actually shorter in the robotic group. However, length of stay, weight loss at one year, and conversions to open were similar between groups.

In key question four, you asked us to look at costs and cost effectiveness of robotic-assisted surgery, and the evidence that we identified was from a hospital perspective. There aren't analyses out there that look from a patient perspective or a societal perspective. So, when we talk about costs here, we're talking about the cost to the hospital.

So, overall, the robotic procedures were generally more costly than laparoscopic or open procedures, and offsets to this cost were the shorter length of stay afforded by the robotic procedure in many instances and also in institutions where they have greater robotic caseloads basically to spread out the cost of the robot over more patients. So, with regard to specific procedures, the strength of evidence was moderate for prostatectomy that the cost was higher and very low to low for other procedures. In general, cost effectiveness studies were limited by very scarce reporting of long-term efficacy results, as Ken mentioned. These were scarcely reported in the literature.

The literature, basically focused on perioperative outcomes. We also did a brief guideline and policy summary. We identified 15 relevant clinical practice guidelines. In these, most were quality rated as being fair quality. One was good quality, 13 were fair, and one was poor. In general, these basically indicated that when the laparoscopic procedure was indicated, the robotic procedure was typically considered an acceptable alternative. With regards

to payer policies, as we've discussed previously, there are no medical national or local coverage determinations.

Since 2005, Medicare has identified robotic-assisted surgery as a nonreportable code and does not provide any additional reimbursement. Similarly, private payers, such as Aetna, Group Health, and Blue Cross/Blue Shield do not provide additional reimbursement for the robotic-assisted procedure. So, just briefly to summarize what Ken and I have spoken about today, we did identify moderate strength of evidence for a few procedures. Particularly in the comparison on this slide between the robotic procedure and the open procedure we found increased operative times but decreased length of stay and estimated blood loss across prostatectomy, hysterectomy, and cystectomy. We also found moderate strength of evidence comparing the robotic procedure to the laparoscopic procedure finding similar or decreased operative times and prostatectomy, hysterectomy, fundoplication, and Roux-en-Y gastric bypass.

Additionally, there were similar or decreased length of stay compared to the laparoscopic procedure for prostatectomy, hysterectomy, cystectomy, fundoplication, and colorectal resection.

Finally, similarly decreased estimated blood loss for prostatectomy, hysterectomy, cystectomy, and colorectal resection when the robotic procedure is used.

Looking at safety, we generally found that adverse events and rates of complications were similar between groups. The exception to this largely being hysterectomy. Additionally, lack of... there's overall a lack of evidence around improvements in surgical outcomes with increasing experience for most procedures other than those we just discussed, particularly prostatectomy where there's the largest evidence base. Additionally, robotic procedures were more costly than their comparators. Offsets to this in terms of hospital costs being shorter length of stay and those performing more robotic procedures.

There are some limitations to the evidence that we should note. You'll note that largely the evidence that we're discussing today is low and very low quality with a few procedures for which we have

moderate strength of evidence, but largely this evidence base was retrospective studies with methodological limitations that included small sample sizes, variable control groups, baseline group differences, and some inadequate control of confounders that typically bias in favor of the robotic group. In the meta-analyses, there were numerous instances in which significant heterogeneity was noted across trials, and long-term outcomes were not studied for most procedures. This, in turn, limited the economic studies by not being able to incorporate these long-term outcomes. So, with that, we're ready for your questions.

Seth Schwartz: I'm interested, because the Canadian report served as one of the bases for this, why you chose not to include their economic studies... their economic statements?

Kendra Bunker: Their economic statement was with regard to...

Seth Schwartz: The cost of the procedures.

Kendra Bunker: Those are included. I'm sorry. I must be misunderstanding.

Seth Schwartz: Can you show me where they're included.

Chris Standaert: Slide 19 is what they're referring to. They're saying they're more costly, but for the hospital, because the hospital has to put the investment into the machine, as opposed to costly to the payers, because they don't really pay anything more for it, is what they're saying.

Craig Blackmore: Other questions?

Carson Odegard: I had a question. When it gets down to the costs, were you able to segregate it into fixed costs and variable costs per procedure? In other words, knowing there's a full investment for the big equipment coming up, but is there a change in variable costs per procedure?

Ken Gleitsmann: The answer is yes at a level, and we tried to show that caseload is that level. For instance, there are studies that show caseloads of over 200 begin to make an impact on the incremental costs of the procedure, and that is in our report. Yes. So, there is a level at

which, as the robot is used more, that the incremental costs do go down. Right.

Chris Standaert: Did you find any published data to get at the question [inaudible] of the state that does the use of the robot result in an increase in the number of procedures overall, or is it just that it's being used as an alternative in procedures so that the overall rate of surgical intervention for prostate cancer or for hysterectomy or whatever is staying about the same? Or is there some evidence that the introduction of the robot actually increases the rate of those procedures being performed? Was there data on that anywhere that you saw?

Ken Gleitsmann: I'm sorry. I thought you were addressing the state agencies.

Craig Blackmore: No. No. I just can't look at you and talk in the mike at the same time.

Kendra Bunker: That's fine. We did not review that specifically. I have seen evidence to that effect, but we did not review it as a part of this.

Jeffery LaRochelle: I can address that to some extent in that the... I can tell you overall the rate of prostatectomy, for instance, has not changed dramatically over the last five years when robotic use has increased. So, to that extent, in one area where you might see a difference in the number of overall procedures is a partial nephrectomy. Partial nephrectomy is done robotically more often now, but you're going to see not... you're not going to see... you're going to see an overall increase in the number of partial nephrectomies probably at the expense of radical nephrectomies, for instance. So, yes. Sometimes, having a robotic approach allows you to do a different procedure, so you might not see much in overall increase in that, but you might see a decline in a different kind of procedure. I can tell you that would probably... it's certainly in nephrectomy I suspect that nephrectomy rates are dropping while partials are increasing.

Craig Blackmore: Theoretically, but we don't have data on that.

Jeffery LaRochelle: Well I mean... it's not in the report, but I do have data that I could show you that's showing that radical nephrectomy is declining while partial nephrectomy is increasing, and it's speculated, and

there's probably good evidence, that it is mostly because robotic partials are increasing. Sorry if I introduce it as data that I can't produce, but I can tell you with a high level of confidence that is in fact...

Craig Blackmore: We'll take it under advisement.

Jeffery LaRochelle: Okay.

Craig Blackmore: Any other questions?

Michelle Simon: Yeah.

Craig Blackmore: Oh go ahead.

Michelle Simon: I have one question. In your report, you said there's no Medicare, local, or national coverage decision, and we did see a presentation by somebody here earlier who showed a list of all these different people that cover and they mentioned Medicare Advantage, I'm just curious if you could speak to that.

Kendra Bunker: In our review, we only looked at the local coverage determinations for this region. So, they may be from other regions, as far as I'm aware.

Michelle Simon: So, your mention of national actually wasn't true?

Kendra Bunker: No, there are... there is no national coverage determination.

Michelle Simon: There is none.

Kendra Bunker: Right.

Michelle Simon: Okay.

Kendra Bunker: Correct.

Craig Blackmore: So, I have a question around the issue of robotic prostatectomy, which is the area that you identified as moderate evidence of effectiveness, and I'm trying to understand what is required to have moderate evidence, and if I look at this, I think there's no randomized clinical trials, if I've got this right. There's no

controlled prospective trials with comparison groups that are selected and bias on various confounding variables. What I'm seeing are, I think, and you can tell me if I'm wrong, large case series with historical controls, which would have, I would think, a strong potential for bias. Can you clarify that for me?

Ken Gleitsmann: Yes. In fact, I will also refer you to the report, which has a mention of this in the executive summary and in the methods section, but just... I'm just going to read, if you don't mind, the definition of moderate.

Craig Blackmore: Thank you.

Ken Gleitsmann: And the first point I'll make is I agree, there was no high level of evidence in our quality assessment, and high would mean that further research is very unlikely to change our confidence in the estimate of a fact. I'm just summarizing. Moderate... further research is likely to have an important impact on our confidence in the estimate of a fact and may change the estimate. Typical sets of studies would be RCTs with some limitations or, and the... or is important here, or well-formed observational studies with additional strengths that guard against potential bias and have large estimates of effect. So, it's about sample size, effect size, for the observational studies.

Craig Blackmore: I'm struggling with sample size and effect size guiding against bias. I can see other characteristics of the study that might guide against bias. Are there other aspects besides size? I mean, did they try to control for age? Did they use some sort of matching? Is there some way?

Ken Gleitsmann: When we do our quality assessment tool is in the... is in our appendices, and I think one thing that may help, I'll give you an example since we're talking about prostatectomy. What we're showing in our moderate strength of evidence is statistical significance, and so I think one thing that clinicians will be ready to have pointed out is there is a big difference sometimes between statistical significance and clinical significance. Specifically to your point, operative times, when you're comparing robotic to laparoscopic, prostatectomy shows on the slide and in the text that there is decreased operative time comparing robots to laparoscopic. That time, the point estimate is a minus 22

minutes. So, is that clinically significant? It's statistically significant, so that's one example of what... there is moderate strength of evidence that this effect size is seen in this body of evidence that includes 55 studies and their quality ratings. On the other hand, the estimated blood loss between robot and open prostatectomy is a minus 470 mL. That's statistically significant. So, to me, as a clinician, it would... there's a big difference. That's just to illustrate the difference between statistical and clinical significance in that particular comparator, and their confidence intervals with those, as well.

Craig Blackmore: So, I mean the issue that comes up, particularly with new technologies, is often when we have new technologies we apply them under the most ideal circumstances and the easiest patients. We're learning, and if one compares that group to the patients who are so complex that we're still doing the open, there's going to be a huge difference, and sample size gets around that in the sense that you have more experience, but you know?

Ken Gleitsmann: I agree. I don't think I was using sample size as an end-all, but it's just one thing. In this particular group of... this particular body of evidence, for instance, surgical experience was one of the major points in quality assessing an article or a study, and the one high study for instance that was identified by CADTH for robotic versus open prostatectomy was a Fukuhara Study out of Italy and in that particular study, it was a well-done study, but one of the key things was that they identified one of the things that could be a confounder throughout, which is surgical experience. So, they precisely defined what they meant by surgical experience, which surgeons, how many were in the... and what their previous experience had been with both laparoscopic, even though that wasn't their comparator to robotic, so...

Craig Blackmore: And did they have a mechanism to match the patients in the group in terms of comorbidities, in terms of severity of illness, in terms of...

Ken Gleitsmann: There were... there were two ways that were done in these studies that we looked at, all these studies across. There were two propensity-matched studies. That's just one way to do it. But, there were indications in all of the systematic reviews and in the CADTH that indicated what differences there were between

baseline... in the baseline differences of patient characteristics and Kendra mentioned that typically in prostatic patients, the patients with the robotic arm were younger and had lower grades of cancer or stage of cancer. So, those baseline differences would change the quality rating of that study and that was a commonly noted problem in studies, in the methodology.

Craig Blackmore: Other questions? Well, it's about 2:45. Generally, we'd take a break. It seems like a good time. Take about 15 minutes and then come back and have our more in-depth discussion and head towards a conclusion. So, we'll resume at 3:00.

All right, who am I missing? Well, we have a quorum, and I'm going to call the meeting back to order. The next item on the agenda is the committee discussion and decision. So, this is our opportunity as a committee to discuss the topic amongst ourselves still using our resources for further information, as needed. So, I'd like to start off just by seeing if anyone has any other questions for the agencies or the vendor or the clinical expert at this point? Are there any questions or issues to be clarified? Okay.

So, what's been useful in the past is for one or several members of the committee to start the discussion by giving us an idea of where they stand, what they believe the data tells us or where they think the questions might be or sort of where they are in a working position. It's not binding, but to just start off and give us some grounding for the discussion. So, is there anyone who would like to take the lead and give us a summary of where we are at this point? Should we all have more coffee before we start this discussion? Seth's reaching for the microphone.

Seth Schwartz: I'm willing to take a stab at it. Well I think, you know, there's obviously some discrepancy a little bit in what we kind of thought our task was going to be and what has become clear is the way this technology is perceived, which is that it is more of a tool than an intervention, per se. When we look at the evidence that's been presented, I think it's fairly clear that there are some potential advantages in terms of decreased risk of blood loss and hospital length of stay, potentially decrease in risk of complications in a number of different procedures. The question of cost, we know this is an expensive tool, but we haven't gotten

any data that's really convincing in terms of it being necessarily more expensive, because there are some potential offsets, and clearly there are indications for it. So, I'm having a hard time thinking of any way in which we could say this is not something that we should cover, and I can't think of any restrictions, necessarily, that we could put on it that would be meaningful in terms of conditions.

Craig Blackmore: Can I get a sense? Are there other perspectives? Support for that perspective?

Kevin Walsh: Well, I guess I just want to talk about the cost part of it. Um, this cost is hidden in everything else the hospital does, or everything else the hospital charges you for and me for and everybody else and their brother for who comes in. So, we have to just, I mean, we can't come up with a number. Canada came up with a number because they've got a closed system, and that's what I was alluding to in the statement I'd made before, and maybe that... and I don't know if that... if the cost of the machine is going to be offset by the potential hospital savings of length of stay, but there's a fixed cost for the hospital and a maintenance, an overhead cost... a fixed overhead cost. So, I don't know how much that's going to impact it, but it's not cost neutral. We shouldn't discuss this as if it's cost neutral. That's magical thinking.

Seth Schwartz: Well, you may be right, but I don't know that you're right. I don't think I've seen the data to tell me whether you're right or wrong, you know? Whether this is cost neutral, cost savings, or expensive. I mean, inherently it seems expensive, but I can't say that soundly on data that tells me it's more expensive than the alternative.

Chris Standaert: I don't think there's data on that, and I think if you, you know, so it's \$2 million, so you do 10,000 procedures with it. You're talking what \$200 a procedure, you know? But then you're costing hospital stay by half a day, a day? That more than covers... I mean that's the thing. It's sort of that... the aggregate of the math for the whole system when you have a closed system like a Canadian thing, it's not clear, but it isn't totally clear to me that it's going to be a lot more expensive either. And in a system for the citizens of Washington State, for example, I don't have any evidence to

indicate that it's more expensive for them, because there's no charge for anybody using it. So, I don't know that I have any data that is more expensive to the people of our state. And again, a closed system has a big upfront cost, but does that aggregate out at some point? I don't think we know.

Craig Blackmore: Any other perspectives? Carson.

Carson Odegard: I do have one question for the... our expert. Could you give us an idea of say the top three procedures that we're looking at here, what the difference in blood loss is? Because, I mean, I can get a handle on length of stay and hospital time, surgical time and that type of thing, but when you're talking about a certain procedure and you've got a lot of reduction in blood loss and then another procedure that maybe it's not that different. Could you give us a perspective?

Craig Blackmore: I think I would shift that question over to the vendor. That's really a data-driven question. You want to know difference in blood loss based on the evidence, right?

Carson Odegard: I didn't see it in... well, if it is in the evidence, that'd be great.

Ken Gleitsmann: I think if we give you the top three evidence basis, they would be prostatectomy, hysterectomy, and cystectomy, and for those procedures it depends on the comparator and the procedure, and I'm happy to give you those numbers. They're in the tables of evidence in the CADTH, page 37 of the report would be for instance robotic versus open prostatectomy and blood loss in that procedure, the pooled meta-analysis blood loss that was 21 studies reviewed, was a minus 470. I think I gave you that as an example. So, that would be that procedure, and as opposed to the laparoscopic comparator, which for that procedure included 10 studies, and the pooled result was a minus rounded off to 90 mL, and we can go through that with the other two if you'd like.

Carson Odegard: Okay.

Ken Gleitsmann: Is that helpful?

Carson Odegard: Yeah, that's helpful. Thank you.

- Ken Gleitsmann: So, for hysterectomy, open this is 14 procedures, blood loss... this is a weighted mean difference, robotic is minus 222 mL less in that comparator, as opposed to comparing hysterectomy and laparoscopic robotic versus laparoscopic, and in that case it's a minus 60, actually a minus 61 mL.
- Carson Odegard: Okay.
- Ken Gleitsmann: So, it really.
- Carson Odegard: That's good. Yeah.
- Michelle Simon: Can you do the same thing for length of stay?
- Ken Gleitsmann: Sure. Easily. So, again, the same comparators, this is robotic prostatectomy versus open, and length of stay in pooled results is a minus 1.5 days, rounding it off in 19 studies. For robotic versus laparoscopic length of stay, pooled results from seven studies is a minus 0.8 days. For hysterectomy, robot versus open length of stay of pooled results of 15 studies weighted mean difference is a minus 2.6 days. So, that's hysterectomy and open and for the hysterectomy versus robot versus lap is weighted mean average or difference of a minus 0.22 days. That was not significant in 11 studies. So, of all those comparators, the last comparator I gave you is the only one that's not significantly less for robotic versus the comparator. Did I say that wrong? All of them, except the last one are... including the last one, I'm sorry. Yes, I miss-stated that, sorry. So, it was small, but it's significant. They're all significant. I'm sorry. And those are the first four tables in your report.
- Craig Blackmore: I guess I have a little different take on the issue and just to give us a different perspective, I'm not at all sure this is effective. I think the data is dreadful. There is a bunch of case series of I operated on some people, and I compared them to data from before. There's a few radical prostatectomies, which seem to be the one thing we know the most about. There's a few studies where there's an attempt to control for some baseline confounders, but there's not a single randomized or nonrandomized clinical trial here at all. I can just imagine if we looked at vertebroplasty in the absence of the clinical trial data, we would have said this is great, and then the randomized clinical trials come out and, you know,

you get a very different picture. So, I'm not at all convinced that this is effective. Do I think it's worse? No. I don't have good data on that either. So, I think you can sort of accept the argument that it's just like using a different clamp, and it's part of the procedure, and we should cover it on that basis. It doesn't seem to be particularly dangerous. Or, you can maybe accept the argument that we really can't do a randomized trial because it's so disruptive. I struggle with that to be honest. But, I'm not... I think of the decisions we've had to make, seldom have we had such poor evidence despite the large number of procedures, as what we're faced with here. Richard?

Richard Phillips: A little question about... I don't quite really know how to figure the costs, because when we're looking at the cost of the procedure no matter how many they do, there's no additional cost to the state, as far as I can see. I mean, we all know there's a capital cost, and that's a separate issue. I'm not sure it's something we should be dealing with in this... in the confines of this group, and it seems to me if there is no additional cost, and maybe that's open to conjecture. Maybe there is increased costs, but my guess is there's less variable cost because of the decreased length of stay, etc. All that aside, I just don't know where to put cost in this whole thing. Do we put the whole picture, the capital investments? Is that part of our charge? Or should we just sort of deal with the variable costs of per procedure?

Chris Standaert: I struggle along the same line. I mean, do you say to a hospital you can't put in a fancier waiting room, because that's going to cost you a lot of money, which you're going to have recoup by doing more to my patients? Do you not get a fancier lighting system for your OR because your surgeons... I mean, that's... it runs in the same thing to me, and I sit there and go I know it's more expensive. It's clearly expensive and [inaudible] 10,000 procedures, but it's clearly more expensive, but that's a difficult thing to sort of regulate. What kind of screwdriver? What kind of drill? What kind of whatever does the hospital buy for its surgeons? I don't know.

Seth Schwartz: Let me just give you a historical perspective. If it's not governed, what will happen is market forces will take over, and every hospital in the state will be trying to buy a da Vinci, because it will give them a competitive advantage, in their mind, and get them

more patients. That's why every hospital in the state has an MRI that can afford to have one. So, I understand your point, but take it to its end point. I mean, its end point is if this is not governed, and maybe this is beyond the prevue of this group. I'm not saying it should be, but I'm just, again, look at reality.

Chris Standaert: I guess, but then, I mean that's... we don't decide whether Swedish can go buy a new MRI scanner. That seems an odd thing for us to decide, and what decides that is the market. I understand hospitals try and buy this because they think it's a competitive advantage, or they think they have... they can get them faculty or staff that are facile with it who can do procedures that can't be done so readily without it, and as a market... it expands their sort of scope. I get that, but I assume at some point that gets regulated... that sort of behavior has to get regulated by the marketplace, because I don't know how you would administer that.

Kevin Walsh: Well, the flip side of that is that here you have a procedure that we were looking at, it takes longer, and surgeons don't get paid anymore for it, yet they all want to do it. So, why is that? And I mean that's kind of... and then I look at the data and I agree with Craig. I mean, it's not great data, but there's a lot of it and it's all going in the same direction, that basically the complications seem to be the same or less and some of the other features that affect patient outcomes are the same or better.

Craig Blackmore: Everybody loved vertebroplasty. Everybody loved bone marrow transplant for women with breast cancer. There's innumerable examples where the initial results are promising, the initial uncontrolled trials are promising. I mean, that's normal. And then data changes.

David McCulloch: Craig, those are different. Those were very specific, new, different interventions. This is just a really expensive, really sophisticated tool that a whole bunch of surgeons think gives them better precision to do surgery with less invasion and better outcomes. I mean, it is... it's like a... it's not comparable to the vertebroplasty or bone marrow transplantation.

Craig Blackmore: Yeah, I think you make an argument that it's a different kind of scalpel or a different kind of clamp.

- David McCulloch: Right. Mm-hm.
- Craig Blackmore: And then it becomes, you sort of have a different bar, and you say well, you know, I don't need randomized clinical trial data for every new generation CT scanner I put in. But at the same time, should I pay for that? And the answer is no, but if the surgeons in the hospital feel there's some advantage to it, as more of a business argument or whatever, then I don't have a problem with that. But that's different from saying the state should be shelling out some extra cash for this extra spin that is unproven, and I see those differently, and maybe that's me, maybe that's artificial, but that's sort of what I'm struggling with.
- Michelle Simon: But even if we decided that we don't like that, and we decide we shouldn't cover it, there's no way for the agencies to operationalize that decision, it sounds like. So, I don't really understand what we're trying to do here.
- Craig Blackmore: I think, again, this is an opinion. This is my one voice of ten here. You know, I think we can make a decision that says... personally, I would say the effectiveness here is unproven. You know, it's promising. It's unproven. And I would say that the state should provide no additional reimbursement for this. So, the decision isn't about doing laparoscopic something. It's about additional reimbursement for using the robot.
- Michelle Simon: So, in the event in the future if codes do come up, they won't...
- Craig Blackmore: There's no additional reimbursement. You get paid whatever you get paid for doing the procedure. You can do it however you want to do it and, you know, that's how... it doesn't address sort of the overhead costs rising and these sort of more abstract implications of cost, which are very meaningful, but we don't have a good handle on. I don't think that's inconsistent with what we're... sort of what we've been asked. I don't know how to get beyond that point, and I'm certainly looking for more opinions.
- Chris Standaert: I'd like to go back to what you said before about comparing it to other things. I don't think vertebroplasty is a fair comparison. I think if you put it into like radiology, you know, it's a 1.5 versus a 3 Tesla magnet; 3-Teslas are expensive, you get paid the same

reimbursement for a lumbar MRI on a 3-Tesla or a 1.5. The 3 costs a hell of a lot more. I don't think it gives you any more data. The only thing my 3-Teslas are better than my 1.5 is it's a lot more expensive for the hospital to run the thing and have it sitting there. They chose to buy it, because they think there's some finite spaces where it's more helpful and it's helpful marketing-wise, and I don't know. They like the cool toy. I don't know why they bought it, but it was a lot more expensive than 1.5, and they like it, but it's not... I don't think it's our place to say they can't have a 3-Tesla magnet and do lumbar MRIs on them, even though they get... they have to pay for the magnet, they get paid no more for it, and it provides no additional clinical information. They chose to do that with their equipment. Why would I say you can't do that? And I think the state is actually asking for... I have to go back to what they said, but they said, you know, they want the right to decide what to pay for this when and if they decide it gets paid for.

Craig Blackmore: I don't have a problem with that analogy. I have a problem with saying this thing is effective, because I don't know if it is.

Chris Standaert: I don't know that 3-T magnets are effective.

Craig Blackmore: I don't either. That's why I don't have a problem [inaudible]. And I don't have a problem with... I have trouble saying, on some level, you... we will no longer pay for the procedure if you turn on the robot. That seems sort of silly to me. But at the same time, I don't think there's any sort of strong evidence that thing is adding value such that the state should be shelling out some extra money for it. So, yeah. I mean, I'll let other people talk. Joann, what do you think?

Joann Elmore: I agree with you that the overall quality of most of the evidence in the published literature is poor. There may be statistical significance, but we have to think about clinical significance, as well. It looks promising in many areas, but it's still unproven in many areas, and as of early 2012 in the State of Washington, more than \$50 million has already been spent in installing them, 37, I guess, systems. This probably goes beyond our mandate, but I almost wish that we as a group could state cover with conditions that if it's used, it has to be clearly documented that it was used so that the agencies would actually be able to follow utilization,

and I don't know if it's in our mandate to say that if there is a request for additional funding when this is used that we feel from our current review of the literature that no additional funding above and beyond the regular procedure is warranted at this time.

Marie Brown: That would be hard to do, though, because we don't know what the data is going to be like between now and when they might add additional code. I mean, if they added an additional code, it would likely be due to some evidence, and I'm not sure we're going to.

Chris Standaert: Maybe you're overestimating them.

Marie Brown: Will there ever be any RCTs in this kind of process? Were there when laparoscope was first used for like... in the 70s for tubal ligation? Did they... when they started using that particular technology did people ever randomize people at that point into use of the new laparoscope or was it all case series analysis. Is that the best we can hope for in a new technology, I guess is my question?

Chris Standaert: It's a bit like doing an appendectomy. I mean, do they do a scope or is it open? It depends on what the surgeon thinks he'll do best with... or he or she will do best with, and I don't know if it's been studied.

Craig Blackmore: Richard?

Richard Phillips: Yeah, I think one thing we're in the unfortunate situation, or maybe the fortunate situation that we're really on that geometric curve where everything's expanding. It would have been great if we could have maybe been involved in this decision ten years ago when it started, but right now things are changing so fast, and the fact is that we don't know how to really assess safety from the data that's given us, because we... I think they've come up with some threshold of what's safe in terms of number of cases, etc. We don't have that, but we do know that the experienced people seem to do a better job at it than the inexperienced people. And one other last point is that this technology is a little bit different too, because what it's doing is it's showing that there are some procedures that can only be done with this technology. As an

example, I would say having done heart surgery in the past that I couldn't do certain mitral valve procedures. Well, I could, but there are about 20% of them where I couldn't see the damn valve. It was frustrating as could be. Now they can sit down at the console, they can do it, and they can do it right, and it's wonderful. It's a new technology that there's no comparator about it. It's something that's... it's revolutionary in that regard.

So, I don't think it's fair to say well let's split it like radical prostatectomy versus the robotic prostatectomy, because that might be a comparator, but there are a large number of the procedures, because of the ability to manipulate the robot the way that you can, that it makes some procedures that weren't done... weren't possible in the past to be very possible and very safe and much safer than what we used to do them.

Craig Blackmore: See, now, I would agree with everything you said, except the last part. We don't know if they're safe or not, because we don't have data.

Richard Phillips: Well we say in certain hands we know that it's safe.

Craig Blackmore: I don't know that. I don't know that because I don't know that there's any data on it. I don't know that doing these procedures we didn't used to be able to do is a good thing. Nobody's shown that. That's one of the things I'm struggling with. We can do more, which has potential to be good, but I don't know if it's good.

Richard Phillips: Well, you're not going to have randomized control trials to do that, but based on...

Craig Blackmore: We may not.

Richard Phillips: ...experience from Spokane, for example, compared to what I know was done in the past on mitral valves, it's far better. It may be just because they're better than the average bear.

Michelle Simon: Could I ask the evidence vendors if you have any data that really speaks directly to the experience of the surgeon?

Ken Gleitsmann: Yes.

Woman: We did have... the bulk of the evidence was about prostatectomy, which we discussed and, you know, when you talk about surgeon experience, there are a lot of different definitions within the literature about what constitutes an experienced surgeon and, you know, this range across different studies from sometimes the experienced surgeons were those who had done ten cases and sometimes it was, you know, hundreds. It was many, many more. And so there's a lot of variation within that about what constitutes an experienced surgeon and most of the literature that we identified across the variety of procedures that did look at surgeon experience basically compared the first 25 cases to the last 25 cases and looked at the improvements there, and within that there was the case of prostatectomy where you see some added benefit from surgeon experience. For other procedures, we were only seeing statistically significant findings with regard to decreased operative times, which might be expected.

Kevin Walsh: I'm struggling a bit with Craig's comments that we're not seeing any evidence here. I mean, I think part of the way you presented this, there were so many studies that you gave us kind of a meta-analysis level view of it, this high-level view of yeah, this is moderate-level evidence to support. So, I was just looking into the prostatectomy data a little bit, because that's the one that we apparently know the most about and so within that, there was one study that was rated as high quality and then there were a number that were rated as good, and I'm wondering if you can make any comment about those studies or tell us a little more about those studies that actually might be closer, because I mean, we're never going to have randomized trial data on this sort of thing? So, we have to look. I mean, evidence-based medicine dictates that we look at the best available data. So, it may be bad, but it's the best there is. So, I'd like to know what that shows us.

Ken Gleitsmann: Yeah, thanks. Yeah, so, the study I mentioned that was the one study out of all this that was high quality was a study by Fukuhara, which is in the report, and that was an Italian study and that was a comparative analysis of prospectively... by the way, there were 26 prospective prostatectomy studies, in that particular study, there were 103 robotic cases and 105 open compared, and the surgeons' experience, you had to have at least a number of surgeries to qualify to be in the arm for the robotic group. So,

they were all equally trained surgeons, and there were four surgeons, and they looked at outcomes, and they looked at outcomes... all the outcomes that we've discussed.

Kevin Walsh: In terms of the... was there anything about how the patients got into one group or the other? Was it patient choice? Was there anything about comparing those two patient populations?

Ken Gleitsmann: No. It was an observational, but it was the prospective...

Kevin Walsh: Were there any baseline characteristic differences between those or anything about that?

Ken Gleitsmann: The baseline characteristics were the same, why is why it was... one of the reasons it was rated as a high-quality study, but no. Typically, as in this study, it was a matter of patient selection by the physician and the patient choice.

Kevin Walsh: Maybe for our clinical expert, is there any... any thoughts about why you might make that decision if you had both available? Are there any big differences?

Jeffery LaRochelle: Well, nowadays I don't think... I think the decision is made based on what you do better. Honestly, patient baseline characteristics don't play very highly into this. I think early on, a lot of surgeons would not do a robotic surgery if you could palpate the tumor on rectal examination, but that's kind of fallen by the wayside with experience, as people have become more comfortable with their visual assessment of the prostate rather than sort of the using your fingers down there. So, I don't think that the clinical... the baseline characteristics of the patient are not going to play very much into blood loss, length of stay and things like that. They just won't have a very strong effect, because honestly, it's a surgery that's fairly, I want so say algorithmic, but there's not a lot of variability, even in somebody who's obese or so forth. It's just not going to change the surgery dramatically, as far as outcomes are concerned, so. I don't think those baseline characteristics probably have a strong effect on the measurements that you're looking at.

Kevin Walsh: Okay. What I'm just trying to get at is so we have an unselected patient population that we're comparing. Is there... might there

be some characteristics that they chose... the surgeons hand chose the ones that were going to be better for robotic surgery, or is it equivalent, and it sounds like...

Jeffery LaRochelle: I think what I might ask of the vendor, the study, I can't recall off hand, the robotic surgeons might have been the robotic surgeons and the open surgeons might have been the open surgeons. I don't think that you had guys doing both. I don't think you had surgeons doing both. I think you just had experienced surgeons in each category, and they were looking at them going forward.

Chris Standaert: That's true? Was that the answer from the vendor?

Woman: Yes.

Chris Standaert: Okay. I hear voices behind me.

Craig Blackmore: I would struggle with calling that a high-quality study, personally.

Richard Phillips: Yeah.

Woman: The high-quality rating is actually provided by CADTH, but one thing that I do want to underscore with regard to the prostatectomy evidence was that, you know, we did have 26 prospective studies within that evidence base, so these aren't just all historical case series. There was... there were a number of studies that were prospective and did... they were rated as good quality, because they did a good job controlling for confounding and actually within our report, we have a table breaking down the meta-analyses. So, there is the overall pooled meta-analysis and then it's broken down also by study quality. So, if you want to look only at the high to good quality studies, you can look at the meta-analyses of just those studies, and we do see in many places what was significant in the overall pooled meta-analysis may not be significant in the high to good-quality study meta-analysis. So, maybe that helps.

Carson Odegard: I have a question for our expert. Has the Urologic Society or do you know of any of the other societies who have come up with guidelines for credentialing minimal cases... recommendations?

Jeffery LaRochelle: That's pretty much on an institutional basis. Honestly, I don't know any off hand that are issued by the societies, say for by the AUA or any ACOG, I can't speak to anything outside of urology, but I think the regulation of our... who is given privileges to use the robot are based on institutions and it's either based... you can kind of be grandfathered in based on previous experience at wherever you were before you came to that facility or based on specific training received either in a fellowship program that does minimally-invasive surgery or through da Vinci... through Intuitive Surgical, as well, does provide training. Again, I think some institutions require some specific training that would be received by the maker of the machine if you don't have that prior experience. I can't say whether most institutions do that, but I do believe most do. I can't tell you that with certainty, but most institutions have those requirements in place now.

Craig Blackmore: Anybody else have a comment?

Chris Standaert: I did not hear or see a lot of safety concerns with this, so as of safety issues I didn't see much in there. Is it just sort of one of those.

Carson Odegard: I didn't see much in the data at all.

Chris Standaert: Huh?

Carson Odegard: I didn't see much as far as safety.

Chris Standaert: Yeah. Not much in the way of problems.

Carson Odegard: No.

Michelle Simon: That doesn't necessarily mean it's safe.

Chris Standaert: No.

Michelle Simon: We just don't see the data.

Chris Standaert: Right.

Carson Odegard: Even minimally-invasive has its risks.

- Chris Standaert: But it's not a... you know, we had BMP in there as a question of the cancer issue and some other things and so that... there's no.
- Craig Blackmore: We're clearly comparing invasive procedures, so they all carry some risk.
- Chris Standaert: Oh yeah. Yeah.
- Craig Blackmore: We haven't seen evidence, I don't think, that shows us it's any worse than anything else.
- Joann Elmore: The biggest concern is during the learning curve of early use when this gets disseminated into groups that aren't the academic experts and those that are high volume.
- Chris Standaert: Mm-hm.
- Craig Blackmore: Okay. We have to figure out how to organize this, which can be a challenge. I guess I need some input from the agency directors on what our decisions mean and I'm particularly struggling with this question if we say no coverage, I need to understand what that means and if it means if they turn on the robot they don't get paid for doing the radical prostatectomy or is that something that's within our discretion. I guess I'd like some input from the directors on implementation. Can you help me?
- Gary Franklin: This is Gary Franklin. I have a much more optimistic view of what you might decide, and I think I'm hearing here what... the kind of thing you said before earlier recommending the possibility of coverage but not paying for extra codes. Just making a decision like that... this thing is burgeoning. It will dramatically increase. It will have an upsurge in costs somehow. We don't understand exactly how that might happen, but just making that decision, number one, you're going to have to relook at it in 18 months, so that will give you an opportunity to look at new data that might be better than this sort of fancy case series compared to historical controls, which is extremely low-level evidence. Just making that kind of a decision alone would be tremendously helpful. Number one, it would support us and say not covering any additional codes that come out until more evidence comes out. Number two, the community will be on notice that we're watching this thing. You're watching this thing, and we're going to come back

and look at it again if we need to. So I think it would be tremendously helpful. It is dramatically expanding. I think it is an example of a very expensive potentially extremely useful technology, but we don't know that yet. So, this is going to send the signal, we need better data here. Why aren't there better comparison trials. That's ridiculous. So, I think that what you said earlier would be very helpful in this kind of a decision.

Craig Blackmore: So, just in terms of operationalizing that, I mean, we haven't sort of phrased things in exactly that way before, but that's something that you guys could work with on an operational level.

Gary Franklin: Well, L&I already more or less is doing what you sort of suggested earlier. We don't say they can't do the surgery with that technology, but we also don't cover that hit pick code, which to me those... it's the appearance of those kinds of codes that is going to become more and more prevalent in the near future.

Chris Standaert: Do you guys have a sentence in your slides saying leave authority to determine added payment to agencies? Is that what you... is that okay? Is that helpful for us to say that?

Gary Franklin: Leave the...

Richard Phillips: Payment out.

Gary Franklin: [inaudible]. Yes.

Chris Standaert: Leave authority to determine added payment to...

Gary Franklin: Yes.

Chris Standaert: Is this what they requested in there, or suggested? However you want to put that word.

Gary Franklin: But without the kind of policy that L&I already has, for example, to not pay for these extra codes and actually it's the same policy for many other payers, would be... would not be inconsistent with kind of the direction you're heading.

- Richard Philips: Could I ask for clarification on that. When you say not paying for the extra codes, that means if somebody does a procedure with robotic surgery, you don't pay for it at all?
- Group: No.
- Gary Franklin: No. It doesn't mean that at all. We pay for the surgery, but we just don't pay for it if they try to do add-on bills or modifiers.
- Richard Phillips: Well, that's what I'm wondering about. What is the... see, my understanding was that nobody paid for those extra codes. Am I wrong about that?
- Gary Franklin: Well, it isn't that there isn't or won't be...
- Richard Philips: I mean Medicare doesn't pay for it. Nobody pays for it, right?
- Chris Standaert: At the moment, nobody pays for it.
- Richard Phillips: So, I mean in a sense aren't you consistent with what's going on in Medicare and Medicaid?
- Gary Franklin: Very consistent with what's going on there, yeah.
- Richard Phillips: Yeah, well maybe I have a simplistic way of looking at it, but I just wanted to understand it.
- Gary Franklin: It's all consistent so far.
- Chris Standaert: This is sort of odd. Is that actually a condition? So, if we were to say cover but allow the agency to determine payment in the future, should that become an issue, that's kind of a weird thing to say. Is that a condition?
- Craig Blackmore: I was going to suggest... I think that the committee, tell me if I'm wrong, that the committee would not be comfortable saying if the robot's turned on, we're not paying for the procedure.
- Marie Brown: No.
- Richard Phillips: Right.

- Craig Blackmore: So, I think we would phrase a non-coverage decision as meaning no additional payment beyond the procedure without the robot.
- Richard Phillips: Right.
- Craig Blackmore: For the robot. A coverage decision would mean, you know, we pay for whatever... if there's a new code that comes around or there's some mechanism to bill for, we would pay that extra amount for the robot, and then a coverage with conditions decision would be if a mechanism is there to pay for it, we would pay for the robot for certain conditions or certain populations or certain whatever other criteria we came up with. So, that I think is how we should phrase our decision into one of those three categories.
- Chris Standaert: I find this very odd. We're talking about making a condition for what might potentially happen in the future but isn't happening now.
- Joann Elmore: And that isn't a condition.
- Chris Standaert: That's a very odd... we don't.
- Richard Phillips: Well, it's a condition, but...
- Craig Blackmore: That's the question I was trying to ask the agency directors, and they felt comfortable with being able to implement that.
- Chris Standaert: It's just... we don't... so...
- Seth Schwartz: You know, Craig...
- Craig Blackmore: You won't, you know... I'm going to stop you for a second and...
- Chris Standaert: That's an odd way... semantically... all this stuff.
- Craig Blackmore: I want comments on the framework. I'm not... I'm not soliciting a vote on whether you would vote a certain way. I just want comments on whether we can frame it into one of those three choices I've outlined or not.
- Chris Standaert: But you're saying a noncoverage means just what you said.

- Craig Blackmore: Means no additional payment for using the robot.
- Chris Standaert: So, noncoverage... there is no coverage with conditions unless we're going to put a box around when people can use this and when they can't use it. Cover... cover would...
- Joann Elmore: Would mean if they added a new code, it would cover it.
- Chris Standaert: That's just totally weird. But you can... cover with conditions would be, you could make a condition that this is a condition. That's not what you're talking about.
- Craig Blackmore: This is not a condition. No. I can't make payment a condition, but I can define it this way. Seth, did you have a comment on my structure, here?
- Seth Schwartz: I'm just trying to understand what the stem is going to look like. So, it's for...
- Craig Blackmore: Stem is robotic surgery.
- Seth Schwartz: I mean, what is it going to... I guess that's what I was trying to.
- Craig Blackmore: It's going to look like...
- Richard Phillips: Cover with a mandate.
- Craig Blackmore: Coverage of additional reimbursement for use of the robot on surgical procedures is covered, not covered, covered with conditions.
- Seth Schwartz: So, we would only be commenting on additional coverage beyond the procedure?
- Craig Blackmore: Beyond what the procedure is billed or paid without the robot. I'm also entertaining... if people have a different way of structuring this, I'm happy to entertain.
- Seth Schwartz: No, I mean, I understand the point, and I don't disagree with the point. I mean, I think that we've agreed with the tool. We've agreed that it should be... or I shouldn't say we agree, I mean

we've agreed it's a tool and some of us feel, or at least there's some potential to feel that surgeons should be able to use it at their discretion, but we're not convinced that we should... that they should be paid any more for using it than using some other form.

Craig Blackmore: Trying to give us that option.

Seth Schwartz: Right, but so I'm... I'm just... if we're going to state it in that way, if we're going to state that it is a negative decision about using this, we have to be very clear what we're talking about, because I don't want this... I'm concerned that the spirit of the decision is going to be the opposite of what the perspective of the group is.

Chris Standaert: We could cover it under current payment conditions or something like that. I... when you're saying noncover of something, you're really not trying to tell people not to use, and that's what's sort of bothers me that the message comes out noncover when we're really not... I personally don't think we should be regulating... telling people they shouldn't be using this. So, I don't really like saying noncover.

Craig Blackmore: Well, but you're... then you're...

Chris Standaert: What you're saying is you're playing the semantics, but...

Craig Blackmore: But I'm giving you that option. I'm not saying...

Chris Standaert: Right.

Craig Blackmore: You know, I'm giving you the three choices. You can say I think we should just pay for it. I'm trying to set up...

Chris Standaert: But I'm not saying it we should just pay for it. We're not paying for it now. I mean, that's... I'm... that's why I more like the idea of saying you can do it... this is where the whole thing is sort of odd that we're covering a tool. You know? The process is odd, but you can do it, but any payment decision... any decision to extra payment are left up to the state agency.

Craig Blackmore: No, I'm not saying left up to the state. I'm saying we're not paying for it. We're not paying you extra money to use this clamp.

We're not paying you extra money to use this robot. We're not paying you extra money to use the 3-Tesla magnet. Or, you could say, sure, we'll pay you extra money. We haven't figured out the mechanism yet, but you can get paid extra to use the robot.

Richard Phillips: I'm like Seth, though. I don't... you know, a noncoverage basically states we don't want you using the tool. That makes me feel uncomfortable just to say noncoverage.

Craig Blackmore: Joann.

Joann Elmore: How about this pink one that says cover with conditions and the condition be that we do not support additional payment for use of robotic-assisted surgery beyond the basic procedure, and then I would add my second requirement that I really want us to have better utilization data so that every time a robotic-assisted surgery is used, I would like coding so that it could be tracked by agencies.

Craig Blackmore: So, cover with conditions means we will only pay for it under the following circumstances. So, what are the... what are the circumstances? We'll pay for it if we don't pay for it?

Joann Elmore: If it doesn't cost any more.

Seth Schwartz: I think what's vague about this...

((Crosstalk))

Seth Schwartz: ...the problem created is that we're talking about... what's hard is that we're saying it's a tool to do a procedure. So, are we saying we'll pay for the procedure. Are we really just separating this out and saying will we or will we not pay for the tool. And I think... and when we start talking about extra codes we're saying will we or will we not pay for the tool, which somewhat makes the most sense, but in reality that's not the way it works, because it's a tool for an operation, which we're going to cover or not cover. So, again, there's a lot of semantics involved, but I think even though it doesn't... even though it's kind of an uncomfortable way to use the conditions, I think that probably makes the most sense, because it at least encapsulates that we're going to cover the

procedures that use robotic surgery, but we're not going to cover extra.

Craig Blackmore: So, I don't know that we can do this. We don't have the authority to determine the amount the agencies pay. That's a separate... that's a separate authority that is clearly not ours. So, we can't tell the agencies they can only cover... they can only pay for the robot up to a certain dollar amount. We can say you can pay for it but only as much as this other thing. Do you see what I'm saying? That's telling them how much they're allowed to reimburse, and we don't have the legal authority to tell them how much they can reimburse. I don't think.

Richard Phillips: But if there's added procedures, we can...

Craig Blackmore: But we have the authority to say you can't pay for this procedure.

Richard Phillips: Yeah, right.

Craig Blackmore: But we can't tell them how much.

Michelle Simon: That would be no cover then.

Craig Blackmore: Help me Gary.

Gary Franklin: So, one of the things you recommended earlier in our slide was the possibility of the condition being to leave the authority to determine added payment to the agencies without making a specific statement about what you... what we should and shouldn't pay for. So, that's another possible way to state the condition without getting into saying how much will be paid.

Chris Standaert: And the coverage is the negative decision about payment.

Gary Franklin: Right. The coverage is that the...

Chris Standaert: It can... we think it's reasonable to use and the state can decide how much.

Gary Franklin: And that's it. Reimbursement should be left up to the...

- Chris Standaert: And then we have a cover with condition with that being our condition that the state has the authority to decide if they're going to pay more for it or not.
- Gary Franklin: So, I guess that's one possibility.
- Craig Blackmore: All right. So, Josh tell me about the program laws.
- Josh Morse: Your program law provides you a definition of your coverage determination, which means circumstances under which the technology will be included as a benefit, a covered benefit. It also provides for reimbursement determination. When we frame your findings and decisions, we're doing a two-step process of is it a cover determination and is it a... what is the reimbursement determination? That's how you present your findings. I don't know if that's helpful. For the reimbursement determination, the definition is, means of determination to provide or deny reimbursement for a technology included as a covered benefit, so.
- Chris Standaert: So, we can have it as a covered benefit, yet deny reimbursement for it.
- Seth Schwartz: Or you can provide the conditions for when reimbursement should or should not be provided.
- Chris Standaert: So, we can make it a covered benefit but then deny reimbursement.
- Seth Schwartz: Additional payment, perhaps.
- Craig Blackmore: So, if we said we cover this and the condition is that there be no additional reimbursement... or reimbursement in addition to the procedure, which is what Joann said. And we think that's possible within the framework of our statute.
- Seth Schwartz: That's what I think.
- Craig Blackmore: All right. Okay. So, I guess in terms of how this is structured now, what we're talking about is a noncoverage decision means if you turn on the robot you don't get paid. A coverage without condition decision means the robot will be covered and any mechanism that's derived going forward to bill for it will be

honored by the state. And a coverage with conditions decision means that it will be covered and the condition under discussion, at least one of the conditions under discussion is that no additional reimbursement will be allowed for the use of the robot in that procedure.

Seth Schwartz: No.

Craig Blackmore: No.

Seth Schwartz: No that's... everything that you said is based on an assumption that the state has the ability to distinguish when cases are done with a robot or not, and they don't.

Man: [inaudible].

Seth Schwartz: But are you asking...

Joann Elmore: That was... that's why I had my second point, that I would require that.

Man: [inaudible].

Seth Schwartz: All I'm trying to point out is that we need Joann's second point to do any of the three things that you just mentioned.

Craig Blackmore: So, you know, I'm sort of trying to work through... we got the big picture framework and then we drill down on what the conditions are and how they're worded. My initial framework didn't fly, so we're going to framework number two. In terms of the big framework, so I think that's a detail of how we phrase the conditions, right?

Seth Schwartz: I'm not trying to be picky here, but the reality is that if we say no coverage, unless the state decides that they're going to prospectively ask every time whether robotic surgery is going to be used or not and when people say yes they say no we won't cover it, that's the only way to... I mean that's the only way to get at the issue.

Craig Blackmore: Or we could get out a no coverage decision under that framework, but I'm sort of assuming we're not headed for a no

coverage decision. No coverage meaning if you turn on the robot you don't get paid for anything. Maybe there's... maybe there are people on the committee that are headed that way. I didn't get the sense that the committee, overall, was. So, that... if we're really heading in that direction, then we probably need to phrase things differently, but I don't think the majority of the committee thinks that's where we should end up. Am I wrong? Do we think turning on the robot disqualifies you from payment?

Group: No.

Michelle Simon: We're just saying we don't want to have additional payment if you do use a robot.

Joann Elmore: And we want to know when you're using it.

Craig Blackmore: So is that...

Joanne Elmore: Until there's data that shows that it's superior in terms of outcomes, we don't want to incentivize the use of the robot.

Michelle Simon: So, just to have a new flavor on the discussion, are we going to just say it's good for all conditions or are we going to try to utilize some of the evidence report at all? It does seem that there is some moderate evidence that for at least three conditions the robotic prostatectomy and the hysterectomy and cystectomy that there's some good... some moderate evidence that suggests it's worthwhile or... because it's not randomized controlled trials, we're going to just say nothing about that at all? I mean, how do you all feel about that? I'm not saying one way or the other. I just want to have that discussion, or not.

Chris Standaert: I don't know... no. What I was about to say is sort of somewhat related to that. I think in the language if we say... I agree that... frankly I find this whole thing odd, because we're being asked coverage on something that we don't cover or pay for already, and the language is very tortured, and I agree that there shouldn't be an extra charge for it now, which there isn't, and maybe there are things, like the things you're talking about, that it might actually be beneficial to be using this on and maybe the state will want to pay more because maybe they want to encourage people to do those, because they may turn out to be better. I don't think

the data is there to say that now. I think if we say... so I'm not strongly either way. If we put in there saying there should be no additional payment for this ever, then if the data arrives and this turns out to be beneficial and the state actually wants to incentivize it, they come back to us and it goes through the whole process again. If we say what they said, we leave the authority to determine up to them, they decide it's beneficial for them to pay more, they can make that choice, and it doesn't come back through our process again to make that choice for them. So, just in terms of language we can be absolute or we can leave it up to them, which changes sort of how this would play down the road.

Richard Phillips: The payments are constantly evolving, just like the technology. So, in the services and what's going to be billed is evolving. So, I don't know how we can... we don't have a crystal ball in that arena. So, you know, I think if we can leave it up to the agencies to make that decision.

Michelle Simon: I'm comfortable leaving the payment piece up to them, but we're not here just for cost. I mean, we're here for safety, and we're here for efficacy, too. So, aren't we just kind of giving up on those two pieces and just talking about the cost?

Craig Blackmore: I mean, I don't know. I was voicing the opinion that I didn't think there was sufficient evidence for any of these conditions to make a statement that these are effective and they should be paid for, but that may not be the opinion of the committee overall, so, you know.

Kevin Walsh: I didn't feel that the evidence was impressive that the... there was some decreased length of stay in some cases in some types of procedures. I didn't think the EBL difference was compelling. There's increased operative time for most of these procedures. So, really the length of stay is the only real benefit that is measurable, or that's been demonstrated, and I didn't think that the differences... the differences in length of stay between the procedures was so dramatic that it needed... that certain other procedures needed to be distinguished.

Joann Elmore: Maybe the differences are not in the perioperative outcomes, but the data that should be looked at is the sequelae, both short-term. What are complications in the first week? What is the data on

return to work? Is there... I mean, those may be, and from what I understand, nobody's looking at those. They're just looking at perioperative side effects.

Ken Gleitsmann: That was one of our limitations of the evidence base was that they were... there were no long... even cancer recurrence, there were no long-term quality of life kinds of outcomes that were identified.

Joanne Elmore: And that's the key step to know whether something's...

Seth Schwartz: There were... I think there were a couple other pieces. Correct me if I'm wrong, but there was some data on... in at least a few of the ones of improved negative margin rates.

Ken Gleitsmann: But, there was a lot of selection bias in that one.

Seth Schwartz: I understand the data is problematic, but I mean.

Ken Gleitsmann: Yes.

Seth Schwartz: There's that, and the other thing that I thought we saw was that...

Ken Gleitsmann: For lower cancer stages, right. Earlier cancers.

Seth Schwartz: And then there was the other question was about... of impotency rates. I thought there was some data on differential impotency rates for a prostatectomy.

Ken Gleitsmann: True. At one year, there were increased continence and increased sexual function return, or faster.

Seth Schwartz: And again, I don't know what the quality of those... can you make any comment on the quality of the studies that data came from?

Ken Gleitsmann: Sure. That was a good-quality systematic review and we have the pulled data.

Seth Schwartz: I mean, that's pretty compelling and Kevin I would also disagree with you a little bit on the blood loss data. I think there was some significant data on different transfusion rates, which is pretty

substantial, and I thought that for virtually every procedure there was less blood loss.

Chris Standaert: I must have read that... when I saw those arrows saying increased sexual dysfunction, I sort of read it the other way around. So, actually it's not... it almost looked like they were worse by the way the arrows were going. There was an increased... so it's actually decreased problems. Decreased rates of problems, but the arrows were going up on the slides, which threw me the other way. So lower rates of, okay.

Seth Schwartz: Lower rates of incontinence. Increased...

Ken Gleitsmann: And actually, I can split that out to the good studies if it's interesting. Again, the pool... we gave you the pooled results for those and those were, again, urinary continence. This just happens to be the reported as improved with robotic compared to open and robotic compared to lap was not significant in that case, and if you look at the good studies and look at just the good studies, they were not significant in either of those comparators.

Joann Elmore: The one-year continence rates were not significant?

Ken Gleitsmann: The one-year continence rates... and that... if you want to look at return of sexual function for the good studies, not significant. They are in the open group and not significant in the... I'm sorry, not reported in the lap group.

Seth Schwartz: Just as I guessed. What were the... what direction were the trends in those studies?

Ken Gleitsmann: Both of those... oh, for the pooled?

Seth Schwartz: No. For the pooled, you said significant. For the higher-quality studies, you said it's not significant.

Ken Gleitsmann: Yeah.

Seth Schwartz: Was the data in the same direction as the pooled and everything?

Ken Gleitsmann: Yes.

Craig Blackmore: So, again, and these are all done with, I assume, un-blinded assessment of outcomes? The surgeons just saying...

Ken Gleitsmann: Yes.

Craig Blackmore: ...how'd you feel? Better than I operated on you, right? Sorry, Seth. I just think this is some of the worst data we've ever had to deal with. I don't know.

Seth Schwartz: Well, yeah. I mean, yeah, I think part of the difference between you and I is that I operate in the surgical world all the time, and this is about as good as we see, so. It's so better than radiology, believe me.

Michelle Simon: So, I guess my question is do we feel like the data is any better for those top three conditions that seem to have some suggestion, or are we just... it's all grey and let's just ignore it all? I don't know. I don't know how you all feel about it. Usually, we look at evidence and is it compelling? Should we cover it? If the evidence is safe and effective and cost effective, then we say yes.

Craig Blackmore: So, why don't we... why don't we sort of put that on hold for a minute. If we get into the situation where we're discussing what the conditions are, that's going to be one of the considerations is are we going to treat those differently.

Michelle Simon: Okay.

Craig Blackmore: And so, we'll come back to that. I want to get us sort of more focused in on what that looks like. So, again, just to kind of get back to our strange framework, if I can get this... if I can conceptualize this. We're going to be making a vote with our three choices and so a choice of coverage, unlimited coverage means we're covering it and if some mechanism comes up to pay for it, we're doing it. We're paying for it... for everything. No coverage means if you turn on the robot you don't get paid anything no matter what, if the state knows it.

Coverage with conditions, one of the conditions we've talked about and we've not framed exactly but is the idea that coverage... reimbursement will not be any additional amounts than what is covered for the underlying procedure just because

the robot's used. So, that's where we are, and so then now we're at the point of saying are there additional conditions that the committee believes we should incorporate, and so one condition that we're hearing from Michelle is that we would basically cover with conditions would mean the reimbursement piece I just mentioned, except for specified procedures, and we could... the three that were mentioned were radical prostatectomy, what else?

Hysterectomy and cystectomy. So, discussion around whether any one or all three of those should have a different status and I guess I... I'll ask the question of the committee, are we at the point where we are really defining our conditions, and then I think we probably are if I answer my own question. Probably at this point what we need to do is get Margaret or Christine to throw up a slide and basically vote on each proposed condition to come up with a final list that we're comfortable with and then have a vote on that. Is that...

Michelle Simon: We could do a straw poll to see.

Craig Blackmore: I'm sorry.

Michelle Simon: We could do a straw poll to see....

Chris Standaert: Yeah.

Michelle Simon: ...who wants to cover, no cover, cover with conditions. Unless you feel like you know that.

Craig Blackmore: Well, maybe we should take a straw poll. I mean, I...

Chris Standaert: Can I answer the first question about... Michelle's question about these three procedures that we have more data on?

Craig Blackmore: Sure.

Chris Standaert: One problem that I have thinking of them as a separate thing is that we have a three-legged stool. We have efficacy, safety, and cost. At the moment, there is no cost to the system for this procedure, and we have... so, we're talking about cost in a very abstract sense. You don't have much data on that, but at the

moment there's no increased cost to the system for the procedure that we can identify. If the cost is 1 million dollars per procedure, it clearly would not... that would tip my stool the other way, and I wouldn't pay for it, and if there, you know, so without the hypothetical sort of data there, I think there's no basis for making a decision. I think the evidence is too poor to make a decision to allow them as a separate condition because that is such an unknown.

Michelle Simon: So that would lead you to include or not include?

Chris Standaert: I wouldn't call them out as separate things.

Craig Blackmore: Okay. So, I want to just... I want to get this organized and then drill down on this concept a little more, but I think the suggestion to do a straw poll is a good one, and what I want to use the straw poll for is to sort of formalize that we're in the place of coverage or coverage with conditions. So, I'm putting that out as a straw hypothesis and I want a show of hands that we're all basically in one of those two places. We're not in the place of don't turn on the robot or we're not paying. So, can I get... can I just get nonbinding confirmation that we're in the place of cover or cover with conditions to be defined.

Michelle Simon: Can I say one thing. Sorry. If we say no cover, you're saying it means if they turn on the robot they won't get paid, but there's no way for the agencies to know that currently. So, it's not really saying that. It's just saying that they're not going to pay for any additional code.

Craig Blackmore: No, it isn't. It's saying... it's saying the procedures and to do this are not covered. They potentially have the mechanism to figure that out, and if somebody follows the letter of the law and coded correctly they would lose 13 thousand dollars or whatever it was.

Joann Elmore: I think that will be more apparent if we actually put the population down there the way we did this morning and then we'll be able to see that it's people planning surgery.

David McCulloch: I'm struggling, Craig. It's... this is like saying, well we'll cover it but you can't use green scalpels. I mean, we'll cover it, I mean. This is a really expensive tool that surgeons think, in certain

circumstances, help them, and I think we should be saying we cover this, but reimbursement for it either is no addition or is up to the state. I don't think we can say more than that in a field that's constantly... it's like.

Craig Blackmore: So, but I'm not disagreeing with you. I'm just trying to get us there, and the first thing I want to do is get rid of the idea that procedures that involve the robot are not paid for. I don't think anybody is there, and I want to just confirm that. We can just confirm it by nods of heads, and I'm seeing a lot of nods. So, there's my straw. So, we're either covering or we're covering with conditions unofficially, and the condition lists that we're generating... we're generating that now, and the first condition is the reimbursement will not be in any additional amount above the original procedure. We can massage that. So, you use a green scalpel, but we're not giving you any more cash. Then, another condition that has been proposed is that an exception, or an additional scenario, is that for the procedures listed, radical prostatectomy, cystectomy, and hysterectomy there may be a belief of the committee that the evidence there is strong enough that additional reimbursement might be valid, and so this is for discussion. This is not a...

Man: That's not the point she's making.

Michelle Simon: That's not the point I'm making.

Craig Blackmore: That's not the point.

Seth Schwartz: Because you didn't really make a point.

Michelle Simon: No.

Craig Blackmore: Well, then I misunderstood her, and I apologize. So, we're going to have to try again.

Michelle Simon: I'm saying that the data for anything beyond these three procedures is so poor I can't imagine we would say we would cover it.

Man: Well, it's poor for those three, too.

- Michelle Simon: It is poor for those three, but it's...
- Craig Blackmore: So, what do you mean by not cover it?
- Michelle Simon: Not paying for it and not covering it.
- Craig Blackmore: Do you mean, if somebody uses it they are no longer reimbursed for the hysterectomy they just did with it, or do you mean they don't get additional funds for it.
- Michelle Simon: You know, I guess I am saying that, because I don't know that it's safe. I don't know that it's efficacious.
- Chris Standaert: So, are you saying...
- Michelle Simon: And I don't know about the cost.
- Chris Standaert: So, the endoscopic mitral valve replacement, which is only done this way, would not be paid for?
- Michelle Simon: That doesn't have a comparator.
- Chris Standaert: And some of the other...
- Michelle Simon: And that's not what we initially looked at. It isn't... we didn't even look at that.
- Chris Standaert: But there are lots of procedures like that where somebody just... that's the only way they think they can get at something.
- Craig Blackmore: So, that's a no coverage decision.
- Michelle Simon: Yeah.
- Craig Blackmore: So, okay. We're going to have to do another straw vote. So, I'm hearing a sense that there may be enthusiasm for complete noncoverage in conditions other than the three in which we have the most data. Is that fair?
- Michelle Simon: Yeah.

Craig Blackmore: And so I want to know if that's true. Is there enthusiasm for entertaining a noncoverage decision around some or all of the procedures?

Joann Elmore: No.

Michelle Simon: I think I'm probably alone in that, but I will say that, you know, these procedures can still be done in an IRB, in a trial, any of those sort of procedures where we're actually collecting data on it. So, that's the direction I think this should go, and I'm sure I'm alone in that, but I just want to make that point.

Craig Blackmore: Okay. I mean, is there more enthusiasm for that? I don't want to just assume that.

Joann Elmore: Mm-mm.

Craig Blackmore: Okay. I'm not seeing enthusiasm. So, we're going to go back to lumping... we're going to stay with lumping them all together and so I guess hearing that, there isn't the need to include those three as an exception to this rule, because that was... nobody's pushing that. So, are there other conditions that we might think about should we elect to do a coverage with conditions decision?

Chris Standaert: I sort of lean 60/40 towards letting them have the language that they put in their slide.

Richard Phillips: I agree.

Craig Blackmore: Okay. So, let's put that up there, and we can talk about it.

Chris Standaert: I slightly prefer that language, because it... it just... it lets them deal with a rapidly-changing environment, as they see appropriate, in terms of payment rather than having to come back to us. That's the only reason I think that way. If there... if other people want the other one, like I said, I'm about 60/40... one of those two.

Joann Elmore: Can I recommend wording for it then?

Craig Blackmore: Sure.

- Joann Elmore: Okay. The stem... if you want to type this. The stem would be among patients undergoing surgery... for patients undergoing surgery where robotic-assisted surgery is considered by the practicing clinician. Something like that for the stem.
- Marie Brown: Or adults with planned surgeries is the way they have it here.
- Joann Elmore: Something like that. Okay, so you have that stem, and then the first bullet would be no additional payment for use of robotic-assisted surgery beyond the underlying procedure is currently indicated. Then a second sentence would be the authority to determine additional payment in the future is left to the agencies. So, the first sentence is no additional payment for use of robotic-assisted surgery beyond the underlying procedure is currently indicated.
- Carson Odegard: Can I ask, what's the difference between that and leaving the reimbursement to the agency? I mean, the agency's not going to pay anything more. Isn't that really the same thing?
- Joann Elmore: It's kind of a statement saying that there's no data showing this is better. That's our way of making that statement.
- Carson Odegard: Well, Chris was saying that maybe what it does is it gives a little bit more leeway for the medical directors to do what the current state of policy is at the time.
- Joann Elmore: This is so rapidly evolving.
- Carson Odegard: That's why... I guess that's what I'm getting at.
- Joann Elmore: I think that my saying the authority to determine additional payment is left up to the agencies.
- Carson Odegard: Well, if we come up with code, say down the line new codes are developed within a year. They can make the decision whether to pay or not. My guess is they're not going to pay anything for it. I may be wrong.
- Craig Blackmore: I guess I'm going to push back and I'm going to say the reason I don't think we should be paying at this time is because I don't think there's evidence to support it, and I think our job as the

HTCC is to evaluate the evidence and saying let the agencies decide when there's enough evidence to pay for it is bunting our job. So, personally, I would not choose that option.

Carson Odegard: Yeah. Then I think we choose between the...

Craig Blackmore: That's an opinion. I mean, that's one.

Carson Odegard: Yeah. I mean then we go either no conditions or conditions. I guess that's where it comes down to.

Craig Blackmore: We'll just give a minute to try to get some text up here.

Carson Odegard: I liked your comment, Joann, about putting in the monitoring of this. You know, having codes on every one of them so they can follow it. I think that's important. I agree with you on that. I didn't see it on there, but.

Joann Elmore: It'll be point two when she's ready to type it. Okay. Point two, physicians must clearly identify when RAS is used to allow agencies to track utilization and outcome.

Carson Odegard: But that implies some kind of registry, does it not?

Marie Brown: Yeah.

Man: Potentially, right?

Joann Elmore: The potential if they ever want to look at outcomes. Because right now, we don't know how many are being done. There's no requirement you have to use those codes. You don't make any more money by adding the codes.

Marie Brown: I don't think you need either, clearly.

Joann Elmore: To track utilization and outcome.

Man: In order to track.

Seth Schwartz: Craig, I'm sorry. So, one thing you could say is that agencies may be... what did you say about them? Agencies may require a

coding sufficient to be able to tell when robotic surgery is being done, something like that. Could be permissive.

Joann Elmore: Dating it.

Seth Schwartz: The condition could be permissive, but at least we'd be sending a signal that if we do do that same prospective UR, they'd have to supply those codes.

Michelle Simon: That's good.

Joann Elmore: Mm-hm.

Craig Blackmore: Can we word this around that?

Joann Elmore: So, instead of physicians must clearly identify, more emphatic, agencies may require physicians to clearly identify when RAS...

Carson Odegard: And shouldn't that be billing providers rather than physicians?

Marie Brown: Yes.

Joann Elmore: Sure. Good point. Yes.

Michelle Simon: Do you want a bunch of codes in there or not?

Joann Elmore: I don't think you need billing.

Man: That's the relationship to the agency, though. It's a billing relationship.

Joann Elmore: Well, they may want it before rather than after.

Craig Blackmore: Okay. So, now I'd like us to make a choice between no additional payment for use of robotic-assisted surgery beyond that for the underlying procedure and reimbursement. The authority for determining additional payment will be left to the state agencies. So, do we as a committee say this will not be paid... do we as a committee say there will be no additional payment, or do we as a committee say it's up to the agencies to decide if there will be additional payment? Those are our choices for this line, and I'd like, well, comments.

- David McCulloch: The point you were making, Craig, is that given the relatively poor evidence, we should take the authority to say given that poor evidence, no additional payment should be made. If additional evidence comes out that you know for prostatectomy that's actually clearly, and proper RCT's been done better, then this provides a future statement to recommend to the state something different. I, at this point...
- Craig Blackmore: That's what I...
- David McCulloch: Yeah. I'd be fine with that.
- Craig Blackmore: So, I'd like a... again, I'd like a show of hands and so how many would say no additional payment until the committee says otherwise, basically? That would be roughly five. And how many would say leaving it to the agencies discretion. I can read five. Sorry?
- Chris Standaert: In the future.
- Craig Blackmore: Well, the future's tomorrow. I mean.
- Joann Elmore: But I want to emphatically state today that there's no data.
- Craig Blackmore: Okay, but I have... how many hands do I have for the?
- Chris Standaert: [inaudible] the same thing, so. Personally, I agree with... I agree with your first statement and then leaving it to agencies in the future. The other choice would be putting the first statement in and saying no... or somehow making it more definitive there will be no payment and not mentioning anything about agencies in the future or anything. Is that what you're saying?
- Craig Blackmore: Right.
- Joann Elmore: I like having the two and the reason I like having the two is the first shows that we don't feel that additional payment is currently indicated. I like adding the second because then we leave it up to them if in the future things change. Otherwise, they have to come back to us every six months.

- Craig Blackmore: But that's our job.
- Marie Brown: Mm-hm.
- Joann Elmore: Well, if they... they can come back to us if they want.
- Chris Standaert: Yeah. They can come back to us whenever they want.
- Craig Blackmore: Okay. So, again... so, we've got a couple choices. So, I guess the choice is really we're gonna keep the no additional sentence, and we're going to the third sentence, leave authority as the optional one. So, the people who think we should have the leave authority to determine added payment in the future if you will to state agencies, can I have a show of hands on including that piece? Which I'm looking at about five, and of course, there's ten of us. So, people who think we should not include that piece will be five. So, I guess...
- Joann Elmore: Well, I'm happy leaving it out then.
- Chris Standaert: Can I ask, for the people who don't want that sentence in, the objection to leaving the authority to determine added payment to the state agencies is, what's the objection to that exactly?
- Craig Blackmore: My objection is I don't think there's evidence to show that this is effective and should be paid.
- Chris Standaert: Well, we said that. That's what the first sentence is, right there.
- Craig Blackmore: So, why would we, you know, our job is to say if something is effective and say even cost effective and we're saying it isn't, or we don't know if it is, so the only way for me to change from I don't know to I know is to have more data, and leaving it to the agencies doesn't give me more data.
- Marie Brown: Or different data.
- Michelle Simon: We're making the decision today. Today. This is the condition.
- Chris Standaert: Right.

- Michelle Simon: Not like in the future. We could say that for everything if we decided to do that.
- Craig Blackmore: Yeah. We could say, hey we're not going to cover this unless the agencies think we should cover it tomorrow.
- Chris Standaert: Okay. So, take out that sentence.
- Joann Elmore: Okay. Take out the leave the sentence.
- Chris Standaert: Have that sentence taken out.
- Joann Elmore: I'm okay. How many people are okay with taking it out?
- Craig Blackmore: More than five.
- Richard Phillips: Yeah. More than five.
- Craig Blackmore: Okay. Take it out. Okay. So, we are making very good progress, and this is a healthy discussion, and so are there other perspective conditions?
- Recording: No. There doesn't appear to be any activity in this meeting. If you would like to [inaudible].
- Craig Blackmore: I guess we should adjourn then shouldn't we? Wow. Are there are other conditions that we need to add?
- Richard Phillips: The 18-month look-back will occur automatically, right? So, we don't need to add anything about that?
- Craig Blackmore: No, that's in the statute.
- Marie Brown: Mm-hm.
- Craig Blackmore: Okay. So, yes.
- David McCulloch: I mean, I really like this. I mean, especially the [inaudible] because I was really frustrated this morning that we just didn't get the kind of cost and utilization data from the state agencies that we should be able to get. I mean, what is the total number of prostatectomies that were covered going up, and is this just

replacing. I think over... this will, given the interest in... out there, to use this, a recommendation like this is going to drive the agencies to get clearer data. It might drive... encourage better studies to be done to prove that it's actually superior in certain conditions, in which case the future might look better.

Joann Elmore: Right. That's the bottom line. The funding and the companies, that people will start looking at rather than doing multiple case series that there will be RCTs at the beginning of a technology once it's reasonably safe, right?

Michelle Simon: This may require [inaudible]. What this is actually telling me is they have to collect this.

Joann Elmore: I started off saying that they had to.

Kevin Walsh: I don't know. I think when... when I'm looking at this, I'm thinking, I mean, I don't think people are going to start doing randomized trials here, but I think that when you get a new technology that's exciting and everyone wants to use it, it gets used on everything. I think there probably are clear areas where this is the right thing to do, and we can debate the data, but I think there's some suggestions useful there. There are probably other conditions lower down that list where it may prove not to be that good, and if there's some meaningful use concepts involved here saying hey, we're watching you, that it may eventually get to the point where it's clear that it's going to be used in certain circumstances, and there's no benefit to using the other one. So, if there's no data to support using it, people won't use it in those other conditions. That's kind of where I hope this goes. So, a condition like this is basically saying, we're watching you.

Craig Blackmore: So, is the committee comfortable with proceeding to voting at this point? I don't want anybody to feel like we've forced this particular pathway. Are we comfortable with that?

Group: Yeah.

Craig Blackmore: Okay. Okay. Then, let's do that. Let's turn to our decision tool, which...

- Kevin Walsh: I just have one quick question, Craig. We don't... normally we say, you know, cover, cover with conditions. This is going to be a cover with conditions determination, but it doesn't really say that in the stem there. So, it will specify cover with conditions, right?
- Richard Phillips: This is the condition.
- Carson Odegard: Yeah. It will say that.
- Craig Blackmore: Right. Right.
- Joann Elmore: Cover with conditions.
- Kevin Walsh: Okay. Yeah, again, I just want to be clear that we're not saying, you know, back to the original.
- Craig Blackmore: So, among patients undergoing surgery where robotic-assisted surgery is recommended by the attending surgeon, coverage... we'll charge staff...
- Kevin Walsh: With the procedure will be covered with these conditions?
- Craig Blackmore: We will charge staff, if we elect to do this, we will charge staff with a draft decisions and findings document that reflects these as the conditions. Is that workable, Josh?
- Josh Morse: Yes.
- Craig Blackmore: Yes, okay.
- Seth Schwartz: May I ask a question about the stem?
- Craig Blackmore: Yeah.
- Seth Schwartz: So, the stem applies to...
- Joann Elmore: Adults.
- Seth Schwartz: ...covered conditions? Or where...
- Joann Elmore: Among patients and adults. It's the first sentence.

- Seth Schwartz: ...the original procedure was already deemed covered? Not just when it's... we're going to use a robot for some surgeries?
- Craig Blackmore: Say that again. I didn't understand that.
- Seth Schwartz: The procedure, itself, needs to be a covered condition?
- Joann Elmore: Oh, right.
- Michelle Simon: The underlying surgical procedure, yes.
- Seth Schwartz: Needs to be medically necessary or covered?
- Craig Blackmore: Yeah.
- Seth Schwartz: The way you have it phrased now..
- Craig Blackmore: They could operate on something that is not usually covered. By using the robot they get covered. So, yeah. Well, remind me... when we come back to this remind me in the charge to clarify that, okay?
- Seth Schwartz: Okay.
- Craig Blackmore: So, let's go to our coverage and reimbursement determination analytic tool. So, we're all familiar with this tool. It's to help us get to the decision about is it safe, is it effective, and does it provide value, improve outcome, cost effectiveness, and the principles for our decision making are laid out here. They're all familiar to the committee. There's also an indication of existing guidelines, which we've heard about, as well as Medicare coverage, and there is no national coverage determination. Then, our staff have prepopulated the document with the outcomes, which they believe are relevant to the committee and now it's our opportunity to ensure that this list includes the outcomes that we've considered important. So, under safety outcomes, we have adverse offense, morbidity, mortality, reoperation, excess blood loss, extended hospital stay, operative time. Are there other safety outcomes here that are... other safety outcomes that the committee felt important in deliberation that are not included here? Okay. Then efficacy and effectiveness, and there's some overlap here, morbidity and mortality, healing time, length of

stay, blood loss again, positive margin rate, cancer recurrence, quality of life, operative time, and obviously some of these we have not a lot of information on, but those are the outcomes that try to consider in our deliberation. Are there any other outcomes that are not indicated here that the committee has felt important to the discussion?

Kevin Walsh: I'd say decreased complications. I mean, I'm just thinking of things like incontinence and [inaudible] malfunction.

Craig Blackmore: For morbidity, we can specify incontinence, impotence, okay. And special populations, we didn't really go into this in much detail. There wasn't a lot of information available. Any other special populations that we felt relevant for the discussion?

Joann Elmore: The only evidence, or the main evidence, was around large BMI.

Craig Blackmore: Okay, so large BMI, which is on here, is something we'd heard about in the discussion. Cost, there's the issue of total health care cost, societal cost, direct and indirect costs. There's also fixed and variable costs, which we can add on here, and then the issue of cost effectiveness. Any other cost outcomes that... okay. Okay, that gets us to the first voting question. This is a nonbinding vote, and it's a determination of whether there is sufficient evidence under some or all situations that the technology is effective, safe, or cost effective, and we're going to use our tan cards and the first question will be, is the use of the robot of unproven, equivalent, less, or more effectiveness when compared to, and in this case the comparison would be basically performing the procedure without the use of the robot. If you believe under some or all situations it is more effective, you would vote for more. Then, your other choices are unproven, equivalent, and less. So, if I could have the nonbinding cards.

Josh Morse: I see three more and seven unproven.

Craig Blackmore: Next is the safety issue. Again, your choices are unproven, equivalent, less, or more safe with respect to interventions not using the robot and under some or all situations is the technology safe?

Josh Morse: Two more, seven unproven, and one equivalent.

- Craig Blackmore: And then finally, cost effectiveness under the same parameters.
- Josh Morse: Ten unproven.
- Craig Blackmore: So that allows the committee members to understand the perspective, get a feel for where we are. It also allows us to do further discussion. Is there anything anybody wants to dig into further at this point, or shall we proceed with the next step, which is the binding coverage decision?
- Joann Elmore: Next step.
- Craig Blackmore: Not hearing further comments, we'll proceed with the next step. I'm going to try to explain this one more time to be clear. So, we're going to be voting for not covered, covered unconditionally, or covered under certain conditions. A not covered vote, in this context, would mean that the use of the robot disqualifies payment for the procedure. A decision for unconditional coverage would mean that the use of the robot does not disqualify payment but also allows for payment based on any mechanism of payment that becomes available going forward and that payment would be in addition to the payment for the underlying surgical procedure. A decision for coverage with conditions would be that the procedure would be covered, but there would be no additional payment for the use of robotic-assisted surgery beyond that for the underlying procedure is currently indicated, and the agencies may require billing providers to clearly identify when robotic-assisted surgery is used in order to track utilization and outcome. I will also stipulate that the procedures for which we are allowing coverage under either cover or cover with conditions are only those that are currently covered by the state agencies. Is that clear? It's a little complex, so I want to make sure we all understand what we're voting for. Okay. So then, let's have the vote.
- Josh Morse: Ten cover with conditions.
- Craig Blackmore: So, we're required to either conform with Medicare national coverage decisions or detail why on an evidence basis for why we did not, and in this case there is no Medicare national coverage decision, so we are compliant with that, and I will ask the staff to

formulate draft findings and decisions document, which we'll vote on at the next meeting. Thank you all very much, and we are adjourned.