Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Cardiac Magnetic Resonance Angiography

November 19, 2021

DISCLAIMER

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Shelia Rege: Well good morning, everybody. Welcome to the November 19 HTC committee meeting. My name is Sheila Rege, and chair of the committee and I want to remind everyone listening in, that this is an independent community as a committee of 11 community healthcare practitioners and our charges to review, evidence-based assessments of health technologies. This whole process is being recorded. So, hopefully, nobody has a problem with that. Our decisions on whether the technology is covered will be either one with a covered without conditions, covered with conditions or not covered. And our decisions are mandatory for state purchase programs unless there's a statutory conflict, and they are exemptions for IRB studies. So, this is a serious responsibility, and we are tasked with making these decisions based on the question: one, is it safe, two, is it effective, and three, does it provide value. We try and and make sure and are open to suggestions that this process has to be open inclusive, and Josh will explain more after we do roll call. and at the roll call if all the committee members will mention the name specialty, and whether they have any clinical or research experience, as well as any conflict with the procedure being discussed this morning. Cardiac Magnetic Resonance Angiography, which we are calling CMRA, both in children and adults. We also do have a clinical expert, Dr. James Kirk, Kirkpatrick, and Dr. Kirkpatrick if you would also, when, when, Melanie does the roll call, just let us know about you, just like any committee member your clinical research experience and or conflicts. Thank you, Melanie, I'll hand it over to you for roll call. And if you could start by introducing yourself and your role in this process. Hey yeah, thanks.

Melanie Golob: I am Melanie Golob ,I am the Health Technology Assessment Program Manager here at the Health Care Authority. And, yeah, just here to kind

of support the process, so I'll start with roll call I think we have the majority of people. So let's start at the top with John Bramhall just go ahead and say, say here, we can check your audio that way.

John Bramhall: Yes, sure. I think you can hear me okay.

Melanie Golob: Yeah.

John Bramhall: Yeah, I'm here. And just as an introduction I'm an anesthesiologist at the University of Washington. I work at Harborview and I think I have no conflict whatsoever with the subject matter.

Melanie Golob: Great, thank you. And then next we have Larry Birger who I believe was not able to join today.

Shelia Rege: That is correct, Dr. Birger texted me late yesterday saying he may not be able to join, and I believe he sent an email as well.

Melanie Golob: Okay. And next we have a Clint Daniels.

Clint Daniels: Hi, good morning, I'm Clint Daniels. I'm a chiropractor, the chief chiropractor at VA Puget Sound. I do have some research experience. Its primarily conservative spine care related, and I don't believe I have any conflicts of interest for the topic today.

Melanie Golob: Great, thank you. And next Janna Friedly.

Janna Friedly: Hi, I'm Janna Friedly. I am a physiatrist by training at the University of Washington and Harborview Medical Center, and I have research experience primarily in back pain research, and chronic pain, and I have no specific clinical research experience with this topic or any conflicts to disclose.

Melanie Golob: Okay, great. Thank you. And next is Chris Hearne.

Chris Hearne: My name is Chris Hearne, I'm a nurse practitioner. I work for Swedish in the hospital medicine group. And I don't think I have any conflicts or specific experience with this technology.

Melanie Golob: Okay, great. Thank you. And next on the list was Conor Kleweno, but I believe he is not able to join as well.

Sheila Rege: Correct.

Melanie Golob: So we will move on to Christoph Lee.

Christoph Lee: Hi, Christoph Lee. I'm professor of Radiology at the University of Washington Seattle Cancer Care Alliance. My clinical focus and research

is in breast cancer screening technologies. I don't do cardiac MRI. The last time I was exposed to is probably in residency about 15 years ago.

Melanie Golob: Great, thank you. And we'll keep going alphabetically down the list, Laurie Mischley.

Laurie Mischley: I'm here, I'm a naturopathic physician and my research experience, I do a lot of epidemiology research, and I do run a few studies in the radiology department using MRI, but certainly not cardiac. I have no experience with hearts at all. But as a clinician, the first 10 years of my practice I did a lot of MS and so I was exposed to a lot of gadolinium-based concerns and fears and things like that, so other than that I have no experience, and no conflicts to report.

Melanie Golob: Great, thank you. And Sheila Rege.

Sheila Rege: Sheila Rege, radiation oncologist, in the Tri Cities, Washington and no conflicts with cardiac magnetic resonance angiography. The, the only time the cardiologists with us talk about issues is just kind of the cardiac threat versus the cancer threat. But no, but no conflicts and no, no, clinical experience in this. Thank you.

Melanie Golob: Okay, great. Thank you. Mika Sinanan.

Mika Sinanan: Hi, I'm here. GI surgery based at the university, research experience in surgical robotics and simulation sciences, and I have no conflicts.

Melanie Golob: Great, thank you. And Tony Yen, I don't know if he's here yet. Okay, and I will go to our clinical expert, James Kirkpatrick.

Jim Kirkpatrick: Thank you so much for this opportunity. I'm also at the University of Washington, and I'm the section chief of cardiac imaging and a director of echocardiography, so I guess those give me some conflicts, right off the bat. I don't have any industry relationships at all.

Melanie Golob: Okay, great. Thank you all, and Dr. Rege, back to you.

Sheila Rege: Thank you. Barring any questions before we start, I would like to move onto the next item on our agenda, which is the HTA update. Giving you a minute for questions, raise your hand if you have any questions. Great. Josh, I would give, give it back to you if you'll introduce yourself and your role in this process and then give us an update. Thank you.

Josh Morse: Yes. Good morning. I'm Josh Morse, I'm the program director for the Health Technology Assessment Program. And we'll do our brief presentation here. Can you confirm you're seeing the full screen?

Melanie Golob: Yes, we are.

Josh Morse: Excellent. Thank you and good morning, thanks everybody for being here. And I think Dr. Yen has a conflict today as well so he will not be present, but we do have a quorum. Okay, so I think as everybody knows we're using Zoom, and you should be familiar with the webinar controls at this point, but if you have any questions please let us know. This is some detail here. If anybody is joining by phone, there are some instructions here, using star six to mute or unmute yourself, and star nine to raise your hand. Those are the methods to use for this technology. So, again, some meeting reminders so this meeting is being recorded. A transcript of the proceedings will be made available on our website. Following the meeting, it takes us a few weeks to generate the minutes, and the transcripts, at a minimum, a few weeks for the transcript sometimes longer. When participating, please state your name and of course use your microphone so that we can hear. Some program background. The Health Technology Assessment Program is administered by the Health Care Authority. The HTA program is designed to bring evidence reports to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures, tests, and tests based on evidence for their safety, efficacy or effectiveness and cost effectiveness. Multiple state agencies that purchase healthcare participate to identify topics and implement policy decisions, these include the Health Care Authority and the program's Uniform Medical Plan and Medicaid, that are managed by the Health Care Authority, the Department of Labor and Industries and the Workers Compensation Program, and the Department of Corrections also uses these decisions. These agencies, implement the determinations of the HTCC within their existing statutory frameworks. So, the purpose of this process is to ensure that medical treatments, devices, and services paid for with state healthcare dollars are safe and proven to work. This program provides resources for state agencies that purchase healthcare. It developed scientific, evidence-based reports on selected medical devices procedures and tests for review by the HTCC, and the program supports the HTCC to make determinations for the selected medical devices, procedures, or tests, based on the available evidence. There are multiple ways for people to participate in this process. We have a public website, and the URL is there on the slide on the HCA website. Anyone may sign up to receive program notifications that we send out via our, what's called our GovDelivery email system. People may provide comment on topics when they are proposed. And then when they are selected on key questions as we develop the topics, on draft and final

reports, and on draft decisions. And anyone may attend these HTC meetings. These are public meetings; anyone may present comments directly to the committee at the appropriate time on the agenda today. And anyone may petition, may provide a petition and nominate a technology for review or for rereview. So those wishing to provide public comment attendees scheduled to provide public comment will be temporarily reassigned as a panelist, and provided the option to unmute and turn on their camera if desired. A pop-up window will ask you to rejoin the meeting as a panelist. Comments will be, we'll ask you to please limit your comments to four minutes. When you're finished providing public comment, your role will revert back to an attendee and there'll be a brief pause in the meeting while you rejoin. If you're not signed up in advance, please indicate your interest to provide comment, using the chat function, prior to your comment period. The volume of signups will help determine the amount of time available for each person. And we ask that all who are providing comment today please disclose any potential conflicts of interest prior to making a comment. So our agenda today is the topic cardiac magnetic resonance imaging, we're using the acronym CMRA. We don't have other issues on the agenda today. And we do not have previous meeting business at this point, our minutes are not ready for review at this point. So, I got ahead of myself here, here is the agenda we'll have the agency medical directors presentation, followed by the opportunity for public comment. There are no pre signed up public comments at this time. So, we'll see if anybody wishes to sign up for a comment this morning we'll then have an evidence report presentation from the Center for Evidence-Based Policy, followed by a committee Question and Answer around the evidence and discussion and decision. After today's meeting, we will work to, on a draft determination. If the committee reaches the draft determination today, produce that and minutes to send them out for review and the public comment period for two weeks on any determination. If there are any questions about anything happening, regarding to the, related to this process, please let me know.

Sheila Rege: Josh, if I could ask a process question. I know the committee members, because this is hard to kind of do this the same as we would be in person. So, on the Zoom the committee members our panelists and can speak at anytime. But just like in in our, you know, in person, committee meetings, we have a special time when we accept public comments, is that correct, and can you kind of just go over that process a little bit to clarify that?

Josh Morse: Yes, the committee has designated a public comment period on the agenda. It's a 40-minute window of time typically that we carve out to make comment period available. Comment outside of that is, doesn't, it does not happen during the meeting itself that's for committee time.

Sheila Rege: And so that today will start at 8:50am for anybody listening to know, correct?

Josh Morse: That is, let me view our agenda. Scheduled public comment is at 8:50. Yes.

Sheila Rege: Great. And then the process of for people wanting to make public comment Melanie, if you could let us know about that process just so there's no confusion when we come to that.

Melanie Golob: Yes. So, we didn't have anyone sign up in advance to give public comment. So when we approach that time in our agenda, then we'll ask for anyone who wants to give public comment. They will be allowed up to four minutes, and I will, as Josh mentioned in his presentation I'll promote them to panelists temporarily, and they will be allowed to turn on their camera during that time, if so desired, and give their public comment. And they will be moved back to an attendee. So that'll be when we give public comment. Thanks.

Sheila Rege: Great. Any questions from committee members. If not, then if we could project the, the next item of business is the November 5 meeting and Janna, since I was not present for that would you mind taking over this portion of the meeting for approval of those minutes.

Josh Morse: Actually we do not have the minutes prepared for review today, we will have them ready for your next meeting, and currently the next meeting is scheduled for March 18th. We did mention the potential for an interim meeting but at this point, the program is planning to hold review of determinations from the November 5th, and the minutes from that and bring that back to the committee in March, at our planned meeting.

Sheila Rege: Thank you.

Josh Morse: So I apologize for not having the minutes ready, we're just, we're not, weren't able to get those ready for you today.

Sheila Rege: We rarely ever have meetings this closely scheduled. So, you know, we just had, we thought it would be a lot of work to put this topic with last times meeting, so this is an unusual circumstance. Thank you, Josh, understandable. And we will then move to the Washington, the next

item, Washington State utilization. Is that, is that by Judy Zerzan-Thul is that the next item on the agenda?

Josh Morse: Yes, it is

Judy Zerzan-Thul: I think that's me.

Sheila Rege: Thank you and if you would introduce yourself, your role in this process. I don't think you have to say anything about conflicts, but if you wish to or experience clinical experience in this, that would be welcome, thank you.

Judy Zerzan-Thul: Sure, good morning, everyone. I'm Judy Zerzan-Thul. I'm the Chief Medical Officer at the Health Care Authority and I am a general internist by training and practice. I for sure have no conflicts and I have never done anything around cardiac MRA, let alone MRI, but this was a fun topic to research and so, I look forward to the discussion today. And I think Melanie, do you have my slides?

Josh Morse: I have your slides Judy if you'd like me to project--

Judy Zerzan-Thul: --or am I supposed to have my slides. You have my slides! I'm like, someone has my slides.

Josh Morse: I'm happy to do it.

Judy Zerzan-Thul: Okay.

Josh Morse: Just take me a second here.

Judy Zerzan-Thul: Oh no worries. Yeah, well I'll just start talking actually, so. So, this is cardiac magnetic resonance angiography. So MRA, as opposed to cardiac MRI, and that is important because we are not talking about MRIs, we are only talking about MRAs and when that is helpful. So as a reminder, next slide please. CMRA, focus is really on the blood vessels and not the tissues, so it's particularly targeted towards that and it looks at cardiac or vascular anatomy, function, perfusion, those sorts of things. Sorry, Josh, can you do the next slide? Thanks. So, in this report, it is compared to invasive coronary angiography, sort of the usual way we look at blood vessels. And also, coronary CT angiography, which we reviewed at the last topic. We picked this topic because there were stakeholder and legislative concerns. Some of those concerns focused around prior authorization and whether that was hard or not, or appropriate. And there were also a handful of anecdotes about cardiac MRA being used more often, and potentially being used in place of other technologies and so we wanted to take a better look at that. Next slide please. So, these are the agency medical director concerns. I'll note that after we had

decided this as a topic, we downgraded the safety to low, the risks of CMRA, just like any other MRI technology, which is reasonably safe, some concern about contrast here and there but really, this is a pretty safe technology. The efficacy had medium concerns and the cost was high. So, this, it hasn't been used a lot in L&I, and so we have combined the Medicaid, the Uniform Medical Plan and the L&I numbers for the last four years to show you our utilization of that. I'll also say here and later that it's a little tricky, because there actually isn't a code for MRA, there's a code for cardiac MRI, but not for MRA, and so there was some, you know, figuring out to make sure that we were really looking at MRA. So, in looking at these numbers, to let you know about the UMP, we have around 200, a year. And that's been relatively stable but slowly increasing. It's definitely been increasing more on the Medicaid side. And so, you can see that in 2017, there were about 650 people, and in 2020, there were 777, so a reasonable increase. And you can see that it tends to happen more in males than females. And then down below is the amount paid. I'll also make a note here that this only includes the exam itself. It doesn't include the visit, the facility fee, interpretation, contrasts those sorts of things. And also, just as a reminder, this is lower than you might probably expect because most of these exams occur in Medicaid which has a lower reimbursement. Next slide. Because cardiac MRA can be used for congenital abnormalities, we thought it might be helpful to look at the age range of who gets these kinds of exams that actually, I have to say, I was a little bit surprised. So, so kids, defined as 20 years and younger, were less than a third of what happened. There was a decent chunk in the 21- to 44-year-olds and then the majority of exams, about half, or in 45 years old and above, which does sort of suggest that this is being used less for, for anatomic kinds of things and perhaps more for coronary artery disease kinds of things. Next slide please. As I mentioned earlier, there isn't an MRA code specifically, so these are the codes that are for cardiac MRI or MRA. And you can see the fees for Medicaid and for L&I here. The UMP fees are proprietary, so they're not listed here. And you can see the amount for facilities and for Medicaid. We put this into EAPG, it's a grouper methodology that we reimburse for this and so, it includes, sort of the whole procedure, and it depends on what the diagnosis is what the EAPG pricing is. So next slide. So in this report, I tried to break it up by the five populations that we looked at. And so, as I go through the results, I'll, I'll work on each of these five populations and the key questions that apply to each of them. So, the first, and this was our main question is about CMRA in adults with suspected coronary artery disease, and that is symptomatic, we did not look at asymptomatic

folks. The second population is adults with suspected coronary vessel anomalies. The third is adults who have undergone CABG surgery. The fourth is adults being assessed for cardiac device lead placement, which is another use that was found in the literature. And then finally, is children with suspected or confirmed congenital heart disease. Next slide. So, the key questions are our usual key question, so the first one is, what's the evidence for diagnostic validity and clinical utility, sort of how well does this work and how effective is it, in adults and kids in these five populations? Second, to what are direct harms associated with CMRA? And I'll say that there really wasn't a lot found again. This is similar to MRI technology and other settings, and that is relatively low. Third is, does diagnostic validity or utility vary by the following populations: sex, adults with atypical symptoms, age, comorbidities and settings? And then finally, is there any cost effectiveness or other economic outcomes of using CMRA in these populations? Next slide. So, current state agency policies. Regence covers this with conditions. Most of the Medicaid MCOs cover it with conditions. L&I covers MRI, with a prior authorization. Next slide please. And looking at other policies, CMS does not have a policy on this. AETNA, similar to our population. It may be medically necessary in certain places and in looking all of these policies and sort of trying to lump together, where, where do they say, this is useful. There are five areas: the first is a cardiac or a pericardial mass and evaluation of that, again, that's really more MRI than MRA usually. Second is congenital heart disease, either known or suspected, or if you have it if you have any symptoms. I think that's probably fits into a reason to do MRA. There's sort of a number of vascular anomalies. If there hasn't been prior imaging in these policies that includes Marfan, colocation of the aorta which seems to be a big one. Pre-op for congenital heart disease, anomalous pulmonary dangerous drainage, or pulmonary outflow tract obstruction, and evaluation for suspected coronary anomalies. A fourth area is some cardiomyopathies due to sarcoid amyloidosis, hemochromatosis, those sorts of things. Again, that's really less MRA and more MRI. And then finally, myocarditis if an echo is sub optimal, it may be considered. So next slide. There are two guidelines on cardiac MRA, and both are of good quality. The first one is from the UK and their National Institute for Healthcare and Care Excellence, the NICE, and they are pretty clear do not use this for diagnosing stable angina. So cut and dry. The ACC, American Heart Association has a guideline on this and says that MRA can be useful in the initial evaluation and follow up for congenital heart disease. Serial MRI for quantitative assessment of RV size and function can be helpful, again, anomalous pulmonary veins or coronary arteries

and coarctation are indications for doing this. I will say that both of these guidelines recommend not using this kind of exam for suspected coronary artery disease, which will be similar to my final recommendation once we get there. So, to start looking at each of the populations, adults with suspected coronary artery disease is really where the bulk of the studies included in this report and the bulk of the evidence is. And I will say that the center, when they do their presentation, did a lot of very nice fancy math in pooling these studies and found a sensitivity of 88% for diagnosing coronary disease and specificity of 72%, which is pretty similar to other kinds of imaging, trying to figure out if someone had coronary disease or not. There were 35 studies that looked at diagnostic test's accuracy. There were four randomized controlled trials and 10 non-randomized studies, and this was considered a high quality of evidence. They found in their review that CMRA was associated with fewer invasive tests and that was only in two studies, but they were of, and that is a moderate certainty, and that it was not associated with reduced mortality or reduced cardiac events. There were very few adverse events and no harms directly related to the CMRA. So, there's some if you do sedation, for an MRI that might have some adverse effects but really not a lot. And this was the only category that had enough data to look at subgroups. And there were no differences by sex single or multi vessel disease, heart rate, or BMI. There was one cost effectiveness study that had very low certain piece of evidence and included both cardiac MRI and MRA and found an 18% change in the preexisting plan of care before the imaging exam, which led to a per patient cost savings as about $2300 from avoided procedures, and additional diagnostic testing that was avoided. So, so there you have it. The second population is adults with suspected coronary anomalies. There were four studies here that were all at high risk of bias, because of patient selection of lack of blinding or no comparison group before studies found that an MRA was highly can coordinate with surgical and angiography finding and that it may identify some vessel anomalies not found with traditional angiography so there's potentially the usefulness for that. There was also one patient to avoid the lead for angiography because they had an MRI and so you know trying to figure out is this where this test might be useful, that's there. But in general, this finding was low certainty of evidence. And, and that was that. In the next group, I don't have undergone CABG, thinking about maybe a second cardiac surgery and utilization for that. There were no studies. So, that is short and sweet. The fourth population is adults being assessed for cardiac device lead placement. There were two studies here that had a high risk

of bias because of patient selection, lack of blinding and small sample sizes. One study was 14 people and the other was 19 so this really gives you a sense of these are very small and also nonrandomized trials. And the bottom line is that the technology may be useful to visualize the appropriate name. And my read of it is, there's a number of different ways to find the right vein and, and this is just another one of those. Next slide. And then finally, children with suspected or confirmed congenital heart disease. There were 11 studies for this population that also had high risk of bias because the patient selection lack of blinding and lack of a comparator, and again found that MRA with highly important with both surgical angiography findings. So, that is that is helpful. It can be diagnostic with no additional imaging needed, and is a safe procedure with few adverse events, either related to the MRA or to the anesthesia, that's needed, particularly for smaller kids to get an MRI. So, that brings us to the recommendations. And I would say in general from looking at those populations and the evidence was reported in this. It's not clear that MRA is any better than any other imaging, and in fact, it's probably the same. A couple of weeks ago, we looked at a lot of different ways to search for coronary artery disease and this is probably the same as that. You know, there was some question in the literature of if this may avoid an angiography or other procedures and is MRA less costly than an angiography. And I think that's not super clear. But there's definitely no evidence on patient outcomes, and in most of these studies are really high level of uncertainty. It seems that MRA technology is most helpful when anatomic imaging of the blood vessels is clinically important. And so, while this is not the sort of main focuses report the main focus of the report is coronary artery disease. I think it is reasonable to continue to cover with conditions MRA, for people with known or suspected anatomical issues, cardiac or pericardial mass. Other imaging is inconclusive and there's a need to know the anatomy, but for the, for the main question in the report, I think it is reasonable to not cover for the diagnosis of or evaluation of coronary artery disease, and not to add it to stress MRI. Although stress MRI is outside of the scope of this, because this is similar to other technologies and on the whole is more expensive, I think than other technologies. So, I don't see a need for this to be in the, in the toolbox. That is my report and I'll take any questions now.

Laurie Mischley: This is Laurie, I just had a question I heard you say both, I thought I heard you say that there was no evidence that it was different in costs than any other procedure was kind of equivalent and then I heard you say it's more expensive, probably.

Judy Zerzan-Thul: Um, yeah so, I'm not sure. And, you know, it's hard because there's not a set code, if it's more expensive or the same as angiography, but a coronary CT is for sure less expensive than it, and some of the other studies that we looked at the last time. Stress echo, treadmills if you're trying to figure out if someone has coronary artery disease or not. Most of the other tests are less expensive than this one.

John Bramhall: So then, this is Johnny. Can I ask you, is there any recommendation about workup for vegetation, valve vegetation using MRA?

Judy Zerzan-Thul: Um, I did not see any of that and maybe I'll also punt to the center. There were some studies that looked at whether mitral valve imaging is a little better in certain populations and body habitus if you can't get a good image of that right ventricle with echo or other ways. But yes, again, I think, and I may, I may confuse you with my recommendations because the question here is really about using this technology for coronary artery disease. And so, I think it may have a place in some other anatomic imaging but for coronary artery disease, it's probably not needed.

John Bramhall: Thank you.

Jim Kirkpatrick: That was a very nice overview and review of what literature there is on it. One question I had, and I suspect based on what you said it's not going to be possible to sort this out but. And there's some overlap with other sort of terminology here, but imaging of the proximal aorta. Is that sort of within the scope of vessel imaging? And it's not coronary arteries, but besides coarctation and Marfan syndrome, there are other conditions in which the aorta becomes enlarged, and an MRA has some advantages over CAT scanning and I you know it needed contrast, needed contrast, no radiation, and I would guess that just like with the, the overlap of MRI cardiac MRI with cardiac MRA. It's going to be hard to sort that out so that that's sort of one point, the other sort of similarly is that there are now more adults with congenital heart disease than there are children, due to a variety of different factors so I wonder if a number of those studies linked to the increases actually in the fact that you should that slide that you showed that you're surprised that many adults actually are getting this procedure that may have more to do with that than it does. With the use of it for coronary arteries, to be perfectly honest we have an extremely large adult Congenital Heart Disease Center which covers many different states. And because it's a somewhat specialized test a lot of our cardiac MRI and vascular MRI actually gets done here rather than at a local centers that may have some impact on the numbers.

Judy Zerzan-Thul: Yeah. So, I definitely agree there's a a long laundry list of aortic issues that I didn't go into that probably cardiac or, or other MRI of erratic MRA, whatever gets sorted the right area, including dissection. Which I think if it's a slow dissection is reasonable but when I first was like wait what you're going to wait an hour to see? But you know, there are more chronic dissections and other things that that would kind of fit into that and MRA may be appropriate. And, and that's really sort of outside the scope of this that we're really looking at a coronary artery disease and I agree we would not, we would still want to cover that and that would be sort of lumped into reasons to do an MRA. And then yes, I do agree there are more adults that are, are living with congenital heart disease. And again, I do think that that's a reasonable thing to do, especially as you're trying to sort out what might be going on and wanting to use that as follow up and the, the guidelines, do include that as a, as a reason to look at this. So yes, and I don't think our data shows that. Although I will say there were at least a couple plans when we were talking to them about this technology that said they're seeing requests for cardiac MRA, to decide if there's coronary artery disease or not and so that's part of where this came about because I think the end, they were like oh there's probably other tests to figure out if they have coronary disease or not you know it's sort of more expensive one to do that. And all things being equal, it, it seems to be similar to any other way of figuring out whether someone has coronary artery disease. And I guess the advantage, I'd say, if you're at the point of doing an angio, or an MRA, that that angio is probably better because you can put a stent in, if it's single vessel disease, or you can even do something about it, rather than an MRA. You can see there's a narrowing and then have to go do angio after that to do something about it. So that makes it, you know, a little trickier and probably not cost effective, and Christoph you've been waiting patiently with your hand up.

Christoph Lee: Thanks Judy. No, I just want to go back to your cost slide. You said that you have concerns about the cost. And what was shown, it didn't strike me as something that was trending towards much more use, and much more costs over time. And I think, I think for me, when we think about cost effectiveness, I do want to look at the comparator which is in basically coronary angiography, and look at the cost versus that, because it, you dimension in certain circumstances, the MRA could be diagnostic without additional tests. So, just wondering if we know anything about the differential costs, versus basic coronary angiography maybe, Jim knows off the top of his head. Cost differences.

Jim Kirkpatrick: It can, should be considerably less than coronary angiography. Judy's point about being able to do something about it and having to go on to cornea invasive coronary angiography is different. I don't know the exact cost difference between a CT coronary angiography, and an MRA coronary angiography to be honest, but I would guess that they're probably in, it is somewhat I think I mentioned earlier, the MRA would be more expensive. It is a longer test, but on the other side it doesn't involve radiation or contrast that I had an aided contrast and

Christoph Lee: Jim, maybe you could also talk about just the adverse events, because I understand the contrast issues in both, both exams, but my impression of this the coronary angiography is that there is a small, but real risk of death, heart attack and stroke.

Jim Kirkpatrick: Yeah, absolutely. It's a bit of an apples and oranges comparison is certainly the, the diagnostic part you could say is arriving at the diagnosis and both arriving at the diagnosis, but in terms of have the option to be able to do something afterwards the fact that they are layered or stacked type of testing, and also that you are getting more information from the cardiac MRA a potentially vessel early vessel wall characteristics to some extent if you're looking for that. While characteristics to some extent if you're looking for that. And then it was mentioned I thought was a pretty important issue that when you do a, an invasive coronary angiography you have to stick the catheter inside the artery and inject the dye there in order to find out that the vessel is there. Now you can do what's called a route shot you can inject can't coordinate the contrast into the aortic route and see which vessels, it goes into, but both of those techniques do risk missing anomalous vessels which are picked up by cardiac MRI and by cardiac CT, because you pretty much see all the vessels when it when it comes out if you have a good quality study of course. So there are there are some differences between the techniques but just making it very specific to the question of diagnosing coronary artery disease invasive coronary angiography has really been the gold standard for aluminum narrowing, and to my knowledge, CT has has sort of expanded that up a bit in looking at the vessel walls and I believe there's been more work looking at vessel walls and CT then there has been an MRA, so I don't know what kind of advantage, MRA actual composition and types of plaque instead of just aluminum narrowing which which you can get from all three modalities.

Christoph Lee: Thank you.

Sheila Rege: Any, any more questions for Judy, before we at 850? I believe we are going to be opening up the lines for public comment. I have a question for anybody who has expertise in this. Can anybody with an MRI, do cardiac MRA, or is there certain technical criteria that are needed? Can some, an MRI from 15 years ago we used? Was there a special MRI?

Jim Kirkpatrick: The first sort of decision point is whether or not contrast is utilized. And so just sort of any MRI looking at you know you can get an MRI of the heart and get a lot of information out of it without using any contrast at all, and but you cannot really get sort of diagnosis of the vessels quite as well. The other issues is I believe there are certain protocols that are necessary to look at different things they're, they're a bit different than the protocols that are used to look at the myocardial composition, for instance, or what's going on with the heart, whether it's inflammation or scarring or that sort of thing. But I do believe that you need to have the proper things I don't know Christoph do you have a better sense of that.

Christoph Lee: No, no I don't, I think my understanding is pretty limited in that sense.

Sheila Rege: And we'll have to see what the studies, if any of the studies, had any description of criteria that was used for the equipment. That may be a question that we can get help with

Jim Kirkpatrick: Aren't part of what it there's, there's sort of different MRI machines with higher what's called tesla? I think that the coronary angiography and correct me if I'm wrong Judy, if you seen this but I think you can perform coronary angiography on most of those MRI machines? I don't MRI machines, I don't know if there's any advantage to using a three Tesla versus a 1.5.

Laurie Mischley: On the table of results they have the tesla of all the in there were a lot of 1.5 on there.

Beth Shaw: Particularly in children. These the 1.5.

Sheila Rege: Because I mean if we put anybody through this, we want to make sure we get a good quality study so that was, you know, it's, this is a tough enough studied to undergo, and that, that was all I was looking for clarification on, thank you. Any other questions? Judy thank you for a really excellent presentation and hard work on reviewing everything. I would like us to open up the lines. And, again, for all of us as panelists and I am guilty of this too I asked the question without saying this is Sheila Rege, while identifying ourselves for the transcripts to be to be accurate, but anybody coming in. Josh, or Melanie, if you can again give

us what they need to provide us, and how many minutes they would have before opening the lines. Thank you.

Melanie Golob: Okay, I can, I can do that. So, for those that want to provide public comment, I think there's not too many attendees, and I think some of those are agency staff or other state agencies. But for those that want to provide public comment please raise your hand. Use that raise hand function, and we will promote you to a panelist and you will have four minutes to provide public comment. At which point, you can turn your video on, if you so choose, and provide your public comments, and then you will be changed back to an attendee once your public comment concludes, and we have up to 40 minutes for the public comment portion. So unless I forgot anything, then we can open it up for public comment, and anyone that wants to give it go ahead and raise hand.

Josh Morse: Looks like we had somebody just join the attendee list.

Melanie Golob: And so, to repeat what we just said if you want to give public comment during this portion of the meeting, please, please raise your hand, using the raise hand function in Zoom.

Josh Morse: There is a hand raised there.

Melanie Golob: And they should be rejoining the panelists. Okay, so it looks like Randy Otto and Mark Ferguson if you want to give public comment, please introduce yourself and state any conflicts of interest. Dr. Rege, am I forgetting anything, or Josh?

Shelia Rege: You will have four minutes if you could give us your name. Conflicts of interest, including whether anybody's paying for your time to be with us here. We'd appreciate it and thank you again for attending.

Randy Otto: Certainly. Hi, I'm Randy Otto and the Medical Director for pediatric cardiology at Seattle Children's, and with me is Dr. Mark Ferguson, who is the CO director of the cardiovascular imaging program here at Seattle Children's Hospital. We're both employed by university as faculty. We're not employed or paid by anybody else from that regard. And we deal at Children's with pediatric imaging, and we do both, perform cardiovascular magnetic resonance imaging in kids, most importantly congenital heart disease, also, for myocarditis and some other indications. And we probably had some questions as to the scope of what was being considered in this forum, we bind you know cardiovascular magnetic resonance imaging for congenital heart disease and some other indications incredibly valuable. If the discussion is coronary artery disease

which I think on the adult side is much so the concern, that's a little bit different topic for us we do at times use MRI for coronary artery disease but most of that is performed with CT.

Mark Ferguson: So, I guess if I can comment for a moment. First of all, I just like to emphasize that in terms of cardiac magnetic resonance angiography. In the setting of congenital heart disease, or other or top of these is really fundamental and critical to our assessment of these patients. We have a wide scope of indications, the fall into that. It may be for the initial sort of baseline assessment, understand the pathophysiology the underlying anatomy, giving our surgeons a picture so to speak and how to plan their approach, so it's really fundamental to that assessment. It may be for a follow up after an intervention, because many of these kids will develop complications. So, just two days ago we had an 11-year-old patient. History of trunk and arteriosus was repaired, with an RV to PA conduit. There was concern that there was stenosis of that conduit, while using MR angiography, we can really visualize that you can see it, you can show it to the surgeons, you can talk about what is going to be the intervention is going to be a percutaneous intervention, is it going to be an open-heart surgery. Pretty big deal, and this is the sort of information that we can get with angiography. Even to the point where we can use the data set to make 3d models. So physical or digital models that again the surgeons can use that to help plan the surgeries so if you have, you know, a small child, an infant with complex heart disease, and you're trying to figure out what is the pathway for repair. That is very important information. And so, we routinely use angiography. Routinely.

Melanie Golob: Okay, thank you to you both for giving public comment appreciating, appreciate you taking the time to do that. So next, the next public comment that raised their hand was. I apologize in advance for this name, Sujatha Buddhe. So go ahead and unmute yourself, and you will have four minutes and please state your name, conflicts of interest, and if anyone is paying you to, to provide comment.

Sujatha Buddhe: Thank you I am Sujatha Buddhe from Seattle Children's Hospital and the same group as Randy and Mark, I'm a pediatric cardiologist, and then also do cardiac MRI, and then the co-director for cardiac MRI. I completely agree with Mark, Mark and Randy said and appreciate their comments. It's, again, the value of cardiac MRI is huge, I'm also a physician who's involved in echocardiography so kind of the bread and butter test for, for the children that any heart disease, but there is no way that an echo can ever replace MRI the amount of information we get from MRI is huge,

whether it's for congenital heart disease where we see the anatomy, and the angiogram that will see the function of the heart and the MRI and the details of the myocardial that MRI provides is completely unique to MRI. The details of the myocardial that MRI provides is completely unique to MRI. It's not just congenital heart disease, its cardiomyopathy is, and children who have a heart muscle problem, who are born with that but this can be progressive over time, and in turn that and this is extremely valuable for us to let us know when we can let the patient play sports, do we need to place an ICD so that they don't have a sudden cardiac, event. So again, this is huge and you know this information has even recently post vaccine, we have seen children they'll have myocarditis, and the information that MRI has provided has been extremely valuable in directing of you know what are the risks with vaccine and who needs to be vaccinated and what precautions we need to take. It has given us the opportunity to publish things within a short time, that helped us define you know the way we vaccinate children.

Melanie Golob: Okay, thank you so much for public comment. I appreciate it. So, at this time again, any attendees who want to give public comment, please raise your hand. [pause] I'll ask once more, anyone who wants to give public comment, please use the raise hand function in Zoom. If not, we can, Dr Rege if you so choose, take an early break before moving on to the presentation.

Sheila Rege: Yes, because the public comment was scheduled to go on till 9:30, what I would recommend is we're scheduled also for 10-minute break after that. But I don't want anybody to not have the chance, do we have a process that if anybody comes in now, between now and 9:30 that they are allowed to comment?

Josh Morse: Yes. Typically, we will check back in at the end of the comment period, see if anybody has joined during the comment period and we can circle back to that.

Sheila Rege: Right, and and and I don't know if you have a way of projecting while we're gone on break for 10 minutes, so from nine to 9:10 that you know please remain on if you want to comment, in some way. I don't know if people can see the chat but let's try and figure out how to let people know if they come in in the next five minutes that we will be back at nine 9:10.

Josh Morse: Can do, thank you.

Sheila Rege: Well then, we will take a break for 10 minutes and come back and begin the next phase.

Josh Morse: Dr. Rege, I can share the agenda briefly if you'd like to see the agenda again,

Sheila Rege: That would be good and please let us know that if there's anybody who who's raised their hand for public comment.

Josh Morse: It looks like Dr. Buddhe just raised, the hand again.

Sheila Rege: Since we have time, I would be open to having Dr. Buddhe speak again unless there is an objection from committee members. Barring, seeing none, we will allow Dr. Buddhe to speak.

Sujatha Buddhe: Thank you, I appreciate that. Sorry, I just wanted to make sure I added one more very important comment that for MR angiogram. We usually do that in children who had not just surgery, like a core patient who had tense and surgeries, but also children that connective tissue disease where they will need multiple scans in their life, because they thought they have a progressive condition, or they have a condition that can have complications later in life. And these things cannot be seen by Echo, and CT scan has radiation, especially if you're doing lot of them so in that in those situations, the lack of radiation MRI, and the anatomy, it shows us it's huge. Similarly, Turner Syndrome and children but wrong connections of, you know, structures in the heart. Multiple scans that's a huge value also babies with vascular anomalies where you know they're bonded. Some structures in the body in the aorta, which cause vascular ring and all CT MRI avoids radiation which CT doesn't. Thanks for that.

Shelia Rege: Thank you, Melanie anybody else?

Melanie Golob: I haven't seen anyone else join. So, one more call to, to give public comment, if you wish to give public comment, please use the raise hand function in Zoom.

Sheila Rege: And I know clinicians are busy and we, you know, maybe coming in closer to 9:30 so if we can get started and Melanie you still monitor whether somebody raises their hand, will you be able to keep an eye on that—

Melanie Golob: Yes, definitely.

Sheila Rege: --while we move onto the next. So thank you, we're going to be looking at the evidence report from the OHSU team Beth Shaw, Megan Rushkin and Valerie King. Welcome, if you could introduce yourselves and your role in this process, and any conflicts if you have some. Thank you.

Beth Shaw: Hi, well I'll kick off. My name is Beth Shaw, I'm a senior systematic reviewer at the center. I don't have any conflicts of interest in this area. Did you want Val and Megan to introduce themselves as well?

Valerie King: Well, yeah, I can go this is Valerie King, I'm a physician epidemiologist and a professor at Oregon Health and Science University in Portland, and I don't have any financial or other conflicts of interest with this topic, except that we were hired to do this review.

Beth Shaw: I know Megan sometimes has issues with muting, so that may be her challenge. So, I'll kick off with the review them. So, as I said, my name is Beth Shaw and I'm going to be presenting to you, the results of that evidence report on the use of CMRA in adults and children. So, talking about the technology of interest. There is the broader use of cardiac magnetic resonance imaging, and that's an imaging modality that can assess cardiac and vascular anatomy function perfusion and tissue characteristics during a single examination, specifically the focus of this report is CMR angiography, not those why the techniques of CMRA such as stress for fusion. So cardiac magnetic resonance angiography is a specific type of CMRI technique that assesses the coronary vessels and major, major cardiac vessels, such as the proximal aorta So, in practice, CMR angiography can be used alone, or it can be used in combination with those are the same techniques such as stress perfusion or late gadolinium enhancement. In terms of safety. On the next slide, you can see that, again, broadly. Sorry. the next slide please.

Josh Morse: Yes, Beth thank you, I'm working on it and my computer is not cooperating.

Beth Shaw: I suspect that might be the case. Thank you. So broadly again CMRI is generally considered safe. It's not an invasive procedure. There isn't that exposure to ionizing radiation or denoted intravenous conscious medium. However, there are some contraindications and risks associated. So, people may experience, the rare complication of an epidemic systemic fibrosis. So that's particularly older people, individuals with a history of renal disease or dysfunction, or patients with a primary transplant, or the populations have specific risks, so they may be people with implantable federal magnetic devices or particular people who experienced claustrophobia, that can be a you know a contraindication to the use of these types of imaging. And of course, there's allergic reactions to those contrast agents, which can be as severe as anaphylaxis. So, on the next slide you can see the aim of the report here is to review the effectiveness and cost effectiveness of CMRA in adults and children when compared

with in this current angiography or coronary computed tomography angiography. So, while there's been a number of technological advances in CMR angiography in the past decade, its accuracy in clinical utility for diagnosis and routine clinical practice remains unclear. And as Judy said there's low to medium level concerns about the safety, the medium level concerns about the efficacy of CMRA and high-level concern about costs that were identified during the scoping this topic. So, moving now on to the methods. We'll start with the key questions. So, we're looking at the diagnostic validity for the accuracy of CMRA compared with those other techniques, and we're looking at the clinical utility so the effectiveness of CMRA compared with a visit coronary angiography or CCTA. We're looking for those direct arms are also looking for those variations in accuracy effectiveness or harmed by different characteristics, such as sex of the patient, the age of the patient. And whether that different in different settings for example in a high volume setting versus a low volume setting. And of course, we were looking for the cost effectiveness, or the economic impact of the use of CMRA. In terms of the populations. You can see that we have five groups. The major group that we were looking for was adult patients with symptoms of suspected or previously undiagnosed cardiac disease. He presented with stable, typical or atypical symptoms suspicious of coronary artery disease. Unlike the previous review that you saw couple of weeks ago, we excluded people who were presenting in an acute situation. So, patients with that acute presentation, were excluded from this review. The other groups were adults with suspected economy vessel and anomalies adults who do have the CABG surgery, people being assessed for cardiac device lead placement, and that important group of infants and children with suspected or confirmed congenital heart disease. In terms of the interventions were looking for that coordinated Magnetic Resonance angiography so that specific technique, either alone or in combination with other CMRA techniques. Sometimes, it wasn't clear whether they've done the CMA alone, or whether it included as a kind of bundle with those other techniques, but all the studies, specifically said that at some point, and CMRA had been performed on those participants in terms of comparative to diagnostic validity. We were looking comparing it against so there's the coronary angiography or the CCTA, and for clinical utility or effectiveness. We began looking at it compared with the invasive coronary angiography other noninvasive testing usual care or no testing. In terms of outcomes, excuse me, we were looking at for the diagnostic validity. The standard type of outcomes you'd expect sensitivity specificity positive and negative predictive values, and we were also

looking at intra and inter-rater reliability for effective as we were and in terms of again effectiveness, we're also looking at on how to use this technique impacted on care pathways. So, the people's referral for further treatment change. How did it impact on the referral for additional testing. In terms of homes we will keep those hands directly related to CMRA and harms related both to the process and the outcomes of fear my way testing. And in terms of cost effectiveness, again, all the cost effectiveness outcomes or cost utility outcomes and moving on to the specific designs. We were looking for randomized controlled trials. We're also looking for non-randomized comparative studies. We also included non-comparative studies because of the lack of data in some of these groups. We also looked for additional studies and data for those questions around homes. So, we looked at government or other large multi-site registries. And we also looked at the FDA databases and procedures related homes or device three calls and additional studies for those economics, we were looking for cost effectiveness studies or other formal comparative economic value. In terms of methods, we searched a range of databases, we were looking for publications from 2000 words, and our searches were conducted in May of 2021. We use jewel independent screening, we assess the risk of bias and all of the included studies, we calculated relevant test performance statistics with 95% confidence intervals, based on reporting calculated two by two tables. We applied great to those key outcomes. And we were also able to conduct a diagnostic test accuracy meta-analysis within this report. You can see detailed methods. On page 13, as well as he sees a and b. Some moving now into the findings. Just in terms of the overview. This is the study flow the standard plasma diagram. So, you can see our initial search is found just over two and a half thousand hits for this topic. We then work through those attacks and abstract phase, and we screen just over 900 have full text level. And in total in the final report we included 46 studies that have been reported in 49 publications, 23 of those studies were able to be included in the diagnostic test. Accuracy metro analysis, and we also looked at other systematic reviews, which we checked for relevant references. And we also included five relevant clinical practice guidelines. So that's just an overview of the literature included in this report. So, moving down to the findings we'll start with the group. that I think that perhaps the most concerned about. So that's adult for suspected coronary artery disease. So, for this group, we identified 26, and diagnostic testing, because he studies, but no eligible studies of clinical impact. So, across the 26 included diagnostic test accuracy studies, the publication date spanned the time period, we're looking at.

So, the publication date range from 2000 to 2020, the sample sizes range from 10 to 628, and in total included just over 1100 participants. And the majority of those participants were male and the mean age range from 58 to 69 across those studies, again you can see much more detail. As mentioned before, including things like the tesla strength used in those studies on page 33 of your report. And then in the detailed evidence tables, independent, independent thing. We assess most of those studies being that low to moderate risk of bias, and five studies for assessment being high risk with the bias. And the main reason for our concerns about bias there were around patient selection blinding small sample sizes, and the potential for conflicts of interest. So, moving on now, could you present to the results of the diagnostic test accuracy metro analysis. So, while traditional meta-analysis and bolts of quantitative synthesis of data across studies for single outcome, a meta-analysis a diagnostic test accuracy studies need the method that simultaneously synthesizes a pair of outcomes. So, we're talking about sensitivity and specificity. And you can see there, the standard definitions about sensitivity and specificity. And the reason that we need a specific method is because those two measures are very interrelated. And we need to preserve that independence interdependence when combining in a meta-analysis, and given the interdependent relationship between those two measures, they tend to be inversely correlated. But when we analyze them, we need to keep those two measures together. So, in this report. We used bivariate, and the hierarchy hierarchical summary receiver operating curve, the HS role models to directly model sensitivity and specificity, while accounting for that correlation across the two measures. We included all diagnostic tests accuracy studies that evaluated against are predefined reference standards and we included 23 unique studies. All of those 23 studies compared to CMRA with the ICA or invasive coronary angiography, so no studies included in the meta-analysis compared CMRA with coronary computed tomography. So, we pull data across studies where we have more than three studies, reporting that same reference standard, so we have 23 studies and if more than three of those studies reported similar thresholds, using the same reference standard. We conducted analysis according to threshold for some of the studies use different definitions of what suspected of what coronary artery disease was. So, on the next slide. This is the bivariate model. So really at its simplest, you can understand this is basically a pad for support. So, I'll just orient you to the figure. So, on the left-hand side we have the study details. Then we have the threshold that was used to diagnose cardiology to see coronary artery disease, and that's the

threshold that was used. Excuse me, in the invasive coronary angiography, so you can say it was either 50% or 70%. Within have details of the sensitivity and that kind of middle column, and you can see the sensitivity for each study, along with the 95% confidence interval. And then we move on to the specificity. Again, with the estimate by each study, as well as the 95% confidence interval. The studies are ordered by the threshold that the reference standard at the invasive coronary angiography, and then the audit by alphabetically. And at the bottom you can see the summary combined estimate. So, when polls using this bivariant model, the summer sensitivity was 88% with the 95% confidence. Confidence interval of 84 to 91%, and the summary estimate of the specificity was 72%, which with a 95% confidence. Confidence interval of 64% to 78%. So now let's look at the HS ROC model. So, we're going to return to this figure, but I just wanted to kind of give you the bottom line. So, the main takeaway here is that summary estimate the red diamond that you can see towards the top left-hand corner shows the sensitivity and specificity. So again it's 80% and 72% specificity, and the red or brown dotted line just around that red triangle that shows the 95% confidence interval. So, both of these models, the results are the same, because we didn't include any covariance in the model. So, for these two models and the absence of covariance, the results are exactly the same, but you get some more information using this type of model. So, moving on to the next slide. I thought it'd be helpful just to take you through what this receiver operating characteristic curve is showing you. So, on the x axis we have specificity, going from one to zero, from left to right. And on the y axis we have the true positive rate of the sensitivity that goes from zero to one, along the y axis. So, we can represent the effects of changing our threshold. So that's the tradeoff between sensitivity and specificity, and we can represent that graphically by using the receiver operating characteristic of that curve. So, it puts a point on the graphic each threshold value of the test, putting the sensitivity and specificity of the test at that value and then we can connect the point and that creates what's called the curve. So, rockers tend to go from the bottom left-hand corner to the top right-hand corner of the box, and this represents that intuitive tradeoff between sensitivity, which rises as we move up and specificity which drops as we move towards the right, the points in the lower left a threshold of the test where we're very specific but not very sensitive and points in the upper right, a threshold of the test where we're very sensitive. But pull is specific. What we're really aiming for is that point in the top left-hand corner of the rock, where sensitivity is 100% and specificity is 100%. This represents a perfect, but

likely unachievable test. So, the closer the rock curve gets to that top left-hand corner, the better the test is. So, in this example that blue rock curve is better than the green marker and the closer that curve comes to the central diagonal line, or that red dotted line, the worst the test. And on that red line. It's a random, it's random results. So, when it comes to picking a threshold to use in practice, we often try to pick a point that's closest to that top left-hand corner, and that's the closest to that perfect test. And we can also use the area under the curve to assess performance. And again, the higher the area under the curve, the better. In terms of test performance. So now we can look at that HS ROC curve again. And hopefully we can see we've got those same axes. And, again, top left is that perfect test, and that red.is that some estimates, they take centers and 2%, each of the individual circles represents a single study with the size of the circle shown us, which reflects the standard error within that study as a set of red diamond is that summary estimate. Again, 80% and 72%. The red line around that diamond demonstrates and 95% confidence interval. And then the blue line is the HS ROC, ROC curve, and that provides that graphical representation of a test performance balancing, balancing those tradeoffs using different thresholds. And then that larger dashed line that kind of leadership region represents the 95% prediction interval, which provides the visual, visual estimates of the between study variability that cannot be attributed to chance. And that is the region where any future study results are predicted to lie. It's worth noting that I just presented either data for all thresholds. In the reports that you can see that we also found similar results when we analyzed by different thresholds for the reference standard. We had actually pan sensitivity analysis or subgroup analysis by things like the mean age of the patient or indeed the tesla strength, which was asked about earlier, but because of the lack of heterogeneity and stability in the models, we didn't feel that was needed. So, moving on to what all that means in practice. So, in terms of our grade assessment, what we've heard that CMRA have a sensitivity to 88% with that confidence has to fall from 84 to 91% and the specificity of 72% with a confidence interval from 64 to 78%. We assess that as high as having a high certainty of evidence diagnostic test accuracy studies start at high grade when you're looking at a question around diagnostic test accuracy. So, we didn't downgrade his evidence, and that was based on those 23 nonrandomized studies, and in practice, what that would mean in a population of 1000 adults with a 53% prevalence of coronary artery disease. And it's just worth noting that we chose that 53% prevalence because it was the medium prevalence of coronary artery disease

processes, including 23 studies. So, using that medium prevalence of 53%, the use of CMRA testing would result in 466 patients being diagnosed correctly is having coronary artery disease, that's our true positives. It would result in 64 patients incorrectly classified as not having coronary artery disease, so those are false negatives. It would result in 338 patients being diagnosed correctly as not having coronary artery disease, so a true negative and 132 people incorrectly being classified as having coronary artery disease, so are false positives. So that's how that translates into practice in a population, thousand adults. In terms of the observer agreement, we also found that currently magnetic resonance angiography has high levels of the opposite of agreement, both within reviewers, so that intro observer result, and between observers, or inter observer findings, and we assign that as being as moderate certainty of evidence based on one-on-one device study, and we downgraded their one level fitting precision, because of wide confidence intervals. And again, you can see detailed grade tables and Appendix A if you want more information. terms of the clinical utility or the effectiveness, we didn't identify any eligible studies in this population. Judy did mention some studies on clinical effectiveness, and they were included in the draft report, and they focused much more broadly, on the CMRI, and based on some comments that we received during peer review and public consultation and based on some comments that we received during peer review and public consultation, we excluded, those studies. So, we're really looking just for studies that looked at CMRA. So, we don't have any information on how the use of CMRA changes patient outcomes such as mortality, or how it might impact on the clinical pathway. For example, does it result, fewer invasive tests or any changes in management. So, I think there's a real gap there and what we know about the use in that population. Moving on to our findings, the second group. So, this is adult for suspected coronary artery disease. We identified three diagnostic test accuracy studies and one nonrandomized study that assess the clinical impact of these CMRA in this in this population. So, cross the three diagnostic series, the publication date range from 2000 to 2008. So, these are relatively old studies. The sample sizes range from 12 to 26, with only a total of 63 participants in total. And so, again, much smaller numbers. Again, the majority of participants are male, and the mean age range from 38 to 50 across those studies. We assess each of the diagnostic test accuracy studies in that high-risk bias, with concerns again about patient selection blinding small samples. Unclear reporting at the timing of tests, and the lack of reporting generally. And in that single nonrandomized study that looked at clinical impact, it included 19 adults and have no

comparative group, so that was assessed as being a high risk of bias. So, what we're finding from those three diagnostic test accuracy studies. What we found that CMRA is highly concurrent with surgical and invasive coronary angiography findings and the use of this big modality may identify anomalies that are not identified using those are the tests, including invasive coronary angiography. We assess that as having the low certainty of evidence based on 300 randomized studies, and they were downgraded one level each for in precision. It wasn't accessible, and there were small sample sizes and risk of bias, which, you know, all of the studies are at high-risk bias and wants to be actually reported. Some diagnostic measures. So, when compared with ICA CMRA had a sensitivity of 80% and the specificity of hundred percent. Again, we assign that as being low certainty of evidence, and we downgraded one level each for in precision with some wide confidence intervals that you can see there, and again risk bias. This study was at high risk of bias. And again, had a small sample size. And in terms of clinical utility, we have that one study, and this study reported that CMRA may add information on the origin and cause of the anomalies, and can provide the information needed for clinical management, Both avoiding the need for conventional angiography we assign this being very low center of evidence, because this isn't an effective this question, non-randomized study started low in grade for effectiveness and we downgraded one level for risk of bias and in precision, taking us to a very low certainty of evidence for that finding some moving now into the group of adults who had CABG surgery. We didn't talk as didn't find any eligible studies that looked at the use of CMRA in this population, either for diagnostic test accuracy, or for clinical impact. Moving that's how fourth group so this is those adults being assessed the cardiac device lead placement. We found two studies that looked at the diagnostic performance. They were published in 2011 and 2014. Again, small sample size of arable 14 and 19. Again, the majority of participants will male and the mean ages range from 59. Well, mean ages, two studies, no range with 59 and 70. Again, both studies what high risk of bias for similar rationales around patient selection blinding, etc. And we didn't identify any studies looking at the clinical utility in this population. And based on those two studies, we found that CMRA may be useful to help visualize the appropriate vein for cardiac divide his device lead placement. And we had low certainty of evidence based on two non-randomized studies, and those lists started out, high in grade for diagnostic testing performance, and we downgraded one level each for risk of bias and imprecision. As noted, before, in terms of clinical utility, there were no eligible studies identified. So that's the next slide, Josh,

you may be back keep. Again, some studies mentioned in the medical director's presentation did include CMRA, so we've excluded those after peer review didn't identify any clinical skills and this population. So, moving now on to the findings for children with suspected or confirmed congenital heart disease. Overall, we identified 12 studies, six to filter diagnostic test accuracy studies and six were nonrandomized studies looking at the clinical impact. So, looking at the six diagnostic test accuracy studies, they will publish from 2000 to 2019 sample sizes range from 21 to 100. Not all studies reported, how many participants were male or female, but were reported most studies, had a majority of male participants, and the mean age in these studies range from four to 11 years with one study that was conducted, only in infants, and that age range from one to 90 days. Each of these studies were assessed as being at high risk of bias, again with concerns about patient selection blinding etc. And also, not all patients in these studies actually underwent the reference standard. Moving on now to the six nonrandomized studies. So, these are looking at the clinical impact in this population of children. They were published in 2001 to 2018 sample sizes ranging from 14 to 214. And again, were reported most studies had a majority of male participants. And in these studies, the mean age range from three to 23 years. All of these studies were assessed at high risk of bias, because of the lack of comparative group. So, in terms of the findings around diagnostic test performance. CMRA was highly concordant with surgical findings, as well as finding some of the tests, including invasive coronary angiography and coronary computed tomography angiography. And again, they found that the use of CMRA may identify vessel anomalies that weren't identified using those other tests. We have a low scientific evidence based on those six diagnostic test access studies. And there was a high into observed agreement for the use of this modality individualization of coronary artery anomalies. And that's very low center of evidence based on one number and my study, and that was downgraded one level he fit and precision risk and in directness that it was only looking at that single type of visualization. Moving on to clinical, clinical utility based on those six nonrandomized studies, we found that CMRA can be diagnostic in most cases, with no additional imaging needed CMRA can also identify new findings on new diagnosis in the majority of cases where they are present. However, there's lots of uncertainty around that with very little scientific evidence. And that was downgraded one level each for risk bias and in precision again just to remind in non-randomized study started low, when we're looking at effectiveness in the great framework. So, moving out findings around

safety. So, we extracted safety data from those included studies that you've just heard about which reported on adverse events, and we also included two additional studies that looked at the safety a CMRI range children. Now you'll see immediately that these were broader than CMRA alone, but we felt it was important information that you would want to hear about, so we included these two additional studies. One was in 250 children who underwent general anesthesia for CMRI for a variety of congenital conditions, and the other study looked at 143 infants who underwent CMRI with general anesthesia or deep sedation, and that did include CMRA is appropriate for the valuation of congenital heart disease. Both of these studies were assessed as being at high-risk bias, because of the lack of a comparison group. So based on that information from all those included studies as well as those two additional studies and we concluded that in adults, CMRA appears to be a safe procedure, with few adverse events related to the procedure or to the pharmacological agents used low certainty of evidence based on eight and on Monday by the studies. And similarly in children, CMRA appears to be a safe procedure, with few adverse events related to the procedure or to general anesthesia. Again, low certainty of evidence based on those born on my studies, in terms of the FDA reported hands. As I mentioned, we also search the US FDA more database, the last five years, and the medical device reports. And you can see the details of these in appendix F. So, we found 253 entries in the database. So that's where the voluntary user facility distributed and manufacturing reports of adverse events, but those were related to an MRI scanner use. So, it's not specific to CMRA, and we weren't able to analyze reports by the indication, and many of the entries will not specific to the use of CMRA alone. So based on those two databases with those caveats, again, it appears that adverse events for the use of CMRI appear to be minimal in both adults and children. However, patients may be exposed to harm, such as burns lots of hearing tinnitus through the use of MRI, all the other procedures that are associated with the MRI so that might be general anesthesia in young children, or gadolinium contrast agents and people will diminish renal function. And also, MRI may not be suitable for people who are unable to tolerate MRI. So, for example, people with severe claustrophobia. So, let's look now at the findings by variation by patient or setting characteristic. We found very limited data, and that was only in the population of adult for suspected coronary artery disease. There was no real clear variation by patient characteristics. So, for example by sex, age, single or multi vessel disease, we didn't find any information on the house setting characteristics might impact on the performance of this

test for that might be high volume versus low versus settings. We didn't identify, identify any information, and even where we did find information it tended to be single studies, only. So, it's very difficult to draw conclusions on variation based on a single study. And as you've heard many of those studies themselves were very small, even in total. So, looking out at the findings the cost effectiveness and economic impact, again, we didn't identify any eligible studies on the cost effectiveness or an economic impacts of her new Magnetic Resonance angiography again in the draft report we did include some information, but that really was focused on CMRI. And again, based on information that we received during public consultation and peer review, we excluded those in from their studies. So, we didn't find any direct information on the use of sent CRMA cr coronary magnetic resonance angiography related to cost effectiveness. And I think this is important just to know that you remember cost the impact of cost was assessed as being a major concern when this topic was scoped that's potentially a big gap in the evidence base. We also looked within this report for ongoing studies of CMRA, and we didn't identify any eligible ongoing ongoing studies looking at this modality, and any of the populations of interest. So, we'll look now at the findings from those clinical practice guidelines and selected pair of coverage determinations. So, as you know, there's many, many guidelines out there on cardiac imaging for many different types of cardiac disease, but very few guidelines specifically mentioned the use of CMRA, and its use and treatment pathways. So, when we looked at those guidelines we identified one clinical practice guidelines and to appropriateness criteria documents, developed by the American College of Radiology on the use of coronary magnetic resonance angiography and adults with suspected coronary artery disease. We also found two guidelines on the use of CMRA in adults with congenital heart disease that we included as being relevant to the subgroup of adults with suspected coronary vessel anomalies, we assessed two of those guidelines as being a good methodological quality, with the remainder of the guidelines being the moderate methodological quality, because of a lack of description of passion involvement and editorial independence. We didn't identify any other eligible clinical practice guidelines for those other populations such as adulthood undergone CABG, or indeed children with clinical. Sorry, children with congenital heart disease. And just to stay is not that there aren't guidelines out there on imaging for those populations. It just didn't make any specific mentioned coronary magnetic resonance angiography. So, look first at that population of adults with suspected coronary artery disease and as you can see, the

guidelines from NICE explicitly state do not use magnetic coronary angiography for diagnosing stable angina. The two guidelines or criteria of appropriateness criteria, and the American College of Radiology say that the use of CMRA may be appropriate in patients with chronic chest pain. and with a high probability of safety, and they all use may also be appropriate in patients with chronic chest pain in human non cardiac etiology is unlikely and have a low to intermediate probability so some differences in recommendations there. It's also worth noting that in, in the document. It's also worth noting that in, in the document, the SEO expert panel also noted that CMRA should be limited to sites with extensive experience and appropriate capabilities, some recognition there with the training and experience needed to conduct cardiac imaging, and particularly CMI something we heard about both today and in the previous meeting. In the previous meeting we also talked about the very recently published 2021 guidelines. So those were the joint guidelines for the evaluation and diagnose chest pain, and I did look at that and obviously it didn't come up in our searches which were done earlier in the year, but that guideline makes no specific mention of CMR angiography. They do talk about the use of stress perfusion CMRA And that is recommended as an option for various scenarios, but no specific mentioned of CMR angiography. So, moving now to the group of the bar we also found some guidelines. This was around adults with congenital heart disease, and their PET to be more consensus for this population with many supportive recommendations for the use of CMRA in the evaluation diagnosis and monitoring of adults with known or suspected congenital heart disease. And you can see the details of which specific types of congenital heart disease, or which particular anomalies. CMRA is recommended for, and that is in your report. So, in summary, recommendations from good and moderate methodological guidelines, support the use for CMR angiography and adults with congenital heart disease, including people with coronary vessels anomalies. However, there's much less consensus for the use of CMRA for adults with suspect suspected coronary artery disease, with only conditional recommendations from the American College of Radiology and a do not do recommendation from NICE. In terms of selected pay coverage determinations, we didn't identify any current Medicare national coverage determinations of any local coverage determinations relevant to Washington on the use of this technology. Each of the three private payers that will review did have coverage policies for this modality. And overall, they cover the use of CMRA for congenital heart disease or vessel anomalies, but do not consider the use of CCMRA for other indications,

such as suspected coronary artery disease to be medically necessary. So in conclusion, when compared with invasive coronary angiography, CMRA is a good test results with suspected coronary artery disease, with an overall estimated accuracy of 89%. However, there's no direct evidence on the effectiveness of this technique and change in clinical practice or in improving outcomes for patients with coronary artery disease. Also, the economic impact of the use of this technology in patients with suspected coronary artery disease, when compared to standard care is just it's just you know we didn't identify any evidence. And in those other populations where anatomical imaging of the vessels is clinically important CMA does appear to be a useful test for CMRA, often performance as well as that invasive coronary angiography, and maybe it may be able to identify other anomalies, not identified using that test. However, it should be noted that invasive coronary angiography may not actually be the gold standard for the diagnosis of coronary anomalies. And it's also perhaps worth noting that as we just heard from one of the commenters was that people with congenital heart disease and other vessel anomalies, often require a range of tests to fully understand the vasculature and testing or monitoring maybe over that person's lifetime. CMRA also appears to be a useful tool and informing and changing clinical pathways and actions and adults and children is vascular and that needs to be visualized, which would be expected to lead to improved surgical on other outcomes, although we didn't see direct evidence of that. In terms of safety adverse events appear to be minimal in both adults and children. So, in general, the use of MRI, more broadly, is considered to be a safe procedure. So, patients are not exposed to the harmful effects by ionizing radiation that are used in other imaging modalities, such as computed tomography and patients they also evolved the risks associated with invasive testing, such as radiation exposure and test related complications or with surgery. If CMRA is used as an alternative, in some way for the clinical practice guidelines and policies, they tended to be in agreement on the use of this technique and adults with congenital heart disease, including people with coronary vessels anomalies. However, there was no real clear consensus on the use the CMRA for adults respected coronary artery disease. So, in summary, it performs well as a test the visualized vessels and can be useful when clinicians need to understand the vascular anatomy. It also appears to be a safe alternative for many patients. However, there's a lack of data on patient outcomes and the impact of the use of this modality and clinical decision making and specific, specifically on the cost effectiveness in any of the populations of interest. So overall belief,

there's a lot of uncertainty around the political impact of the findings from the paucity of clinical outcome studies. Thank you.

Sheila Rege: Thank you, that was a really good presentation, and if anybody wants, we can post the link to the material that's being referenced. Melanie, I don't know if you can. In case of questions. I'm open to questions for that, Beth, Megan or Valerie from the panels.

Mika Sinanan: Hi, Mika Sinanan and I'll, I'll start off with a couple of questions, thank you for that presentation. One of the questions that came up as you were presenting a piece, what was around the nice recommendations. While you were making a presentation, I quickly looked up the UK has at least as of 2017 6.1 MRI scanners per million versus 38.1 in the US. So, I just wonder, do you have an appreciation over multiple reviews about the NICE recommendations and whether they are linked to the, to the availability of the technology there and does that change over time, mean how much do we pay attention to their recommendation as being evidence based as opposed to resource limited? So that's a question.

Beth Shaw: Okay, my initial response. First of all, I, I didn't know whether to declare this as an interest, but I did start work on the nice guidelines for cardiac imaging, and many many years ago but I only worked on the initial phase of it, so I wasn't involved in the recommendation development. So, I can only make a guess on what their best is recommendation on without going back into it. But normally nice would not consider availability, as being a barrier to treatment. So that may be something that would be discussed by the committee as being a challenge to implementation. And so, feasibility of implementing that recommendation would be discussed, but it certainly would not, would not stop a recommendation being made, that would be something that would be considered after. So, my guess would be for do not do recommend recommendation, it would either be that was that it was deemed as being cost ineffective. You know that it was just too much money for very little value, or that really the evidence show, know that the with either no evidence of effectiveness, or that was evidence that it just wasn't effective. That would be my guess.

Mika Sinanan: Great, thank you.

Valerie King: Mika, this is Valerie King as well. And that the directionality goes the other way that the lack of a recommendation by NICE leads to fewer scanners per, population.

Mika Sinanan: Thank you. That's helpful to me. So, the other question that I haven't came up at several points in your analysis is that this technology appears to be showing things at a greater accuracy, demonstrating anomalies, for example, in the vascular anatomy that are not shown, even by invasive angiography, but I presume later confirmed anatomically because there has to be a reference standard. And so, it almost seems like this is voice to become because of its higher sensitivity. A new reference standard. Is that?

Beth Shaw: Studies where they found that CMRA found additional anomalies compared with ICF was yes confirmed by surgery. But I wouldn't say that that means that CMRA should replace invasive coronary angiography. These tended to be small studies. And I think, you know, again, what we've heard from the experts today is that each of these techniques looks at something slightly different. And I think when you've got those more complex cases, you may be looking for different things at different times. I'd welcome Val's clinical perspective though as well.

Valerie King: Yeah, I'm make I think it's a fantastic question, and I think that your experts. Both Dr Kirkpatrick, and those who provided testimony from the pediatric complex congenital anomaly, and other pediatric cardiac disease perspective. Excuse me. You know, clinical practice is out ahead of where the evidence I think here. So, what we're able to say from the evidence is that we think that across conditions, this is probably a very accurate test or set of tests as it were, and that we don't have a huge amount of evidence about clinical impact, where we do have evidence of clinical impact tends to be around these anomalous arteries or other congenital types of defects, and I think your ex their testimony from the folks from Seattle Children's really bear that out. It's going to be extremely difficult with congenital anomalies, to mount, any sort of sample size, that helps get you there. Because this really has become a standard of care. And because each of these conditions, each of these people who have these conditions are unique, and you're looking for something particularly different, particularly for surgical planning. So, I I have great sympathy with them as a clinician, and somebody who does maternity care that these children often have anomalies that are very different one to the next so it's hard to mount a study that comes with all that complexity.

Mika Sinanan: Thanks, and my, my last question is around the topic of bundling of studies which Beth you referenced. How it seems to me that that is a con founder to the analysis of the data because if these studies are routinely

bundled in clinical practice? It may be hard to sort out this one particular from the bundle and and did any of the data, elucidate that individual benefit of this, when it was bundled from the rest of the bundle.

Beth Shaw: When we extracted the data for the meta-analysis where we reported the angiography parts on its own. That's what we've used for the meta-analysis. There are some studies included in there where they are bundled. So, they said we've done CMRA as part of this procedure, it there are very few of those in the data. And when we exclude those it really doesn't make any difference. You know it's not that sensitive to the use of the technique. You know it's not that sensitive to the use of the technique. The worst some data where the looks, which Judy mentioned in a presentation where they looked at the addition of CMRA to the CMRI techniques. But because we weren't looking at that comparison that wasn't a pre specified comparison we've excluded that data was in the draft, but it's excluded in the final.

Mika Sinanan: Thank you.

Sheila Rege: Could you summarize for me the competitors again? And you mentioned that in your slide, and we could pull that back. Um, was it ICA primarily was NICE, and CCTA and King. Can you bring us back to study that had CCTA? They're not ICA or worse, was an either or.

Beth Shaw: We were looking for ICA of the CCTA. And then for the effectiveness, we're looking at ICA versus other noninvasive testing usual care, not testing. So those studies where they looked at the additional benefit of CMRA on top of CMRI. We're looking for diagnostic validity. So, there would have been excluded because that wasn't a comparison, but we would have looked at it, clinical utility that didn't find anything.

Sheila Rege: Any, any questions from the panelists on kind of an understanding of the evidence in terms of what we're being asked to look at in terms of comparators?

Christoph Lee: Sheila, I did have a question along those lines, I think, in my mind, the real debate is whether there's any added value of cardiac MRI to CCTA for suspected CAD and maybe I glanced over this in advance report, but could you summarize, is there any evidence of added value of the MRI oversee CTA?

Beth Shaw: Didn't find any, we didn't find the 23 studies that are included in the meta-analysis, all looked at against cardiac angiography. The word, I think in the three studies that weren't included in the meta-analysis. I think a

couple of those did look at CCTA I may be wrong but there's not much evidence there to certainly very, we didn't find any evidence on the added benefit. The certainly very, we didn't find any evidence on the added benefit. We would have included that if we found it because we felt that was a really important clinical question, but we didn't find anything.

Christoph Lee: Thank you. Ya know, just based on Jim's prior comments it seems like that comparison is where the crux of the debate is and whether you know, because these tests, provide different types of information that could be valuable to the clinician. What is it about the MRI, that could be better than the CTA, and in what situations for suspected CAD, then?

John Bramhall: I'm back, can I just this is John Bramhall. Well can I, I don't want to put you on the spot because there may not be data to answer my question but it look in the early slides in the coronary artery disease world. It looked to me like it was about a 13% false positive I think you had a slide that showed 132, but prediction of 132 out of 1000, people who get the MRA would be judged to be positive for coronary artery disease so so that number to me and my question is, do. Is it reasonable to assume, theoretically, that that group of 132 13% of the patients who get a positive from the MRA. If they went, then to invasive testing that the parameter would be that the invasive testing would not suggest coronary vessel occlusion is that that's that is that the right takeaway from that, that number. Okay. And, and, and so you have to assume then then in the real world. Okay. And, and, and so you have to assume then then in the real world, that there's a significant number of people who, who might have this study, again, coronary artery disease just, it does not seem to be the best modality for that I get it but, but they they get the study. My assumption would be that those 13% of people would then actually go for invasive testing, actually, it would be negative and there would be no stenting and what have you, so that that strikes me as being a fairly significant number of people going through them. As a result of the initial tests for a secondary test, but I'm sorry I'm being long winded here, but these are presumably patients' people who have got clinical signs and symptoms of coronary artery disease, and they would probably in the US system, go for invasive testing anyway. Right. That would be the sort of main mainstream response to CAD that was taught to be responsive to intervention. So, so even, even that additional link between MRA, go for invasive. Even though it's all negative. Those patients would still probably get the invasive tests because of their clinical presentation. So, it's the MRA is the additional costs that is of no benefit. It's not

necessarily the cost of the invasion, which is resulting from a false positive. I sorry I haven't put that really very elegantly but. Am I right,

Shelia Rege: Yes, you're right. Yeah, I think that's all I wanted to know.

Jim Kirkpatrick: I want one caveat to that I think you make an excellent point. I think a lot of people in the chest pain guidelines might suggest that if you are at that point in which you're going to cast them anyway you really shouldn't order any diagnostic tests, it should just go for angiography but if they if you are trying to diagnose it or prog or get some prognostic information to guide whether or not you'd go to invasive coronary angiography that's the benefit of all of these tests. And I think there are a large number of people who fall in that category of, if I got a test that that demonstrated that there was not any significant obstruction, I would not send them to coronary angiography and basically.

Valerie King: Yeah, um John, this is Valerie King remember that the inclusion criteria here were four people with stable or suspected CAD. This is not something where you want to be acutely waiting on the test number one. And number two, I want to turn it around and also say that you've got in this theoretical population of 1000 adults with this particular prevalence of CAD a 6.4% chance of being incorrectly classified as a false negative. So, clinically that might actually be of more concern.

Shelia Rege: I have a question based on this so the sensitivity and specificity and I assume it's much higher in any kind of suspected or confirmed coronary vessel anomalies did, would they data on that, or are we just making an assumption on that based on what was found at the time of surgery?

Valerie King: This is just sorry I'll let that answer that, but there were limited data there.

Beth Shaw: Yeah, I was just gonna have a quick look. This was coronary vessel anomalies.

Sheila Rege: Right, either children or adults. And I just want to make a comment, comment period had ended, we will be monitoring the lines carefully. And I will have Melanie, or Josh, explain the process of how the committee accepts any comments in the future so. Would anybody like to step up to that?

Melanie Golob: Yeah, and I'm happy to say that if there are any people that felt like they wanted to provide further public comments. Our email address is on our website, it's shtap@hca.gov, and you are welcome to provide any further public comments at that email address you can also find the email

address by going to the HTA website within HCA website, the Health Care Authority. So those are the ways that you can provide additional evidence or public comment. Thank you.

Sheila Rege: And Melanie maybe you could put that in the chat box, also for people to easily access from here? Continuing on the discussion I'm sorry to interrupt.

Beth Shaw: We're just looking at that data for the adults with suspected coronary artery disease system suspected coronary vessels anomalies. We only have that single study. It's just on the next slide, I think. Thanks, Josh. Yeah, so we only have that single study, so I wouldn't be confident in saying that shows, CMRA is better in adults with suspected coronary that'll anomalies, then the data for suspected coronary artery disease. I don't feel we could make that comparison. And in terms of children, if I recollect, I don't think any of the studies gave us data to report those kind of, you know, diagnostic outcomes, they just kind of said yeah we did the test. And when when we did the surgery when we found they were pretty much in line or, there were some differences, and they didn't give us that data to the two-by-two table, and then calculations.

Sheila Rege: Any questions on the evidence?

Janna Friedly: I have a, I have a couple of questions, or clarifications or questions. This is Janna Friedly. This goes, maybe this is a, an unanswerable or rhetorical question but going back to what Christoph mentioned about the, it seems like one of the big unanswered questions is. CMRA versus CCTA, you know, for people with CAD and whether whether the MRI has added clinical benefit more should be used in other content? And I'm curious why that comparison, comparison hasn't been done in the literature is there is there a clinical reason why that study has not been done? Or is that just, it is what it is?

Beth Shaw: But I'll give it kind of what I would guess to be a methodological response, and then Val may have a better informed clinical one. I think it's just viewed that invasive coronary angiography is the reference standard. So therefore, people look at you know, they immediately go to that as a reference standard.

Valerie King: I think that's probably true. I would ask Dr Kirkpatrick This is Valerie King speaking, you know, from a clinical perspective as a cardiac imaging expert. Do you have an idea about why that might be?

Jim Kirkpatrick: I think that's really a good point. And also, where I think we are in a position of sort of transitioning eventually away from invasive coronary angiography as a reference standard for certain things, like for instance, whether you have non obstructive disease. But at the moment, most of the studies were in fact looking at obstructive disease and so that's kind of where it was. I do think also that it was considered the reference standard for coronary anomalies although, you could definitely make a strong argument that that was not not a very good reference standard for that. So, I think you're exactly right about that but then there are just these issues of. When you do especially either retrospective or prospective studies, doing to noninvasive studies is just not something that we normally do. You know you would do the noninvasive study then the invasive study, so I think it just from that method logic standpoint. It's, it's a complicated thing to generate and compare those two modalities.

Janna Friedly: I think even in a comparative effectiveness, you know, where it seems like that's that sort of ripe for good comparative effectiveness, study.

Jim Kirkpatrick: I couldn't agree more. I think you're exactly right, that it would be great if something like that, that could be done.

Janna Friedly: And then I had one one other question, and I wanted to clarify I think with Dr. Kirkpatrick. You had mentioned at the beginning the aortic abnormalities and whether whether those were included and I'm, I'm curious. After you know hearing their, their report, how should we be thinking about that piece of it and when and the evidence and, and? Could you sort of reframe that again that that issue, and how that impacts our thinking about the evidence.

Jim Kirkpatrick: Yeah, I can try, as far as I could tell that's outside the scope of the review. I think it's care, we have to be careful and not talking about Coronary Magnetic Resonance angiography, as a whole, because really the term refers to any imaging of any vessels. And so, we certainly wouldn't want to be because they are very different and they use of it to look at the aorta is different than I think what the scope of this is about and my guess is that a lot of the, the data and utilization, not only did it reflects conflating CMRA was CMRI. But, even within CMRA it probably included data on the aorta as well so I think we just have to be careful and in considering those two things separately, that were gets more confusing is is in the congenital round because a lot of aortic delectation is caused by congenital heart disease but not all of it. There's a lot of people who have a aortic enlargements and aortic dissections who don't have any

congenital disorders of the heart, much, much less something like Marfan syndrome are able to stand those, which could be considered I suppose congenital defects of the aortic vascular wall, they actually will, as far as we know, maybe they do have a genetic defect that we don't know about and haven't found yet but. But these assessments of the aorta could certainly be helpful and already used. You know Janna the excellent point that you wouldn't want to wait an hour to diagnose that dissection so that, that is, it's not the ideal test for that certainly because it takes longer than party XETRM excuse me aortic CT to do so but I think just sort of recognizing the scope of the, of the discussion is is probably the main way to frame it my mind.

Janna Friedly: Yeah, well I guess I'm curious. Is that something that needs to be explicitly sort of clarified the that we're not considering that as part of the decision? That was that wasn't clear to me until you you brought that up, or, or I guess I hadn't considered it, but didn't realize that there was that added issue.

Valerie King: Yeah, Janna, this is Valerie King of if, if we had found studies about the ascending aorta, we would have included those if they were known or suspected congenital anomaly. So, if it were an issue of dissection, we would have explicitly excluded it I don't actually recall any of those but they would have been excluded. But anything that had to do with known or suspected congenital abnormality would have been included there just wasn't very much.

Sheila Rege: If we were in person, we would be united be timing how long. What was the presenter was standing on the podium, if it's okay with everybody, I'd like that person to be off the hot seat and put all of us on the hot seat and I kind of want to just go around the room and I am going to take the chair liberty of I know we looked at five categories in the report, the suspected coronary artery disease the suspected coronary vessel anomaly stairs was CABG and cardiac lead placement for adults and children we looked at suspected of confirmed congenital heart disease but as Chair, I would like to take the liberty of saying we considered it as when we're looking at evidence, talk about is it safe is it effective to provide value for coronary artery disease, including the guiding lead placement and everything and suspected vessel anomalies, be children or adults, and I would like us to both speak individually kind of like to go around the table, and we can ask questions, you know, while we're mulling that through and then we can take a five minute break. I'm going

to just go again alphabetically, I'm gonna go from the bottom I don't think Tony Yen is with us so Mika. I'm putting you on the hot seat first.

Mika Sinanan: Okay. Um, well. So, from a safety standpoint, it seems that this is very safe and in fact that is probably one of the principal arguments for using MR to avoid radiation, as the alternative, or to minimize radiation, especially in kids and especially in where multiple studies are necessary, though, we don't have data about the avoidance of radiation risk provided today we did talk about that at the previous review, but that seems to be a key issue from an efficacy standpoint. I suspect that if the cost of this wasn't so high, it wouldn't be as much a discussion. So, it's really cost efficacy and not just efficacy that we're being asked about it appears to have a reasonable sensitivity and specificity though. John, I think you raised some interesting questions based on their data analysis as clarified by Val that it's not 13, it's more like six or 7% false negative rate. I had some questions that I wanted to ask Jim, to help clarify. One was this the male predominance of of both the CAD and the coronary anomaly. Data is that representative of the population or is that a selection bias what didn't come out? One, two, is there a change in the technology over time? And Christoph you may have a comment about that, that makes this a moving target. And it really may change our interpretation of studies that are more than five years old, And I'm interested in the real world, utilization of this and Jim, I think you already commented that you don't do you try to do a noninvasive study when appropriate, but don't do two noninvasive studies so the invasive studies used as an entry to an invasive study in terms of cost efficacy. I don't think we got any data that would point to that so we're interpreting that on the basis of the comparison to invasive coronary angiography as being the gold standard. And so that's my final question back to Jim is is invasive coronary angiography considered to be 100% sensitive and 100% specific? I mean I don't believe any tests like that but what are the sensitivity and specificity numbers that you think about for that because it wasn't provided, we actually haven't gotten any data to suggest that but we're making a comparison to that. My final comment would be that I think that this is technology that is in application in use at the present time. It appears broadly that, there, there is coverage for it, and inclusion in a number of guidelines. It seems to me with the safety and efficacy data that it is something that should be covered but should be covered with conditions. The, I don't see a reason to not cover it, but I also don't see a reason to cover it in a unconstrained fashion

Sheila Rege: And Mika, can you agree or disagree with putting it into two buckets, like the agency director coronary artery disease, and it coronary vessels?

Mika Sinanan: Thank you, and you did ask that. So, it seems to me the data and supportive of coronary artery disease for stable disease. The study population and the questions is poor, and it needs to be more constrained in that population for specific reasons. The data in congenital cases is better though from many non-randomized studies, and the safety concern of multiple studies over time, especially in pediatric populations. Probably adds an extra dimension of value. So, it ought to be more liberally supported in congenital disease and less so in a coronary artery disease, in my opinion.

Sheila Rege: So, we'll answer those questions that Dr Sinanan had. But from an evidence standpoint and so I think, who's on the hot seat Jim for answering it I hope you wrote it down, otherwise we can have a fit into that.

Jim Kirkpatrick: I can try to remember, the first thing I do think there's definitely a bias and all the studies to male predominant bias, I can't see how, especially with such small studies that reflects the population, I actually don't know whether males have more congenital anomalies, or the coronary arteries and it probably depends on which congenital anomalies that we're talking about. But as far as the coronary artery disease, you know the traditional thought is that males have that but now we know that that females do in fact develop this and it may developed at a later age but there's. It's probably just a bias of the studies. What was the next question?

Mika Sinanan: Change in technology over time.

Jim Kirkpatrick: Yeah, absolutely. So, you know, traditionally, and I've probably behind on this but traditionally the thought was the cardiac MRA can actually see the proximal vessels well but cannot see the distal vessels. And so, the idea of being able to exclude proximal obstructive disease is, you can say well that works, you know pretty well, but you know if you really want to diagnose coronary artery disease, then you would not do that because you can't see past the proximal vessels, you don't know what's going on in the distal vessels that probably has changed. I'm just not up enough to know to what extent we can see the distal vessels now with a better scanners. I do think that impacts a little bit on this issue of whether we're because I don't think there are any studies on diagnosing coronary artery disease period, as opposed to diagnosing obstructive coronary disease

which are kind of two different things, and we did see that in the last time we discuss these issues in the SCOT heart trial. Why was there advantages of doing coronary CT? Well, part of it was because he could diagnose any coronary disease and that got people put on Stanton's and had secondary prevention. In, and that probably led to to some improvements, there's a lot of complexities as we discussed last time but but that is a bit of a different question, I think, then, then we're even addressing today, but might impact on the changes in technology and its ability to diagnosis destructive disease versus diagnosing any disease.

Mika Sinanan: So next question, thank you, that was helpful. Real world use, what are your indications or what do you think the indications out to be and should this be a study that is ordered by a primary care physician as opposed to a cardiologist?

Jim Kirkpatrick: I've never actually ordered it for that indication because, as we discussed last time most of the standard techniques that we have for assessing it have similar test characteristics compared with invasive coronary angiography so those would be the stress testing and the coronary CTS. I and I don't know why, there seems to be an interest or at least anecdotal interest in people ordering this more often. My guess would be that someone wants a test akin to the coronary CT, IE and anatomic test, but doesn't want the radiation or it needed contrast, and that that would be that the justification for why one would would want this. But I like I said I haven't ordered it it's, it can be done at our institution certainly is not ubiquitous. It's not something that has as much penetration as even just with the protocols and everything else, let alone the MRI scanners, as coronary CT or any of the stress modality so we talked about last time.

Mika Sinanan: And just as a brief follow up question maybe Christoph can come in about this, I presume that an MRI machine can do this, it's not a specialized them are like a gated MR or something? Are these specialized machines or are they, an MR that you would use for other purposes?

Christoph Lee: You know, I think they use different coils. So, there are different settings that MR itself is indifferent. It's a standard MR unit but you do have to do some type of heart rate control, and you have certain specific coils use for cardiac imaging. That's my understanding.

Mika Sinanan: Thank you. And then my final question to Jim was about the sensitivity and specificity of invasive coronary angiography.

Jim Kirkpatrick: That's a really great question because we've kind of not questioned it for a long time and I to be honest the studies that would have established it

versus, you know pathologic correlations I'm not really up on that and they were done a really long time ago with really old technology. So, it's just been one of those things that it's gotten it's gotten that reputation as being the gold standard for obstructive disease, and it's not entirely well justified I think in the modern era to look at it that, as we've already said it's not as good as some other techniques and actually looking at the vessel wall and determining whether there's coronary disease to begin with, and it also is probably not a very good surrogate for looking at anomalous coronary diseases because it is possible to miss those as as was brought out in the evidence.

Mika Sinanan: So, Janna that's another potential comparative study that may be worthwhile. Thank you, those are all my questions.

Sheila Rege: Thank you. And remember, as we're going around the table kind of talking about it. We're just getting prepared in case we have any questions in my mind on safety efficacy and clinical utility in terms of when we do a straw poll of unproven last equivalent more in and some more and all that kind of exercise, and I'm hearing that the comparator would be ICA or CCTA a Laurie if you wouldn't mind going next. Thank you.

Laurie Mischley: Yeah, so I largely agree with Mika sentiments I think that I appreciate that each imaging modality offer something a little bit unique and my goal is really not to handicap the provider. I want to make sure that the diagnostic diagnosing position has the tools available to them to do what needs to be done. I certainly like the idea of preserving the option to avoid radiation and contrast if ionizing contrast If desired, especially if you're getting an equivalent amount of information. And I haven't actually seen compelling data that it is excessively more costly. So, I'm kind of saying the quality of the data, obtain is fairly equivalent. And I'm anticipating that I will write that there's not enough information to make a determination about cost differences for congenital abnormalities. I'm supportive of making sure that this is covered for coronary artery disease, and, you know, obviously I've just said my piece about preserving options, and I think that was it, and efficacy, I think there's not enough data actually to say what happens downstream but in terms of sensitivity and specificity. I see no question to. I see no reason to question that it has something to offer the clinician and the patient.

Sheila Rege: Right. And, and just like you're saying Laurie we're handicap because our charge is to kind of evaluate the, the evidence and the evidence kind of is a little limited and then you know we've heard from the presenters,

about the fact that it is being used at least for the congenital heart issues, but but I really kind of any questions on the evidence and how comfortable we are. I'm going to go to Christoph next unless Laurie, you have any more comments.

Laurie Mischley: Now, the only other thing that I'll add is I just really appreciate me can you bringing up the assumption that the angiography is gold standard, and what we're missing, and it is really difficult for me to make a judgment about comparison something to a gold standard when we don't have data on the gold standard, as much as we'd like and so the assumptions on which we build our decisions. I appreciate you calling them into question, and I think we all need to keep that in mind.

Christoph Lee: Right. So, from my perspective, just taking the cardiac anomalies. I think MRA is very safe. It shows effectiveness. The costs are uncertain. There's not much evidence on cost effectiveness, but I think it's the standard of care for congenital anomalies, heart disease, that includes coronary vessel anomalies. And I don't think it matters, it matters if it's kids or adults, because this is these are lifelong conditions. These individuals are going to get scanned throughout their lives. So just the cumulative ionizing radiation from CTs would be a problem or angiography would be a problem. So, I'd rather they have the option to get cardiac MRAs throughout their lifetime. So, I wouldn't put an age limit on that. For suspected CAD I think the evidence isn't quite there. We know that it's probably safe but the effectiveness and cost data are just not there to go one way or another for me right now. One question I did have for Jim, Sarge questions. what, what situations, would a patient be referred for cardiac MRA versus CTA? Is it, are there certain situations where you'd be like hey, this, let's shuttle this person towards an MRI and CTA for looking at vessels?

Jim Kirkpatrick: Yeah, I think it all revolves around the concerns of radiation and contrast. I had a nice contrast and and being able to avoid those things usually for diagnosis not something you need to see over time the way you do with, with many of the congenital lesions but I would I would think from the structural standpoint that said from the coronary artery standpoint. Again, I don't know, I've never ordered one, but I would guess it's because you want some kind of ability to look at, at least the proximal vessels and you don't want the radiation in the nice contrast.

Sheila Rege: I should have gone alphabetically before Laurie I'm sorry. I actually agree with Christophe. I wouldn't wouldn't say anything else, just in clinical practice, MRIs, I just generally more expensive we we didn't see any data

on that and and get containing contrast, you know could cause the, what is it the kidney issue the systemic fibrosis that's not reversible. So, there is some safety issues in cardiac MRI but like the rest of the people I think the evidence is is limited, but is the clinical practice seems to show that clinicians really believe that it's very helpful with any kind of coronary vessel anomaly evaluation. And I did not have any questions and I, I'm seeing that everybody seems to agree of putting it just in two buckets, rather than going through all five. Next, Jim, would you care to comment? I know we've been asking you, so we've heard some of your comments but if you would care to comment mostly on questions on the evidence, when we start talking about safety and efficacy or providing value in both those buckets.

Jim Kirkpatrick: I have the same questions that everybody does about sort of how cost is, and efficacy would actually intersect in this and I think what Mika said makes a lot of sense and everybody else's said to the idea that perhaps perform preserving the option to use it, if there are concerns about contrast to radiation or for some reason there's not some other test is not necessarily going to help or potentially in conjunction with something else so sometimes we do get young, young people in and we don't know whether it's obstructive coronary disease or whether it's anomalous coronary so I can conceive of a situation in which that might be, you know, sort of a more optimal test, or as part of an assessment of profusion and somebody who may have micro vascular disease, but it seems like that would under the parlance that I'm learning about might be a, you know, with conditions kind of situation as opposed to sort of an automatic. And then it certainly makes sense to avoid the contrast and the radiation when you're just looking at suspected anomalous coronaries and more of the structural issues.

Sheila Rege: Thank you. Oh, Chris, would you like to go next?

Chris Hearne: Sure. So, um, I agree with lumping it into two different categories coronary artery disease and vessel abnormalities, I think, with regard to vessel abnormalities and congenital disease and in that category of things like everyone else I agree that it seems like a good technology. I think, you know, even though we don't have a lot of data on costs, it's safe to assume that the MRI would be more expensive than CT. But nonetheless, I think, you know, especially when we're talking about people with possible congenital heart disease. This is a population that's a pretty high risk for antigenic injuries, just because of their, the length of their exposure to different interventions and, and often from a young age so if

there's a technology available that can minimize that by avoiding radiation, I think that's something really worth considering using. If it's going to give us the equivalent clinical data or, or similar clinical data and it seems like that's the case. I'm interested if we with regard to the coronary artery disease I'm what I'm interested in, to see if we can tease out conditions for which this would be appropriate like Jim was kind of alluding to whether we can find certain populations were using MR for suspected CAD would be appropriate and, and whether we can kind of carve that out, or not.

Sheila Rege: Was that a question, Chris, or

Chris Hearne: No just a thought.

Shelia Rege: Thank you. Janna, would you like to share?

Janna Friedly: So, I have the benefit of going after after everyone else so I'll keep it brief because I don't think I have much to add differently or anything to add differently. I agree with the two buckets and with suspected anomalies. I agree with everybody's comments about safety and potentially avoiding radiation and advocacy and, you know, lack of data about cost, but seems seems reasonable with a coronary artery disease. You know I wish, I wish that we had the right studies to be able to better compare, you know, to help us to make decisions about when you might use one versus the other. I don't think we have that data to be able to really guide us I can appreciate that there would be circumstances in which it would be helpful, compared to the other options but, but I don't know that we have the right data to really clearly, clearly articulate that are tease that out but. So those are my, my meantime and with the cost I don't, I don't think we have, we have enough data. So, those are those are my thoughts.

Sheila Rege: That's a good thought, same, Clint

Clint Daniels: Clint Daniels. So, I mean, similar to Janna I pretty much agree with what's been said so far I agree with the two buckets. As far as effectiveness, I think it's pretty clear that this is standard practice from our public feedback for sorry for vessel anomalies. And for. I had another question actually for that one on Jim, one of our speakers brought up cardiomyopathy and myocarditis, and I was curious if how clear we need to be whether or not those are part of the scope of our decision? And then for as far as CAD, you know, the same in agreement with everyone and cost and lack of data and things like that. And I thought it was telling

that the the current clinical practice guidelines don't recommend, it's routine use for CAD.

Jim Kirkpatrick: That's my understanding is that myocarditis and other structural cardiac imaging is not part of the scope, and I'd be happy to be corrected if that's not right but I think that they were sort of mentioning some broader areas of cardiac MRI than what we're focused on.

Sheila Rege: I'll let that Beth, Megan or Val speak on that, if there were any studies that were included. But I do not believe that was in one of the key questions.

Beth Shaw: I don't think it was but again phone they have a more clinical informed perspective.

Clint Daniels: Thank you. Yeah, I just I just wanted to make sure we are out of scope so that we don't.

Judy Zerzan-Thul: It is out of scope of this. And, yeah, it's best left alone, and I think there are rare instances when it's helpful in those would continue to be covered.

Clint Daniels: Thanks. Yeah, I just wanted to make sure we didn't unintentionally limit the doctors for those are the providers.

Shelia Rege: John, you have the last word on going around the table.

John Bramhall: Thank you. So, I agree with the two buckets I think coronary artery disease seems to be a separate thing they should be considered separately from the evidence that supports it for structural abnormalities. I was impressed actually just on that last cleanse your last comment I was impressed I was impressed in general with the exhortations and discussion points from the physicians from Seattle Children's that we had earlier on in the day so separate from the objective data. I thought that they presented a very convincing and a very full some request that they still have access to MRA, as a modality. And in their description of their work and their environments, it struck me that, one of the big elements is in planning for major surgery probably with very small children, maybe neonates, and it would seem to me that the cost, the cost of the study is probably become completely irrelevant. If it's as part of a planning for, you know, new cardiac surgery and an infant that's that's my speculation. And so, it cost is really hard thing to to get out one thing we have a lot of information that will help us objectively decide whether it's cost effective in all circumstances which is some, but it strikes me that if it's if it's being used for surgical planning for, you

know, major cardiac thoracic surgery that the cost is irrelevant in comparison with what's coming down the line. The issue Clint that you raise with inflammation. Yeah, I thought that was very interesting and if it's out of scope then I'll shut up, but it does seem that the policy issues that relate to vaccinations strategies, what have you that have come across transom over the last 18 months that probably aren't represented in studies. And so I agree, Clint, I would not want, and also with Jim I would not want anything that we do today to restrict the ability of a physician who's looking at that kind of environment to have a restriction in their ability to tease that out. So that's just a sort of editorial comment from me, and also yes, the comments that have been made before about repetitive scanning repetitive investigations that are required for lifelong can have some patients who've got cardiac abnormalities that are recognized early in life. So, I just make a comment about the safety so objectively, we saw information that suggested the MRA is safe. And I agree, I don't agree, I accept the data. I'll comment though the, you know, in my field of clinical activities in anesthesia we consider the MR sweet to be a hostile environment that's a technical term that we use, it's not pejorative. It's a very hostile environment and part of the hostilities not we're not talking personal hostilities here. We're talking requirement for specialized monitors, because of the magnetic fields that are involved so what happens is that when patients go for MRI, no logical reason why most people conscious lie that unmedicated and get the images done but there's a subsection of people claustrophobic mental health issues, pain, can't lie flat, all those things and when you get to the children's area. There's an interesting dichotomy. I think really small children neonates and young babies can be swaddled, and probably just sort of basically strapped in. I don't mean to be trivial, but you know they can be restrained adequately to get the imaging that's needed but the you know the toggle that through middle age children may well need medication. May they may well need general anesthesia in some circumstances, and so there is a risk associated with general anesthesia and the cost associated with general anesthesia, that's being done in a specialized environment. Having said that, you know, the work that I think Children's has a very well-developed system for providing appropriate sedation age-appropriate sedation for noninvasive studies in like MRI and again objectively the safety profile is there, but it's not without a lot of efforts to make it so safe. I think that's all I have to say I again I was always impressed with the, with the clinical utility that certain practitioners, Jim included associate with MRA

Sheila Rege: Thank you. This is to be more consensus on what I call suspected coronary vessel anomalies. Then, then on the other bucket so before a break if if everybody can hold on, and I would love to see if Melanie can project what kind of what we would have done in person with a straw poll. So, safety of CMRA with ICA or CCTA in terms of whether we think it's. And I would bucket, I wouldn't do adults and children separately just just adults or children unproven less equivalent more and some more and all and let's define that unproven easy less safe, then I guess and ICA or CCTA equivalent more in some more all. Is that pretty clear and I don't know Melanie can project, something for us, and how we would vote for them? This is easier and an in-person meeting.

Melanie Golob: Yeah, happy to do that either. Word or create a quick poll whichever you would prefer. Let us create a quick poll, if we're actually is. We. Yeah, maybe a quick poll would be the easiest, or we can just, we can just do a raise hand or Josh what's easier we've done this before on a topic, I think there's going to be consensus on this, so I wanted to do this before the break.

Josh Morse: She'll are you voting on the strategy for how to ask the questions. Right, so on safety. I think you can have a voice vote. Okay, just see if you have, you know, general consensus I don't think you need to do. These are all informal votes, until we get to the cover do not cover, frankly.

Shelia Rege: So let us. We're just going to do a raise the hand, its zoom in terms of safety of CMRA, with the comparative, ICA or CCTA. How many things in terms of safety, it is unproven, and this would be like we would be holding up placard unproven. And I'm going to try and figure out, everybody's, so I can see if anybody's giving you enough time lot last chance to vote unproven. Next on safe to be less. So less safe, than ICA or CCTA next would be asked safe. As I see it was CCTA next would be more safe, in some. Then ICA or CCTA Melanie Are you counting Josh you're counting at six seven. All right everybody that voted lower your hand and do not reward it's not Chicago, and then more in all in terms of safety of CMRA, compared to ICA or CCTA. John is that your old hand or your new hand? You didn't vote last time. This is what you're wanting, more and all. Everybody’s gotta vote.

Josh Morse: I think that's seven more and one more and all that is all that's the right number today.

Sheila Rege Okay, so we everybody voted, does anybody abstain a 111 us to spend more time on safety, and this is only a suspected coronary vessels anomalies.

Josh Morse: So, I think Melanie does have a Melanie Do you have a sheet able you're able to?

Melanie Golob: Yeah, let me share for this

Josh Morse: For this vote. I thought you were perhaps voting on something else. Dr Rege just a struggle. This is no.

Mika Sinanan: Let me consider that one while we're pulling that up. I just had a quick comment back to Judy and in the agency, you know we've had this numerous people have commented about our lack of data around cost. And then looking at the data that the agency provided, it would be helpful first of all to include the facility fee and the pro fees which they should have, though I don't think they were included in the data was presented, and also to to include the data for the same categories for the comparators. Because that's the cost effectiveness. Part of the cost effectiveness equation that we're being asked to make. It's not something we can dress today but just as a future point it would be helpful if we knew what for example invasive party coronary angiography cost for facility pro fee, etc. And the same thing with CCTA. Thanks.

Judy Zerzan-Thul: Yes, we've actually been chatting about that, and I agree, I think we've been limited in our data before, but our data shop is is fully formed and I think it's helpful and I think before taking a break, maybe we can look it up on the fee schedule and, and let you know but. Yeah.

Mika Sinanan: Great, thank you.

Sheila Rege: So, um, any other questions otherwise we'll just. This is just a straw poll on the, the efficacy the kind of the sensitivity specificity again on coronary suspected coronary vessel anomalies, compared to ICA or CCTA and, and this is based on the evidence. Is it, and I'm going to pull the adults and children together. Is it, how many say it's unproven. Raise your hands. How many say, and that's compared to ICA or CCTA how many say it is less sensitive or specific in terms of efficacy, compared to ICA and or CCTA. Josh Melanie, you let us know once you've counted the votes and we will ask us to layer, Laura hands them.

Melanie Golob: Okay, looks like three, you can go ahead and lower hands.

Sheila Rege: How many things, equivalent to ICA or CCTA.

Melanie Golob: That also looks like three, go ahead and lower hands.

Shelia Rege: How many look how many thing that intimate sensitivity specificity. CMRA is more sensitive a specific compared to ICA or CCTA more in some,

Melanie Golob: Like to, and that should be everyone,

Shelia Rege: and more in all would have known that would you summarize kind of where our thoughts were on that.

Melanie Golob: Yeah, and you should be able to see on the screen, it looks like it was three voted for less. Three voted for equivalent and to voted for more in some specifically looking at advocacy and sensitivity specificity.

Shelia Rege: Any discussion on on this? Raise your hand. What can I do.

Janna Friedly: Yeah, I can I just clarify. So my understanding of the literature is that in calculating the set specificity insensitivity you're comparing it to ICA, at least the studies that we have and so the anything less than one by definition would be less sensitive or specific than ICA, but we don't have data, comparing CCTA to see MRA for specificity specificity insensitivity that I could see a direct comparison. Unless I'm missing something so that that was where my, my thinking was even though the sensitivity and specificity were quite good overall.

Laurie Mischley: And this is Laurie, I'd like to change my morn some to equivalent.

Melanie Golob: Okay. And that's for the sensitivity specificity.

Laurie Mischley: Correct.

Melanie Golob: Okay.

Sheila Rege: Any other discussion? Going on to clinical utility. And this is again, just a suspected coronary vessel anomalies. How many think that CMRA, as compared to ICA was CCT is unproven? Please raise your hand.

Melanie Golob: Ok, I see two go ahead and lower your hands.

Shelia Rege: How many think, it is less has less clinical utility, then ICA or CCTA?

Melanie Golob: Ok, I see two go ahead and lower hands

Sheila Rege: Are the hands being lowered on my screen? They're still up yeah there so.

Melanie Golob: Are those the same votes from the unproven?

Shelia Rege: Yeah, I think so let's start over. I think they're saying no to an unproven, less clinical utility. Then ICA, equivalent clinical utility to ICA. And in my mind I'm using ICA I guess I'm not using CCTA but but no good reason. More in some for clinical utility.

Melanie Golob: Okay, looks like seven.

Shelia Rege: Laura.

Melanie Golob: Okay, I think we only have eight people. Did someone vote twice? Dr. Rege could we do the more some again just I am curious if someone voted twice because we only have eight of 11 HTC members here today.

Shelia Rege: More in some, if you will, raise your hand again.

Melanie Golob: Okay six, thank you.

Sheila Rege: And we will look at cost in terms of CMRA. We don't have any data on this is there is there will have the committee to even vote on this, given that we have no data, it's just a gut feeling.

Laurie Mischley: May as well vote unproven.

Sheila Rege: Okay. Let's vote on cost. How many hands for unproven?

Melanie Golob: Okay, looks like we have seven.

Sheila Rege: Just a straw poll raise of hands. Is anybody implying to say not cover and then I'm going to go to break on on suspected coronary vessel anomalies that bucket is anybody inclined to say not cover is is any anybody here, implying to say cover and when we come back we'll project the agency medical directors and kind of try and figure out a language with anybody up wanting to say covered in all suspected coronary vessel anomalies.

Melanie Golob: Looks like seven, eight.

Sheila Rege: So, sounds like, that's where we're leaning this was the easier one. I think when we come back. I'm, I'm debating actually whether to go through that grid first, or just go for a gut feeling of not covered and and we can. When we come back, and maybe just a five-minute break. That's okay. Does anybody need more than a five-minute break? So, we can maybe get done earlier.

Mika Sinanan: Sheila, Mika I you know I think the value of the vote, is it highlights exactly where the evidence is one way or the other. And, as opposed to just assuming if we go straight to the vote, so low, it adds a little bit of time, there's value in doing that vote as part of the process, because that

way we can specify where we feel that data is most strongest and weakest and

Sheila Rege: And the other question is, if, if the next one will be corner we are suspected. We've got besides symptomatic coronary artery disease, whether we we love children and adults together or just make it adults with obesity, but we don't have evidence on that. I'm implying the data we had was an adult so I'm inclined to keep that adults but. Does anybody have because we're going to try and Melanie based on our comments is going to try and create a similar poll.

Laurie Mischley: This is Laurie I'm not inclined to differentiate between children and adults when we're concerned about congenital anomalies know knocking general, this is the next one quarter again.

Mika Sinanan: But I think that that was outside the scope of the questions, so the data analysis didn't even include children. So we don't have the data to answer that question and children. I think

Sheila Rege: I would agree so I think when we recreate this poll of everybody's agreeable, we will just make it for adults with coronary artery disease, and and then the next question for Melanie has guidance during the break when she's working. Do we want to say a suspected coronary artery disease suspected symptomatic coronary artery disease, given what Jim has talked about?

Mika Sinanan: Stable suspected coronary disease or coronary disease in a stable patient. Something like that. It's not acute.

Judy Zerzan-Thul: Right. So, I and my community, I, I think that, and we talked about this the last time to that asymptomatic people are excluded because they shouldn't get any tests at all. And so, this is really symptomatic people with suspected coronary disease.

Sheila Rege: And not not acute. And that's something we'll have to craft a final but that's that's that's how I think of these patients.

Judy Zerzan-Thul: Studies evaluation, again, similar to not putting someone in an MRI if you think they have an acute dissection. You also wouldn't put someone in a MRI, if you think they're having an active, MI, you just take them to the Cath lab, and that's the right thing to do.

Shelia Rege: Right. So symptomatic patients with suspicion of coronary artery disease. Just that what I'm hearing. Don't be shy Janna.

Janna Friedly: Yeah, I think that sounds, that sounds right.

Sheila Rege: Okay. And, and we will just do adults. And so, in the five-minute break. Come back in five minutes It is 1113. I don't know I don't want to go to 1120 so we will come back at 1118.

Josh Morse: Just for 30 seconds, can we just look at the top of this document. Dr. Rege, just for documentation purposes? I just want to make sure that we're capturing this right so the population you just voted on Oh, where are the results.

Melanie Golob: Oh, sorry there below.

Josh Morse: Sorry, this so this, you just voted on this column here that we've got labeled as population one, and this was really, I guess, category one, and this was you voted on congenital anomalies. Is that right?

Sheila Rege: Correct suspected, suspected coronary vessels anomalies because we talked about the fact that they already can stuff was not looked at you could have a circle villas anomaly. So suspected coronary, I don't know Jim help us out but suspected coronary vessel be in artery or vein

Josh Morse: Right and that included adults and children then in the next vote you're going to address the question about CAD and adults. Is that right?

Sheila Rege: Correct, so it's a suspected symptomatic patient with suspected coronary artery disease, adults. Excellent. That's the polio career thing why we go on break. And now it will be 1120 it yeah and

Josh Morse: So this from the decision eight, this is documenting. Just for the record this is documenting the first voting question. These are the evidence boats and I just wanted to make sure because you've taken a straw poll on your, your final decision but we're still in the straw polling phase, this is not a final vote on coverage. Thank you for your time to think about that. I just wanna make sure we get it, get it properly documented.

Sheila Rege: All right now that's very important. Okay, barring and no questions will come back at 11:20. Welcome back. We will now go on to just doing, again, a straw poll of safety efficacy and weather provides value for symptomatic patients adults with coronary artery disease, and Melanie I think if you could project, a poll that would be helpful. So, let's vote. This is a CMRA. Is it the safety is it unproven compared to ICA or CCTA. Please raise your hands if you think in terms of safety it's unproven. Melanie good,

Melanie Golob: I see one. You can go and learn your head. Thank you.

Shelia Rege: Um, in terms of safety. Is it less safe then ICA or CCTA?

Melanie Golob: Okay, ok I see one.

Shelia Rege: In terms of safety, is it a coronary artery disease is it equivalent to ICA or CCTA.

Melanie Golob: Okay, there were none for that.

Shelia Rege: In terms of safety is CMRA more safe in some compared to ICA or CCTA

Melanie Golob: And I see four for that. Five,

Sheila Rege: Is that everybody? And and then safety isn't more safe in all compared to ICA, or CCTA. Because that you and john was that the last vote.

Melanie Golob: Okay so last vote.

Sheila Rege: Okay, and John you're still up was, were you on the last vote, are you voting more and all know?

John Bramhall: I'm voting more in all again.

Sheila Rege: Okay. I voted less because of the, the true positives and negatives being less than ICA and so I thought that was a issue in symptomatic patients, and that we feel should have coronary artery disease, so that's why I voted it less safe.

John Bramhall: And it's true I'm voting for an old simply because I just find it intellectually difficult to think of a subpopulation of patients where you know sticking a needle in an injecting contrast is going to be safer so that's that's what that's my position. Define there.

Sheila Rege: Well, I would still think they'd good yeah but and and I know all that gating is really hard for patients but anyway. Anybody else took care to comment on why they voted, if you're not part of the majority? Okay, going on to efficacy I guess here sensitivity specificity. CMRA compared to ICA or CCTA. How many think it is unproven?

Melanie Golob: I see five

Sheila Rege: Lower your hands. Anybody who voted. I'll wait till all hands are lowered. Clint, did you have a question your hands still raised. Um, how many and efficacy specificity think it's equivalent CMRA is equivalent to ICA or CCTA.

Melanie Golob: Did you do less.

Sheila Rege: Sorry, less compared to ICA or CTA, thank you for keeping me on my toes.

Melanie Golob: Okay, that's one. How many failed at in terms of efficacy CMRA is equivalent to ICA or CCTA?

Melanie Golob: And that's one for that.

Sheila Rege: And in terms of efficacy how many feel it is more in some say CMRA is more efficacious compared ICA CCTA.

Melanie Golob: And that's one for that and that should be everyone.

Sheila Rege: Anybody want to comment who wasn't in the majority on their thoughts?

Christoph Lee: My take is that MRA gives different information from ICA. And so, in ICA have to inject in certain area to visualize, whereas MRI, you get a global picture of all the vessels.

Sheila Rege: Okay,

Mika Sinanan: Mika Sinanan, and so looking at those receiver operating curves. My take on that is that if it was equivalent. There would be a match, it would be a one to one, equivalency. And because they're, they're not a match. They are less sensitive so that's why I said less sensitive.

Sheila Rege: Moving on, and again, the population is adults symptomatic patients with coronary artery disease or suspected coronary artery disease we're looking at clinical utility, anybody who thinks CMRA is unproven, as in terms of ICA or CCTA based on the evidence raise your hand now.

Melanie Golob: Okay, and we're at seven, go ahead and lower your hands.

Sheila Rege: Very good, thinks, it's less has less clinical utility cure having less clinical utility compared to ICA to CCTA

Melanie Golob: Looks like one for that.

Sheila Rege: And then, anybody thinks in terms of clinical utility it is equivalent to CMRA as being equivalent to ICA or CCTA anybody thinks that in terms of clinical utility it is more in some CMRA has more clinical utility and some compared to ICA or CCTA. And then last is clinical utility more in all cases the CMRA is more as more clinical utility for adult symptomatic patients with suspected coronary artery disease. Think we had it correct.

Laurie Mischley: Yeah, I think I didn't have my hand raised for unproven, but I meant to just do you want to change. I didn't vote I should be; it should be eight unproven I tried to raise my hand.

Melanie Golob: I think Dr. Bramhall was one that was up for less maybe, maybe that was just a remnant of unproven.

John Bramhall: No, I had intended to put up for proven was my intention.

Melanie Golob: Okay. So, I'll mark eight for unproven. Thank you.

Shelia Rege: Um, in terms of cost and CMRA compared to ICA or CCTA is the cost unproven. And if all of us vote one over done with voting just let me know Melanie and we won't go through the others.

Melanie Golob: Hey, I see nine.

Judy Zerzan-Thul: I'm raising my hand, put your schedule on the upside, I have rough cost. If you want them, you may want to change your vote you may not want to keep your votes. you want me to do that now.

Sheila Rege: Yeah. Yes, please.

Judy Zerzan-Thul: So, CCTA is about $290, and that includes the physician non facility fee and the professional fee. And the outpatient stuff. Same thing, and it does not include the exam itself because I think we shared that otherwise but sort of, I think he wanted a sense of what the other costs were for invasive coronary angiography, it is about $2,300 in addition to the thing, and then for the MRI it's about a little over $500 for physician fee and the facility, etc. Your questions about that. So, overall, the, the in the coronary angiogram is much more expensive, the MRI is still more expensive than the CT and. And again, these are Medicaid fee so they're lower than Medicare and lower than commercial.

Mika Sinanan: So, Mika Sinanan. Thanks, Judy, just to be clear, do we add the cost on the previous graphic that you showed what, which was about 187 to two to $300, non-facility fee to $500 for the value just gave us for MRA. So it's actually about 700 to eight to $900. Guess additive Thank you.

John Bramhall: So today this is Johnny and can I just at the very beginning of the meeting we had, we had a reasonably high concern for the cost of the studies. So could you. Is this an appropriate time for you to flesh that out just a little? Is it is it that the cost effectiveness is question by the authority or is it the number of studies that are being done, what is it that makes the, the agency concerned about the cost?

Judy Zerzan-Thul: And so, yeah, I know it's that there are a number of tests, including CT that are that are less expensive for diagnosing coronary artery disease, and less, you need to go to attack but, again, unless you're an unstable, angina situation or something else, you you probably wouldn't go to a

cast for diagnosis. Anyway, in people with stable symptomatic disease, you do a treadmill or stress echo or nuclear medicine scan or CP or MRI. So those are all I think with the evidence of last time and this time, relatively similar to the angiography and so given that, MRI and angiography are the most expensive. And you wouldn't, I don't know, I'd hope that you wouldn't use angiography in a stable patient just to see what's going on you, you do something else first, and you do the angiography when you needed to do something whether that is surgery or you're doing an intervention or, or something like that but that's sort of the place for that.

John Bramhall: Okay. Thank you.

Sheila Rege: Any other questions? Does anybody want to change their vote on cost given that information on adult symptomatic patients with coronary artery disease? So, we're going to we're going to re-vote, it looks like I

Mika Sinanan: Sheila, the problem is the comparison between to ICA versus CCTA. What we were just told is significantly less ICA is significantly more so. I think we have to separate those.

Janna Friedly: And also, is the is the question cost effectiveness or cost?

Josh Morse: I Dr. Friedly, yeah, I was gonna jump in and say that, you know, if you look at your decision aid, this is this section is titled clinical committee evidence votes. So, I, you know, I'm asking myself is this a vote on what was available in the evidence base or is this a combination of the evidence from the systematic review and other sources of evidence which is totally fine on, you know, direct cost and cost effectiveness so Thanks for clarifying that.

Sheila Rege: And I think we really, we really always done cost effectiveness and so I'm inclined. In my mind, that's, that's kind of what what I'm what I think of it. And it should be based on the evidence but there wasn't evidence and now we're trying to pull. I call it anecdotal data based on Medicaid rates. I think we found ourselves in a little circle, but let's go ahead and vote to get us out of this. How many things that cost effectiveness, CMRA is unproven compared to ICA or CCTA.

Melanie Golob: I see seven for that, eight

Shelia Rege: Go ahead and lower hands. So that's all of us right. Okay.

Melanie Golob: Yes, it's

Sheila Rege: Just not not not an official vote but what I'd people leaning towards for stable patients adults. I'm sorry. I've always said and correct me I've always thought of this as symptomatic patients with suspected coronary artery disease, adults, is that what the agency question was, Judy, would you mind helping out here?

Judy Zerzan-Thul: Yes, suspected symptomatic people with suspected coronary disease, adults, that's kind of what, what can I had unless anybody else.

Valerie King: John, this is Valerie King, if I could comment, the scope really was for known stable or suspected. But yes, acute was excluded. They need something else.

Laurie Mischley: And could somebody please clarify what would happen if it were a 16- or 17-year-old is it, how is that evaluated? If we don't make a decision on children today what happens when this test is ordered for children?

Josh Morse: As I read the scope and the questions and I think Dr. King or Dr. Zerzan-Thul can confirm this, that is out of scope. Sorry, go ahead you. Yes.

Judy Zerzan-Thul: Children with coronary artery disease that is not congenital is extremely rare and maybe even nonexistent. So, Yeah,

Laurie Mischley: So, we can. Okay, okay. People, there's no. We excluding children were clarifying, some people are saying adults so are saying people. And it's just. Is there a reason to draw that line what's my question?

Sheila Rege: Good question Is everybody happy with what's being projected on the screen symptomatic adults with known stable or suspected coronary artery disease.

Mika Sinanan: So, Mika Sinanan and I appreciate Laurie's caution, but we were not provided any data in children. So, from an evidence base standpoint, we, it is out of scope we can include somebody for which we don't have any data it seems to me.

Sheila Rege: Any other discussion? And again, this is not the final vote this is just kind of going around the table trying to figure out where we all are. Our thoughts are and then we can always ask for clarification. How many would in that sub in that group symptomatic adults with known stable or suspect coronary artery disease. For CMRA would say not covered.

Melanie Golob: I see three for that.

Sheila Rege: Let me know when everybody's hand is lowered.

Melanie Golob: Okay, they have all been lowered.

Sheila Rege: How many would say, covered with conditions.

Melanie Golob: Okay, there is five.

Sheila Rege: Okay. And that's all that's all of us correct, correct? Okay, I'm usually let people in the minority group, go first. On not covered, does anybody in that group want to speak to CMRA, not covered? I'm happy to go I, I would worried me the most was the fact that that slide in what Beth presented with the specificity insensitivity and my worry is that all those people will not go through an ICA because that's the only follow up if you are concerned that they have coronary artery disease so you put. I mean, what was it a specificity with 72%. My, that was my worry. That's why I bought it the way I did.

Mika Sinanan: Sheila, because some of the sorry I'm confused by what you just said, from what you said I would think that you would want somebody to be covered as opposed to being going straight to an ICA is that, but what you're saying is they shouldn't get any evaluation or, or what.

Sheila Rege: So, in my mind, they're going to most of these people will. So, in my mind CCTA is is just as good I don't think the MRI really adds a lot. I've not seen anything in the evidence, so I couldn't, I couldn't make that jump. I just the specificity and sensitivity were not high enough for me to to do that jump. So, I figured that that was the comparison, I was using in my mind. And it's unlikely I mean physicians think really hard before they put somebody to an ICA And I just,

Mika Sinanan: I'm thinking about the 50-year-old obese diabetic with some degree of kidney failure renal failure creatinine of 2.8. I want to be able to avoid any additional contrast. Until we have to do the ICA. So that,

Judy Zerzan-Thul: And I yeah and I'll just remind you that what you are deciding against is not does someone get an MRI or an IPA, but out of the whole variety of tests, which one. And so, this vote is. That's the comparison of the evidence this time but all those other things that we talked about two weeks ago are still on the table, if you're trying to figure out if somebody has coronary artery disease. So, I guess I do want to caution you that it's, it's not, if we don't cover MRI, everyone immediately gets an angiogram. There's still the, the whole variety of other noninvasive cardiac tests that we talked about the last time that a clinician can choose from.

Sheila Rege: Yeah and and I'm speaking because I've had family members with coronary artery disease and there's a lot of noninvasive tests the stress

Echo, and and stuff that that really plays, you know really has less of a risk. So maybe I'm not looking just to the evidence I just didn't see the evidence swing me for other noninvasive testing or no testing and if there's a high degree of suspicion then yes an ICA.

Clint Daniels: Clint Daniels, let's continue with why I voted the way I did for my coverage as well as I was concerned the other noninvasive test. I didn't see any evidence of this seemed to be considerably better or any specific scenarios where I thought it was the only option.

Janna Friedly: But would it be possible to get this channel? Again, Dr Kirkpatrick, you know, clinical views about that. I think that's what that's where I struggled to with this was, and I mentioned when we before I took the vote, I struggled with trying to identify it seemed like that, from all the discussions that there would be an appropriate scenario for a person to get this, you might consider it, but I wasn't hearing how to articulate that or to identify who that was. And I think that that might be at the crux of some of this is, it is there a scenario in which this is an appropriate test compared to all the other options on the, on the table. The patient that Mika described, would that would this be the appropriate test versus the other options for example?

Jim Kirkpatrick: Think that's, that's a really good question. I could craft a patient populations. A patient scenario in which there really was no other. Well, I shouldn't say no other options but the other options where we're less good. So, for instance, if you take the patient that Mika was mentioning in which you really do not want to give contrast for CTA. And then you give that patient some concern for ventricular tachycardia. Give them a, an amputation. And then we'd also have to give them some reason why a nuclear perfusion test would not be a viable option. And if you put all those things together, then you probably are left with the cardiac MRI, as about the only thing, except. Well, the, I think, in cardiac MRI stress test might even be something that one could could reach for even before the cardiac CMRA angiography. But at any rate, I certainly you could you could find a way to sort of justify somebody. I guess maybe, the other way to think about is something I mentioned earlier and that is that if for some reason you're choosing a test and maybe this doesn't fit into the specific stable symptomatic patient but if for some reason you don't want to give contrast or radiation, and you really want a, an evaluation of the coronary arteries, as opposed to getting a stress test, then that would also make sense in the in that circumstance.

Shelia Rege: But Jim, the, the guidelines, I think came out because of the issue with the accuracy. I'm not supporting it is what I recall in. In this patient population.

Jim Kirkpatrick: The, from what I heard, which I thought was a very nice overview the nice guidelines definitely been supported. And then the question of the radiology society guidelines giving it a maybe appropriate designation and it wasn't mentioned at all in the appropriate and correct me if I'm wrong I don't think it was mentioned at all and appropriate use criteria just wasn't didn't raise to that level of something that they thought people did enough to be able to comment on.

Laurie Mischley: Hey, can we go back to, um, can somebody answer the question about how often this is being used like in terms of the, is it being used excessively frivolously if I remember the data at the beginning, it looked like it wasn't being used a whole bunch, and somebody made the case that the third or so of the adults that for which this was being used may actually be under the congenital heading. Um do we have, can someone remind me of how frequently are people using this for coronary artery disease?

Jim Kirkpatrick: From what I took of the data we don't know and I'm not sure we can know but I, I could be wrong about that and maybe some other data out there.

Judy Zerzan-Thul: Yeah, I don't know that we know with the, the data that we were able to present today. Although I do think that the sort of adults in the 20- to 44-year-old are probably I would hope more likely to be congenital diseases. But that being said, the older older half 45 plus group that we had 45 to 65 group where this was more common, that the other things are also more common in terms of a aortic disease or other things where this might be getting done for so it's hard to say but we we have for sure had planned say that they're getting more requests to do this. So, whatever, whatever that is worth. But it really, really is not clear.

Sheila Rege: Question, what is a contraindication for a CT angiography?

Josh Morse: Sheila, can I just jump in with a thought for a second. Yeah, thank you, Jody. You know when the program started, the idea was to bring technologies that might be emerging or new. And so, you know, that's part of the identification process with a technology like this is, is this ready for, you know, for mass use does the evidence support it so the data from our utilization may not always show a you know, a variation or a concern we might even have zero data because something may not be

in use. But the question still comes to you, because there's some murkiness in the evidence. And you're asked to weigh in based on that evidence, if you think the evidence supports the user doesn't support the use or supports it in certain special populations. So, I just wanted to throw that in there, if the utilization data don't appear to be very helpful. You know, that's part of the reason I think is this is probably a technology that's more on the emerging front and not on the well utilized, and we've identified variation issues or things like that so

Sheila Rege: Does is everybody pretty comfortable with. Based on this discussion that we want to keep, keep kind of our on not covered, covered with conditions covered in all kind of do anybody want to revisit that vote I'll be pretty comfortable that that's where we are?

Clint Daniels: This is Clint Daniels, I have a question the ACR guideline did recommend conditional. Do we know what the conditions were or what the conditional scenario was where they recommended CMR, or CMRA for cab CAD?

Beth Shaw: I can have a look for you, if that's helpful.

Valerie King: Yeah, we can look that up.

Sheila Rege: While they're looking that up. We have more consensus I think on the congenital or whatever we call it, I got to go back and look at my words.

Christoph Lee: Sheila, we can I comment I was just doing some web searches because I recall, and training that we did some coronary MR work without contrast. And apparently, you can do, MRA coronary arteries without contrast. Because you have intrinsic differences and blood flow that acts as a natural contrast agent. So, to clarify it seems like you could do coronary MRAs without gadolinium. No contrast whatsoever.

Sheila Rege: So, I think Christoph we really need to kind of look at the evidence, not just as a, you know, unless there was a paper that looked at it, I think.

Christoph Lee: And I think this should have been pointed out in the evidence report if it hadn't been so perhaps or vendors can comment on that. And if not, maybe Jim can comment.

Beth Shaw: Okay. So, is that a question about whether you can do it with or without contrast?

Christoph Lee: That's correct.

Beth Shaw: Okay, all the details of whether they reported, doing contrast are in the tables. So, I can't remember exactly. You know when they used contrast and when they didn't, but there was certainly some that reported they didn't use contrast and some that did.

Valerie King: That's correct.

Christoph Lee: Yeah, I think that's an important point in terms of safety and clinical indications so patient cannot get IV gadolinium or IV contrast because of their kidneys, MRA is probably indicated over CTA

Sheila Rege: Thank you Christoph Um. Anybody want to change their vote or stay with that vote? We're all good?

Clint Daniels: Clint Daniels, I'm going to switch mine to with conditions.

Sheila Rege: Okay, then. I'd like to start actually with the conditions for something we all kind of seem to be more in consensus with which was the suspected coronary vessels anomalies. Could we start with the agency medical director language could be? And Josh helped me out? Usually you're sitting by my side and can help me where--

Josh Morse: I am right here Sheila.

Shelia Rege: go no go decision tool. Where do we go next with this in a regular meeting, Clinical Decision tool? Where do we go next with this in a regular meeting?

Josh Morse: Yeah, we start working on the draft language and I'll pull that right up here for you. I have a document. So, you'd like me to prepopulate it with the recommendation?

Sheila Rege: Yeah, just on the suspected coronary vessel anomalies. Okay, work on the easy stuff first.

Josh Morse: Okay, So I'll start sharing my screen here. So, hopefully you're seeing the word document with the draft language. Is that accurate.

Clint Daniels: Yes. Great, thank you.

Sheila Rege: Any, any anybody have any suggestions or recommendations for this? If anybody not an agreement with this or would like to help, make it clearer says?

Jim Kirkpatrick: One point to consider with the the cardiac repair cardio mass maybe a bit outside the scope here because that that isn't usually a vascular

consideration that that would usually fall under sort of standard cardiac MRI indications.

Sheila Rege: I was going to say that I mean the only thing I was thinking about was whether they thought that. In terms of the operation, how close the mass was to the anomaly but I, but we didn't have any evidence on that so I'm okay with it being taken away.

Jim Kirkpatrick: That's a good point I guess the other question would be, if that cardiac or pericardial mass represented a, an aneurysm of the coronary sinus or a coronary artery aneurism.

Sheila Rege: So, is it and and no we really need to be this is covered with conditions for people, what should we just say what we voted on suspected coronary vessels anomalies, because it shouldn't be all that's not what we suspected coronary vessels anomalies that's kind of what I had in my mind. Does anybody think we are?

Mika Sinanan: Agreed to that I agree with that.

Sheila Rege: So, non, non, suspected anatomic issues or cardiac or pericardial mass or yeah so they'd be orders, you know, if any one of those conditions.

John Bramhall: Sheila, myocarditis is out of our scope today, correct?

Sheila Rege: Correct, and myocarditis is out of our scope.

Mika Sinanan: So, Sheila, Mika again. Why do we have any of the bullet points?

Janna Friedly: Right, we didn't we didn't cover, not cover with conditions?

Sheila Rege: Okay. Remind me of my vote.

Mika Sinanan: Yes, we voted for cover.

Sheila Rege: Okay, then so there's no conditions is, is that what the group wants so covered for people with suspected coronary vessel anomalies. Do we want to cover? I mean I don't see anybody really going through it, it's a miserable procedure. I don't see anybody going through it every month, but do we want any. I don't know the studies had any guidelines.

Janna Friedly: I don't think we had enough specific information to be able to comment on timing or frequency or anything, or anything like that.

Mika Sinanan: Correct, I agree. Mika Sinanan.

Josh Morse: So, remove these bullets?

Sheila Rege: Right.

John Bramhall: Gone.

Sheila Rege: I, and and as people mean children. So, do you want to say, adults or children or do you want to just to clarify that people didn't mean adults or children?

Mika Sinanan: Yes, that is, better.

John Bramhall: Sheila, why did we delete other structural abnormalities?

Sheila Rege: Mean is that in coronary muscle anomalies is that a bigger bucket, is that a bigger one caucusing?

John Bramhall: To me, to me it is, and I thought that we we've heard information from from the, from the information review related to structural abnormalities that are not vascular. So it may be, it may be just a personal, you know, uncertainty here but it seems that if we don't include something about other structural abnormalities in some way then we're really very restricting, and only looking at vessel vasculature

Sheila Rege: That's a good point. So, are or other structural cardiac because we want to make sure this is cardiac correct?

John Bramhall: Yeah, I think so. I mean, if others don't agree. I do think that that we should include other structures besides the vessels.

Sheila Rege: I let the evidence people is was that clarified and then, Jim, whether you know Cyrus and vs or any of the other structural if this is the modality that people mostly rely on, or is it something else?

Josh Morse: Is that cardiac MRI and not cardiac MRA?

Sheila Rege: Correct. That's kind of where I'm so I just want some advice here.

Jim Kirkpatrick: Yeah, this Jim. I think that would usually be considered cardiac MRI.

John Bramhall: Right. Sorry, every time.

Valerie King: This is Valerie, the only place where we really included any evidence that was MRI or not distinctly MRA was in children with known or suspected congenital anomalies.

Mika Sinanan: So, Sheila, Mika Sinanan. That it seems to me the key issue is, are we talking about congenital heart disease, are we talking about congenital coronary vessel anomalies? Right.

Judy Zerzan-Thul: So, I think some could be could be this in two separate things because sometimes those congenital anomalies aren't figured out until someone's an adult, depending on how much they impact things and so I like the verbiage suspected vessel anomalies. Because, you know, of course they're congenital but they may not come up is that, and it may be based on what you voted on earlier that besides suspected coronary vessel anomalies, you may want to add something about congenital heart disease, or, or something like that. But I also think that this affected anomalies could include congenital because that's not how they get there.

Jim Kirkpatrick: The other their point to make and I have to admit, I don't know if it's used for this but there are acquired coronary vessel abnormalities in children, and in others particularly debilitation of the coronary vessels and and aneurisms that can happen and things like show, excuse me in. Kawasaki disease. So, you may actually want to include those none. Just because again of the issue of no radiation and no comment, no I haven't a contrast me want to include those so maybe, I don't know if anomalies is a good word to fit with that but something that includes that diagnosis as well.

Judy Zerzan-Thul: Yeah, there's definitely congenital and non-congenital anomalies.

Sheila Rege: Right, so what suspected make it more open and or is suspected not good?

Clint Daniels: So, this is Clint Daniels. Should we add known to that to like known and suspected? Because I know that some talked about repeat studies.

Jim Kirkpatrick: I think I said now that I have of thought of Kawasaki disease, I think that makes a lot of sense, because you those do dilate over time. That's a good point.

Sheila Rege: So known or suspected coronary vessel anomalies.

Mika Sinanan: And then, Mika Sinanan. And then add after anomalies or known or suspected congenital heart disease.

Sheila Rege: It would be known.

Valerie King: This is Valerie King I just want to make sure that you know that we explicitly excluded Kawasaki totally makes sense what you're saying clinically. But the scope that we were given was congenital.

Sheila Rege: So, Val, is suspected coronary vessel anomalies then out of the scope is that what you're worried about?

Valerie King: No, no, I think that language covers that I just wanted to clarify that. The wording is going to be fine. I just didn't want you to think that would look for Kawasaki when we have.

Janna Friedly: And, and this this is covering adults or children so I think we need to include the suspected partner vessel anomalies could could we just simplify could we just say with known or suspected coronary vessel anomalies, or congenital heart disease?

Sheila Rege: That's better English.

Janna Friedly: Or pick out the suspected right there?

Clint Daniels: Clint Daniels again. In the Health Care Authority recommendation, it said known suspected anatomical issues, which seems more broad to me, so I just was wondering maybe Jim could comment make sure there's nothing else for missing by saying coronary vessel and congenital heart, specifically?

Sheila Rege: Then Clint can you tell us again repeat what what what you first said?

Clint Daniels: Yeah, the Health Care Authority recommendation of what we should include said known or suspected anatomical issues, which anatomical just seemed a little more broad to me so I just wanted to make sure there's nothing else we're missing.

Sheila Rege: Judy would you would you have a comment on that, when that clarify, or reduce confusion, to change vessel to anatomic?

Judy Zerzan-Thul: Yeah, um, you know in hearing the conversation and thinking about it I think the vessel is probably better because anatomic is probably really MRI and some of these policies and that's what I was trying to sort of summarize included both MRA and MRI. And so, I think the part that is different for MRA is really this this vessel piece, so I think I think this captures it, and is you know sufficiently Goldilocks, not too broad not too narrow. But you know, we'll keep thinking about it and especially when we come back at our next meeting. When we vote on final language, will make sure there isn't anything that's come up but I think I think this is good.

Sheila Rege: I would like to take a five-minute break like we always do when we create language, let us look at this language. And I also want, Josh, if you would, project, what the agency medical director had up on whatever we call it. When we voted adults with a suspected symptomatic coronary artery disease. Yeah, and we'll just then have to think about what we want to do

it just put in what the agency had and then we're going to be changing it because there was people wanting to cover with conditions.

Josh Morse: Okay so cut this piece from.

Sheila Rege: Yeah, copy and paste that piece.

Josh Morse: And then we can change you want to see the language that you had put down in the document the voting document. Is that what you're asking for that Melanie had? Yeah, just messaged it to me.

Sheila Rege: Okay, so you can put that in the break. And this would be where it sounds like the committee is is wanting to cover with conditions for that group and whatever we were talking about. And so, in the break the staff will work on something, so we can start working on that cover with conditions and discuss that.

Josh Morse: Okay, this is the language bullet here that came from your voting document.

Shelia Rege: Okay, so we're going to now start working on that. So, in the five minutes, if somebody could think what they think you had on conditions we want to cover it on, and and what you would propose. And then when we come back, I don't want it in chat I think when we come back, we'll as a committee talk about it is that okay to do a five-minute break we will, that was kind of what we talked about strategy session kind of a breather a coffee break. So come back in five minutes I'm going to give you four minutes, come back at 1215. I'm sorry I was a little late. I'm seeing something in the chat. Let me see. Val you, Beth said something, and Val would before we get there, would you like to comment on as our evidence, kind of what what you're seeing and clarify what's being mentioned in the ACR?

Valerie King: Yes, Sheila, so the ACR document actually has very little detail,

Sheila Rege: Or let can can you send it to Josh, and we pull it? I'm, I was trying to find it and I know Christoph you had mentioned it, but I was I'm having trouble, and

Valerie King: I've got it pulled up so I can send it over. The, the issue with it, let me just get this set and then I'll come back to you, one second. Okay, Josh and Melanie, this is Valerie I've just sent that on to you should be getting it. And if it might be easier to project this.

Josh Morse: Thanks Val, I'm watching for it.

Valerie King: What I've pasted in our, there are a number of recommendations that they make but again this set of recommendations really is across imaging technologies so there are only two of them that are specific to MRA, as a background here, the higher the appropriateness rating, it goes up, it's on a scale of, basically nothing to nine. So, the higher the rating, the more the panel felt that the study for the indication was appropriate. And again, this is the methodology that ACR uses. It's a consensus type of approach, as opposed to another type of more evidence-based guideline approach. And it's mostly in recognition, I think that, that there are not always great comparative studies in radiology or other imaging structures so

Josh Morse: Still not seeing an email. Okay, tell me what document you're looking at, or Dr. Rege did you send me a link to it? Is that the right link?

Sheila Rege: I do not have a link.

Josh Morse: Okay.

Melanie Golob: And Dr. King should be able to share. Val if you want to.

Valerie King: Oh okay.

Melanie Golob: Project if you'd like.

Valerie King: Great. Okay. Yeah, let me know if you can see this something different on the screen.

Melanie Golob: Yes, I can.

Josh Morse: Yeah, we can see it.

Valerie King: Okay, great. So, as you scan down a little bit below the middle of this page, there's MRA chest with and without and with IV contrast appropriateness rating of seven, which, by their rubric is usually appropriate but at the lower end of that and says, complimentary to transthoracic echo can be performed as an alternative to MRI heart function and morphology. If only great vessel anatomic information is needed, and no information is needed about intra cardiac anatomy heart function and flow, which is pretty much the situation that you're looking at here. They go on to say that it's occasionally it may be complementary to MRI heart function morphology, without IV contrast. If you scan down to the third from the bottom, it's MRA chest without contrast that skits inappropriate rating of six which is the top end of the maybe appropriate scale. Again, saying that it can be complimentary to trans thoracic Echo,

and may be performed as an alternative to MRA chest, without and with IV contrast, or to CTA chest with IV contrast.

Beth Shaw: And then I've just put in the link. The link to the two for the adults with suspected coronary artery disease. And I don't think there's as much level of detail as there is for this with the congenital heart disease populations.

Shelia Rege: I'm, I'm actually the one I was seeing and I wanted others help including Jim or Christoph was what I'm used to when radiation oncology we when ACR comes up, they come up with appropriate use criteria and I don't know if I just had an old one when I was researching this, but I had thought they said MRA coronary arteries, without IV contrast usually not appropriate. And maybe there's a newer version and MR MRA coronary arteries with IV contrast, which has radiation, of course, and is is maybe appropriate, but not you know not not usually appropriate. So just just background. Josh, or I don't know. Melanie or Val if you guys have that appropriate use criteria?

Valerie King: So, just to be explicit this is, this is the one on congenital heart disease.

Sheila Rege: Okay, that's the one I'm congenital.

Valerie King: Yeah.

Christoph Lee: Well, since you're sharing

Sheila Rege: That I'm wrong. No, then you are right, that I'm pulling something that's totally different than, no.

Valerie King: Okay.

Sheila Rege: Yours is all correct.

Christoph Lee: Well, since you're sharing your screen, would you have the chronic chest pain, intermediate high probability ACR performance criteria.

Valerie King: I'll look for it.

Christoph Lee: Okay, looks like Beth just sent links in the chat.

Valerie King: Okay, let me stop sharing my screen so that we can get that up for you.

Sheila Rege: So, if we were in person we now go kind of to the second topic, where we have more of a diversity kind of opinions and try and kind of get to that. Now this was incorrect. If this is the one, this was not I think on gone top is that the correct one.

Beth Shaw: But the ACR criteria now.

Sheila Rege: Oh, this whole corner that so this is correct. Okay, yeah is wrong one. So, this is this is correct, exactly what you want the one.

Valerie King: You want the one. Chronic chest pain high prob for coronary artery disease that one.

Christoph Lee: Yeah, we can look at both. This is no longer, intermediate, and then we can look at the high.

Beth Shaw: Yeah. So, this is she looked intermediate one

Christoph Lee: To Sheila's point of pointing out you know the other noninvasive tests. These, if you look at the usually appropriate those are all the tests, or most of the tests that we discussed last time, right CTA ultrasound echo SPECT and all those are usually appropriate for suspected CAD and it looks like MRA coronary arteries with without ideas is maybe appropriate, it's sort of in the middle category there.

Beth Shaw: And then they really don't give any details as to what might be appropriate use it just talks about, you know, it's not as good as other things, but they don't then say so we only recommend you use it in this. And then reveal the one. This is the high probability of coronary artery disease. And you can see here the two highlighted with with them without ID contrast and without IV contrast. I don't know why they've done it like this, but they've given it a five and four. So again, they fall in that may be appropriate categories, but again, know the detail, other than I think in this one we talked about that, to look at the proximal vessels. I think they talked about.

Christoph Lee: Unfortunately, I would give more detail. My guess is that, you know, for some reason, patients can go undergo the usually appropriate exams, and they could fall into the may be appropriate. I'm sure.

Sheila Rege: So, we usually and remind me Josh of the process, when we're in person. We usually kind of look at, you know, our straw vote. And then we went, can you project that back in the cover with conditions and and and then after we craft language that's when we go look at whether there's Medicare or other insurance companies correct is that is that the.

Josh Morse: After you vote you do your final vote you go and you look, do your comparison? Yeah.

Sheila Rege: So, Josh I'm gonna let you lead on on kind of pulling all that back and commenting, to help us.

Josh Morse: Melanie, so okay. Do you want to look at your votes? Is that what you're asking us thinking?

Sheila Rege: Again, on on this topic. Now this would be. Oh boy, it's the spec adults with suspected coronary artery disease.

Josh Morse: So, I think you voted unproven, and for the most part, on the two. I think on sensitivity specificity and clinical utility and now you're. We're ready to look at the draft language is that right?

Sheila Rege: Right, so we were a no we were more in some is that the correct one. Melanie more. Where were we?

Melanie Golob: This is the symptomatic patient suspected coronary artery disease.

Sheila Rege: More and more, more safer. But unproven in advocacy by five majority and clinical utility unproven and eight cost effectiveness, that was debatable because a cost of over unproven unproven. And now, but the world was five to cover a six to cover with conditions, even though we were all a lot of unproven. So I kind of want to. We are we still good with that and then if we are then we need to go to crafting language and what conditions. I'm just got up, you know, and I, I think we've done this before where we think it's a clinical utility is unproven cost effectiveness of unproven. And I'm remembering Lauri saying you know when that happens with simple things that are not big pharma that we don't tend to vote in favor and here we are so I'm just looking for. Give me language now on what conditions. We are trying to cover this on that we think it would be helpful to our patients. I've just, you know, just want to remind us that we we voted on proven, but then we came, and we have to do this with evidence not with what our heart wants it

Janna Friedly: So so Sheila I'll say for myself I'm, I'm, right on, on the edge there because I do feel that it's that it's an unproven and I'm really struggling, it's sounds like there may be very very one-off situations in which this would would be a little bit safer than than an alternative, but, but that that would be a very very specific patient. And so, I'm, I'm really in my mind struggling with. You know how we could frame coverage with conditions that makes sense, versus versus not covered that in our previous decision we had sort of a tiered approach and it, it feels like to me if we do a covered with conditions, it's almost just the the next layer of the tearing that when all of the other tests are not appropriate, clinically appropriate. Then consider this this test is sort of a last last resort. And that's the way my, my mind is is thinking about it but I don't know if that warrants coverage with conditions or, or really, you know, at

this point it's not it's not proven and it's not not appropriate. So, that's my struggle.

John Bramhall: I think Mika put some very specific language in the chat, did we find that helpful?

Mika Sinanan: Oh, yeah.

Sheila Rege: Mika, do you want to go? I didn't see that I'm sorry.

Josh Morse: I will cut that and paste it onto our draft document here

Mika Sinanan: Basically, gets to Janna's point. This this really shouldn't be the exception not the rule under very specific circumstances. And because we agreed that it was a moving target and the technology is improving and that there may be some unique circumstances, that's, that's the basis for it so basically, I said covered with conditions for stable symptomatic adults with known or suspected CAD and the two conditions are in consultation with a cardiologist. And the second is the patient is unable to tolerate or safely participate in other noninvasive anatomic or functional testing.

Janna Friedly: Mika, I like this, and I think it captures when I was just talking about I wish I hadn't seen that, but I want to save me. I want to save me. But but I do wonder if we need to go back to the wording of the previous you know decisions where we have the coverage with conditions to make it consistent, because we used sort of low, intermediate and high risk. Determination right for for CAD so I wonder if we need to be consistent or if that's not necessary and we should be thinking about these completely separately.

Mika Sinanan: Sorry, Janna, I'm not. You mean in the, in the previous conditions for different levels of? Is it different levels of severity of CAD or a safety of the procedure or what?

Sheila Rege: No low, low intermediate a high risk of suspicion. You know there they have the cardiologist have these tools I camera what they call it framing framing him.

Mika Sinanan: With adults with known or high,

Sheila Rege: high risk or.

Janna Friedly: Yeah, and that's that's what we did for the previous the previous. The previous meeting was that we, we said people who are at low risk, you know really don't need imaging so we exclude so I just I'm just wondering if we should be consistent with the language so that it there, because

people are probably going to be looking at all of these, you know, together really or, you know, in a similar context.

Mika Sinanan: Josh, are you going to bring up that language?

Josh Morse: I have typed up your language, Dr. Sinanan and do you want me to bring up the language from the November 5 draft?

Mika Sinanan: No, you could just bring up the language that I put in there we could just change suspected to high risk of with known or high risk of CAD.

Josh Morse: Okay, bear with me for just a second so I can get back to the screen share.

Christoph Lee: This is Christoph where you just the question in terms of evidence for you this time versus last time. I'm not sure if evidence review this time actually stratified by risk. So, I don't know if we can make a statement about low intermediate high risk in our decision just based on the evidence today, but I do like having consistent language, and I think maybe in our next meeting, when we finalize the language for both this session and last, we could talk about how to make everything, consistent. In terms of Mika's draft language, I like this, but I like the second bullet point. I think it's perfect. The first bullet point, just a question that there are cardiology, non-cardiologist ordering studies and managing patients. It might be too limiting to force, decision making conversation with just cardiologists.

Mika Sinanan: Christoph, Mika. So, by the reason I said that is, we should be making this decision with somebody who is insightful about the risks and benefits. The range of options, and in that in our healthcare system is a cardiologist, by and large, who will be both helping manage the patient in the long term but also determining the diagnostic algorithm. So that's to say if if a primary care doctor is managing a patient the patient I talked about earlier. They need to have the patient. They have either discussed the patient and have a document of a consultation with a cardiologist or the patient is already being managed by a cardiologist. And so, this this determination is not being made by a somebody who is less knowledgeable about all the range of options that are there. That was my thinking. Though the wording could certainly be more artful.

Christoph Lee: Totally agree, and I guess the question is, in certain settings, is it not going to be a cardiologist?

Sheila Rege: So, I, I just want to speak. You know, we, the AMA the Council, the committee I'm on we just had a report on private equity and, and coming

into health care, because it is big business and cardiac angiography is profitable and Mika, I'm just challenging you. It would be very easy for a Walmart, to have a cardiologist and the end and check a box patient is unable to tolerate or simply participate in other noninvasive anatomical functional testing. We're all trying to make the life of the doc easier. But usually at least with cancer. Without cancer protocols we have criteria, you know, be it creatinine over 2.8 or something something much more rigorous that a company like that can come in to to the state of Washington and sign up all on Medicaid patients, so I'm just putting that out, and that's because I just gone through a bunch of meetings for for the committee and in very aware of that looming threat

Janna Friedly: And Sheila I think that that was the struggle that we had the last meeting as well in terms of the wording. With this balance of, of being not overly prescriptive, because there are so many different scenarios. And, and being less specific than we are in pre we have been in previous discussions. So that's a real struggle that, I think the committee wrestled with.

Mika Sinanan: Jim, do you have an opinion about language here?

Jim Kirkpatrick: I looking over what you wrote it, it does seem to be I don't remember exactly what happened last time and I think it would be helpful to look at that to to at least get some of the same language, although I, I do think Christoph's point about the evidence not being there in the same way that it was before makes sense but trying to get some harmonization with that. And I think whatever conditions are, are going to be ones that people can try to get around but certainly trying to capture. I think the way you did it particularly the second bullet point with the, the intention of the, of the decision is going to be very helpful.

Mika Sinanan: Do you have an opinion about the question of console in consultation with a cardiologist, is that?

Jim Kirkpatrick: Yeah, that's that's hard because the other issue or to recall is it some cardiologists will not know what you're talking about because they've never heard of it, which is entirely possible in thinking from a statewide standpoint and as you know, we do have the ability for people to call into the university and talk with specialists and get sort of an E console situation that they could actually be helpful in that setting to kind of mitigate that and fulfill the requirement as you as you specified here, I guess, would that count in lieu of an actual office visits telehealth or otherwise to make this decision. I think what you really want is somebody

who knows the different imaging modalities, not necessarily just any cardiologist but somebody who actually is assertive an imaging specialist who can kind of help with that decision, but that's a little hard to write into that and there aren't that many of us probably.

Sheila Rege: Right, right.

Mika Sinanan: So, I don't mean to beat this to death but if I guess I'm concerned about making it too restrictive. If we would just say documented consultation with a cardiologist and hope that a cardiologist who didn't know the difference between different imaging studies would punt on answering that question and say well you need to talk to Kirkpatrick at the University of Washington, you know.

Sheila Rege: I'm actually so I want to go back to the question. And the wording is fine, um, you know, we can we can wordsmith that I do want to ask you the question. Because what I heard at least one Janna brought it up and make it you are agreeing. This is the rare circumstance. What is the path, if, if a rare circumstance comes, and it's not addressed is that does the agency medical director have some leeway or how or just, it's not covered it's not covered what what is our agencies process?

Judy Zerzan-Thul: Yeah. So, Medicaid, because we take your recommendations and then we have to look at them there's potentially a little leeway but there is no leeway in UMP and our peds program and that is what has gotten us into trouble in a couple of other places that if it's not covered it is not covered in all circumstances. So, yeah, and Medicaid, often, sort of takes all of this and, and make similar policies for kids there's EPSDT. So, there would always be a way for something to be covered but if we decided not covered on the Medicaid side that that could be harder to get around. But anyway, I think it's probably probably the right thing for the super rare things is this covered with conditions. And, yeah, this, these two bullets seems good. I don't know how to know I think, Emily and Chris are still on, like, I don't know if it's worth at a premium, or if or we just take it into consideration that like, this is really, you know, to be used after all the other tests have been considered, which is probably the second one has I don't know I'm being very long winded in my long pause or anything else but, yes.

Sheila Rege: So, should we say should not be considered a routine first line diagnostic tool in patients with a stable chest pain with possible obstructive coronary artery disease? Would that help to to put that in there, so you know for longevity later, the agency medical directors, understand that

we were not looking at this for us first line for everybody? I'm just struggling with how to get that out there that this was, this was a cover with conditions. I shouldn't say last resort, but, you know, not just a checkbox out. Don't, don't, I I'm, I'm an entity that only has a hammer which is an MRI and so I think my patient needs an MRI.

Judy Zerzan-Thul: Yeah, I think that would be reasonable. And we can always take it back, cause we'll have some time in between this and our final voting meeting to really kick the tires on that but I think that would be helpful. Off the top of my head.

Sheila Rege: I'll put in what I just said and Josh and Mika, you can, you can opine if that fulfills your kind of thoughts that it should not be worse

Mika Sinanan: I agree, artfully putting it, I think is the difficulty but as not the last resort, but an extreme resort.

Laurie Mischley: And the one thing that has not come up that I'll just say is there is absolutely a population of people who want all of the tests. Right, just one of everything, and I don't think we've actually curated anything here that prevents that both taking less weeks decision and this one into account I just, I don't know that we need to necessarily say it but I want us to keep that in mind that those people, other.

Sheila Rege: Laurie, exactly. I have somebody who went to a concert or stop I have no idea how and got this plethora of cardiac tests and and now has anxiety, beyond. I mean, just just beyond belief. And and it just said that that's Mika, that's, that's what I'm struggling with, because healthcare has changed, and and we need to just make sure that our whatever we were putting together reflects our thought processes.

Emily Transue: This is Emily I just wanted to echo. I agree that I like that purple and I think that'll be helpful for us and implementing it also might want to add an end between the first and second bullet, assuming that that. Thank you.

Sheila Rege: I got a question, I mean cardiologist cardiologist the invasive cardiologist know what what works you know kind of the people who actually know ICAs should be saved, because my cardiologist, either do just regular or they're doing basically kind of like OBGYN, some to just OB and some GYN. So, should be I don't know if you should say invasive. I don't even know that's a specialty.

Jim Kirkpatrick: It is to be honest, they probably have a less chance of knowing anything about this, because that is mostly what they focus on and do clearly there

are many examples to the opposite but I you know thought about it too I think because Mika's is right, just to leave it with cardiologist so it's not restricting this up to the cardiologist, to gain whatever knowledge is necessary to answer the question.

Sheila Rege: I think they call it interventional correct, Jim?

Jim Kirkpatrick: Yes, that is correct. And now we have a subspecialty of interventional called structural interventional

Clint Daniels: Clint Daniels, should we consider moving the third bullet point to be part of the statement? And then end that statement with covered when, and then the two bullets?

Sheila Rege: I like it like this because it, it makes it very clear but how would you?

Josh Morse: I think another option that, you know, Dr. Sinanan had brought up at a previous retreat was, you know, this could be a statement that goes along with this part, and it is a should and not a, you know, may not be or something like that more. You seem to be, you know, kind of making a commentary on on the technology and the evidence. So, it seems like another way you could go.

Clint Daniels: Yeah, I think that's kind of why I thought it should be part of the statement instead of the bullets like seminar CML, CMRA should not be a first line diagnostic tool for stable chest pain and possible interactive CAD is covered with, you know, in consultation cardiologists and I was thinking.

Sheila Rege: Should we take a five-minute break and let the staff and the agency kind of look at how to, how to get our intent and presented back. Would that be okay or do we want to keep trying to wordsmith? What would the and uh we once we come back we can then help the whole thing projected?

Mika Sinanan: Sheila, I think if we just copy that statement the third bullet point as a phrase or sentence right before the covered in the, in the first line just put it up there, and then the, and then we get into the bullet points Yeah,

Sheila Rege: Will there be an 'an' there?

Josh Morse: Something like this?

Mika Sinanan: Period. And then, CMRA is a covered is covered with conditions. And then just take out the third bullet point.

Sheila Rege: Do you think that that strong Mika? The agency medical directors feel that would give them enough flexibility?

Mika Sinanan: I defer to them.

Judy Zerzan-Thul: Yeah, I think that makes sense.

Sheila Rege: Thank you, Clinton, Mika and for clarifying that that that's them stands up bold. Is there any more discussion before we take a break to kind of reflect on this?

Josh Morse: We can work on the grammar here.

Sheila Rege: Okay, well then do a five-minute break. Just as part of our process from our strategic meetings, and during the five-minute break, would you mind uh Josh projecting keeping projected both? And and then we on our voting will have to vote I think both separately on both in case people have a disagreement with the second one. Is that is that good, everybody? And welcome. Okay. So, it's 1252. on. Do we want a full eight-minute break and try and grab lunch, or what what do we want to do or just try and come back in five minutes?

Mika Sinanan: Back in five.

Sheila Rege: Okay, back in five. I think it's time I hope we have everybody back. Thank you. So, um, any any discussion, any thoughts on changing the verbiage on any of this?

Josh Morse: Remove the conditions from the first one. Melanie pointed out that she thinks I didn't get that right from your she's going to pull up the vote document or share it with me.

Melanie Golob: Yeah, and I can either put them on the screen or just send it.

Josh Morse: Can you confirm was the first vote was a vote on this first one is covered?

Melanie Golob: Yeah, covered it all for the coronary but coronary vessels anomalies.

Josh Morse: Okay, so I think there's two ways, Sheila that you can go about this you can do one vote for the whole thing for covered with conditions, And the one is the first item would be that CMRA is covered for adults with known or suspected coronary vessels anomalies are congenital heart disease, if that's you know if this is language you settle on, and the conditions as I say this I don't like that idea I think it should be two separate votes.

Sheila Rege: Yeah, so we'll do by the question I'm usually. I need a second, I mean I as a chair probably shouldn't divide the question but I would recommend, we divide the question would would anybody, make a motion to do so.

Mika Sinanan: Sheila, before we do that, the second statement that I liked the two sentences and the statement. But the first one says obstructed CAD obstructive and the second one doesn't. So, we should be consistent because it'll confuse people. Should we add obstructed to the second statement as well? The second sentence with known or suspected obstructive CAD?

Sheila Rege: I think that would be helpful so after suspected to add obstructive CAD. And I don't know if we want to make it somewhere coronary artery disease or kind of a you know asterisk to say it's coronary artery disease.

Mika Sinanan: So, the first CAD we could just write that out as coronary artery disease and then parenthesis CAD.

Christoph Lee: I agree with having the same language in both sentences, but I am wondering if obstructive should be taken out because it wasn't highlighted in evidence report? We just covered suspected are confirmed CAD.

Clint Daniels: Clint, I think that makes sense to remove it as well.

Josh Morse: Taking it out.

Sheila Rege: And Josh, in a similar way, people would know what CMRA right is right? somewhere, you're gonna --

Josh Morse: Yeah, we'll spell this out in the final document.

Sheila Rege: Perfect. Any other discussion before? We will vote separately on both.

Mika Sinanan: Motion to vote separately on these two statements separately.

Sheila Rege: Anybody?

Clint Daniels: Second.

Sheila Rege: Absent any dissent. Raise your hand if you disagree. We will vote separately so voting now on the first and Josh, I don't know if you can do this highlight that CMRA, the first one. Thank you for doing that. I will let staff take it from here on how they would like the vote to proceed.

Melanie Golob: Josh, I can share the table I put your language and do

Josh Morse: Super, that'd be great. Right, I'm going to stop sharing right now.

Melanie Golob: Okay, so we're voting on language first will be the coronary vessel anomalies or congenital heart disease.

Josh Morse: And I think we're doing the final vote.

Melanie Golob: Oh, but not for language?

Josh Morse: So right Dr. Rege?

Sheila Rege: I was going to, but we can do it, we can do it very process driven because usually that's what we do in real life. So, I would just to make sure we don't have that we're jumping the process because we're virtual. So, Melanie, go ahead.

Melanie Golob: Okay, so let's vote to approve or reject the language for that shown here the CMRA covered for adults or children with known or suspected coronary vessels anomalies or congenital heart disease. So, if you approve go ahead and raise your hand. And it looks like we have eight. Thank you all very much. Go and lower your hands. All right, and then the other vote will be on the language for stable symptomatic adult so CMRA should not be a first line diagnostic tool and patients with stable chest pain with possible coronary artery disease CAD. CMRA is covered with conditions for stable symptomatic adults with known or suspected CAD with the following in consultation with a cardiologist and the patient is unable to tolerate are safely participate in other noninvasive anatomic or functional testing. So, if you approve the language, please raise your hand. Okay, we have eight. Thank you very much. And then Sheila for the next part, do we need to make a motion first to vote on us?

Sheila Rege: I Mika we already did it so I think we can go with that.

Melanie Golob: Okay, so we'll do a vote first on the again the coronary vessel anomalies, or congenital heart disease so votes for not covered. Please raise your hand. Okay, that’s zero votes for covered with conditions. Please raise your hand and votes for covered and all. Right and that's all eight, thank you very much. And next is the stable symptomatic adults with known or suspected CAD, or you need to lower your hand. Oh, thank you. All right. Okay so voting on this vote not covered for this stable symptomatic adults with known or suspected CAD. Okay, one vote for not covered. And next covered with conditions. Okay, and that's seven, and so covered it all. Let me lower the hands before I asked for that one. And then covered in all should be zero because everyone's already voted, but. Okay, great. thank you.

Sheila Rege: I think we're, we're good right we we voted. And I just couldn't make the jump from unproven to to cover with conditions based on the data but I see the other point. Any anybody else? We're all good. I will then take. Josh, do we have any other business to finish?

Josh Morse: We do need to address the two questions. One about to national coverage determination. And the other about clinical guidelines, the committee, if you could please make a statement about. I'm scrolling through the decision aide and I'm happy to project it here. Is the determination consistent with identified Medicare decisions, meaning the national coverage determination which there was not one identified? And the second ask is, and expert guidelines and if not, what evidence is relied upon?

Sheila Rege: So, we're going to have to divide the question again. And so, I think any any, anybody want to talk about Medicare doesn't have any decisions? We may have to change this Josh in the future I think the way, there was a 21st Century Cures Act and maybe having your talk to some of the Mac carriers. I don't think Medicare can do national coverage decisions anymore.

Josh Morse: So, thank you for, we will look into that.

Sheila Rege: So, we may have to change that. And so if anybody wants to comment on this on number one, based on public comment was evidence overlooked in the process that should be considered. Any panelists, want to comment on that?

Josh Morse: That's not the question I'm sorry, It's that we will ask you next time. The question is just about if your determination is aligned are not aligned with Medicare. If you could make a statement as to why it is or isn't and there isn't a Medicare decision here of concerned today. So, I think that's not relevant but there are expert guidelines someday I think you agreed with and some that you may not have perfectly aligned with but I think there is, you know, often you make a statement about that variability and having the latest evidence and so if you could just explain your rationale that would be helpful.

Sheila Rege: I will try to explain for the first coverage decision that we heard from the public and the experts about how this is already kind of standard of care, and based on the evidence. Valerie and her team also confirmed that that was what they were seeing for the, whatever that coronary vessels anomalies, or congenital heart disease. Anybody else want to put

something in that's on that? If not, we'll go to the second. Any, any volunteers for the coverage with conditions?

Christoph Lee: I could just. This is Christophe Lee It looks like our wording and decisions are consistent with a few appropriateness criteria out there and we may see ours and that approval with conditions is consistent.

Mika Sinanan: And as we heard. Mika Sinanan. Then as we heard from the agency, non-coverage decision would make it very difficult for those rare patients for whom this is appropriate to be able to take advantage of the technology, which again for very specific indications may be the appropriate evaluation. And, and Sheila I have one other comment. In our key questions, we did not see any data around adults being assessed for cardiac device lead placement, but it was in the key questions, so I presume since we're not even addressing it, it hasn't shown up in any of our coverage that it is not a covered benefit for that indication?

Sheila Rege: You know, that's a good question. We may want to clarify that with a statement, if, if that's the will of the committee, not covered for cardiac lead placement. That was the fourth bucket in the adults coronary artery disease, unless people think that we should not. Would that be helpful? I'm going to ask them agency medical directors.

Josh Morse: Yeah, that's a good catch. I think that would be helpful. Thank you.

Beth Shaw: I would just say from the evidence we didn't find any evidence on adult post CABG. And, but we did see two studies for the device lead placement.

Sheila Rege: Should we project those studies and and rediscuss that we've missed us post CABG though I think the suspected coronary artery disease covers, regardless of whether you had a CABG or not? But it does not. Does that cover cardiac lead placement and how does? That's a good point. All right.

Jim Kirkpatrick: You could read the second or the first one, excuse me, as looking for anomalies of the coronary sinus and vessels which might influence your cardiac lead placement issues. I think the, but the correct me if I'm wrong but I think the intention of it was sort of routine use prior to cardiac resynchronization therapy to direct where you're going to put the lead and I have not electrophysiologists, I don't think that we do that routinely, but I could be wrong.

Sheila Rege: Valerie was the studies, was that with, in, in conjunction with congenital heart disease and lead placement the two studies, you mentioned, or was that not mentioned was that just generic?

Valerie King: Let me double check on that. Just to remind people there were two non-randomized studies, the total sample size was 27 individuals. And in that study in those two studies they were able to visualize the vein for lead placement but that's about all you can say. So, let me go and look at the evidence tables on those two studies and see if I've got a little bit more detail.

Beth Shaw: Yeah, it was adult schedule to schedule to undergo cardiac resynchronization therapy.

Valerie King: Okay.

Beth Shaw: Yeah, very small samples.

Valerie King: Yep, very specific utilization.

Sheila Rege: That's again vessel anomalies.

Josh Morse: Is there a part of this you'd like to see? That was the CABG finding and

Beth Shaw: Slide 31 so I think the next one.

Mika Sinanan: I don't think we would consider that to be evidence.

Sheila Rege: So, Mika would use, are you suggesting a language that cardiac lead placement, it's not a covered condition?

Mika Sinanan: I don't think we have the evidence to say that it is a covered it ought to be a cover condition.

Sheila Rege: So yes, I think it is. It is not a covered condition. Just a anybody think it should be a covered condition based on what was presented today and also the original report, the final report? Okay and then we'll go back to that. How about the other thing about status post CABG? That had no no data, right? But that's.

Beth Shaw: Yeah, that's right.

Valerie King: That is correct.

Sheila Rege: So, we may have to make it clear that just status was CABG doesn't mean without you know symptomatic coronary artery disease so let's go back to our. Well, let's go back to our language, and I'm open to should be just

saying not covered or, but I don't want to not cover CABG patients who have symptomatic coronary artery disease based on that so.

Valerie King: Sheila, this is Valerie King, I'm wondering if you could speak about it as the only indication as a sole indication.

Sheila Rege: Right. So, somebody give me some wording that says patient status post CABG, or those being considered for cardiac placements are not covered in the absence of blah or something like, you know, and the absence of stable chest pain with possible coronary artery disease Mika, this was your language would you like to help me and how to put this in there?

Mika Sinanan: Thinking. Let me take a look at it again. But I think we dilute that statement by adding to it. I think it's simply a non-covered condition. In the absence of symptomatic CAD host. In the absence.

Sheila Rege: I'll type it in, I'll type it and go-ahead Mika.

Mika Sinanan: In the absence of symptomatic CAD. Last, and then take up the status and post. CMRA is not a covered is not covered.

Sheila Rege: I would add, in the absence of symptomatic coronary artery disease patients who have had CABG, those require requiring cardiac lead placement are not covered. That makes sense. So, we covered both, unless somebody thinks he should recover those that are requiring cardiac lead placement.

Emily Transue: So, Emily, I just want to check for one sec. I'm just so this conversation is sort of about, there, there isn't. You feel that there's enough evidence to say that it shouldn't be covered or sort of more of that there wasn't enough out there to make a decision. Just making sure that we're that we all understand that if we go with this language, it, it will not be paid for at all in those in this setting and and if we want to really discuss this during the discussion just making sure that everybody's comfortable with that, as opposed to say having that piece be out of scope, it's fine that this is what we want to say I just want to make sure that we're about to the implication that you've stopped implications,

Mika Sinanan: Mika Sinanan, Emily thank you for raising that. So, if it is out of scope, then we shouldn't be addressing it, but it did show up in our list of key questions. So that's the reason I raised it as apparently being in scope. Can you clarify that?

Emily Transue: I think that is fair. I think that you could choose to make a decision to not make a policy around that and to leave it to agency discussion or other,

other partners and I think you could ask can back me up here or or disagree. You could say that there wasn't enough to make a decision and choose not to make one, it's also fine can make this decision, if that's what you want to do.

Clint Daniels: Clint Daniels, also I think it makes sense not to make a decision. In this case it's sort of the absence of evidence is not evidence of absence. There's no evidence that it's not affected by their.

Josh Morse: I would say that would be a deviation from prior determinations on the committee, you have these I'm disagreeing with Dr Transue on this. And she gave me the opportunity to, you know, and I think the way we phrase this in the past is you've got your covered and covered with conditions indicators above this line and the way a final document might look is non covered indicators include the following, you know, and those are the could be, if that's where you're landing on the evidence but I think the middle ground would be softer language, as Dr Transue may be suggesting. But I don't think you can just leave it out because I think it'll just frankly be confusing decision to not say anything about it.

Sheila Rege: Because it was one of the key questions, so I think we have to put something in there, and I don't, I mean we've never had announcing there's no there was not enough evidence for us to make a determination on whether it is optimal for routine surveillance of post CABG patients or those requiring cardiac lead placements, I mean I just don't think we have had been given that as an option. Emily Transue so I'm, I'm struggling a little here on process and what would we as a committee are able to do.

Mika Sinanan: So, Sheila, just in response to Josh has comment, if we took the second bullet point above and just copied the same language is not covered comma. Unless the patient is unable to tolerate are safely participate in other noninvasive anatomic or functional testing.

Sheila Rege: We didn't really have data on one and we had weak data on the other so I'm. Well, there we go, we're reaching, we're reaching even more into the bottom of the barrel to, to help. And so, I'm having trouble with that as as a process issue as an evidence-based process issue. Anybody else want to opine me? Mika and I have spoken enough, we are going to now be silent until others figure this out for us.

Janna Friedly: I would, I would agree with you. Sheila that I, we don't have any data so I can't, it's hard for me to make the leap to, including it with coverage with, with a condition. So, I, I liked the sentence as it is.

Laurie Mischley: I don't feel like there's enough data and again My opinion is that it's isn't being used a whole bunch and if there's a situation where a cardiologist thinks that this is the most appropriate test I hate to restrict them in that situation. So, I'm inclined to add the second bullet point to the end, just to give a clinician, that option in those rare circumstances.

Sheila Rege: Anybody else want to opine since I've put me on and Mika on the silent mode for?

Christoph Lee: This is Christoph Lee. If there's an option to not make a covers decision at all, given that we don't have any evidence whatsoever. We're another, and that would be my preference.

Chris Hearne: This is Chris Hearne. Yeah, I agree with that I think if we don't have evidence one way or the other, we shouldn't be making statements about it,

Josh Morse: I'll say this. I think your decision a does address the. Let's go back since we haven't reviewed this in great detail, I think one of the first principles here is, is the evidence availability, you know, if there. If there isn't sufficient evidence to make a decision. For example, on cardiac leads, I think you could make that statement and say you did not land on a decision, due to the due to the evidence, not being sufficient.

Sheila Rege: So, we'll do a, maybe a, unless somebody else wants to opine a raise of hands on whether people would like to the three choices. One saying there was not enough evidence for routine surveillance after CABG, or lead placement to saying not covered in those two conditions, and three saying. And I don't know if you can create a pull that fast, Melanie three saying, in the absence of symptomatic coronary artery disease patients who had CABG or those requiring cardiac leave placements is not. I'm sorry. Yeah, I think that's how we had it right.

Mika Sinanan: Sheila, Mika. So, I will break my silence I think these are two specific indicator applications of the question, can we determine the vascular anatomy of the heart. And what we have seen in the other studies is, this is a reasonably precise and effective means of determining the vascular anatomy and the structural anatomy of the heart. They don't put a lead in with the technology, they simply define which vessels, and what the vascular anomalies are that might influence where to put the vessels and we know we've already said and other studies in our the rest of our coverage decision that it works for those indications. So, the absence of data we have is around specific lead placement studies where they use this to define lead placement, but we have more general studies that

show that you can define the anatomy accurately. For that reason, I think we actually do have some information beyond just the two non-randomized studies that were alluded to in in the report. I do think that it's helpful to help guide people rather than saying nothing about this, that we put in something about it because it deals with two categories of patients who are out there, and for whom the rest of our guidance is unclear. And it will push them in the direction of doing the right thing, I think, which is look for symptomatic patients. And it will use this technology when the patient is unable to tolerate your safety participate in other mechanisms. So that's the rationale I think for including it.

Sheila Rege: Thing I'm, I'm struggling with Mika, and I'm fine with the post CABG in the, in the cardiac lead placement that's, that's an arrhythmia, and these images I see images without gaining you need cardiac gating and if the RR interval is not correct and maybe I have too much information just from radiation oncology extrapolating. I'm just not seeing that something else will be better. I mean it's just not such so used so now, are we, encouraging use without data is, is where I'm struggling. So, but I think we just come to a vote and, and it you know, see where the majority is if people want to cover it with that, then, then we do and. So, how many people would like to just Josh it said, Josh, will you give us a three choices. can you do it in chat or can you do it there or how do we how do we come up with that? So, we know what choices.

Josh Morse: Your choices for cover, cover with conditions are not cover is that what you're asking.

Sheila Rege: No, you had said that we had an option of saying, we did not have enough data. Oh, I see. Okay.

Josh Morse: Yeah, I say that and I could then immediately question myself. I think you need to make a statement. You do need to make a statement in this decision about whether just about it We can't leave it on unwritten. So, if that is if your decision is, is that you don't feel there's sufficient evidence to make a decision in either direction I think that's fine. Or you can make a non-cover decision or you can craft, cover with conditions, I think those are the three choices that I think.

Sheila Rege: Then in that case, and we have to make a decision then let's put forward the statement that's already on the screen in the absence of symptomatic coronary artery patients comma, patients who had CABG, are those required cardiac placement is not covered is that because that the statement you had, or

Mika Sinanan: Is not covered. Well I had suggested adding the second bullet point to the end of that to address the, the rare patient who we need a comic information about but can't tolerate. By contrast, or, or another study. So,

Sheila Rege: So essentially that is the cover you. Is that

Mika Sinanan: Take out the bullet, and just make it a phrase. Yeah, like that is not covered unless the patient.

Sheila Rege: Is less strict than the first resolve a required consultation with a cardiologist.

Mika Sinanan: That's correct. But anybody who's got these things is being seen by cardiologist, it's a family practice doctor doesn't put in a pacemaker or do CABGs so

Janna Friedly: Now but that doesn't mean that the person ordering the test orders it isn't somebody else, you know. So, I think these, these patients may be followed by cardiology but the way that this is worded anybody could order this, I could order this for a patient, even though I'm not a cardiologist. Just because my patient had a CABG. So that just. It strikes me that it is a little bit,

Mika Sinanan: You want to add, unless the patient is being managed by a cardiologist?

Janna Friedly: It just, it just and.

Sheila Rege: Why don't we have a vote on it both ways just is not covered, and then choice number one choice number two is this. No, No, no, no, sorry. So, this is choice number two, and choice number one is taking off that. Yeah. And then just vote, and we'll see where kind of straw poll, this is not the final vote just straw poll, who is leaning towards the first choice was leaning towards the second choice, you know just just to kind of move us along. Straw vote choice one, raise your hands. That's. Josh, would you highlight what we're voting on your

Josh Morse: Voting on this piece right here first.

Sheila Rege: Right, who would be comfortable with that.

Josh Morse: Six people so far that I see and it may be more than that I just not seeing. Melanie Are you able to count?

Melanie Golob: Yes. I can't fix as well. I'm recording as well.

Josh Morse: Thank you very much. Do you want to vote on the second?

Sheila Rege: Correct, the second. So, not that one the other one. Yeah, sorry. Thank you.

Melanie Golob: Nice. I see to for that one. Three that's more than eight.

Sheila Rege: Did you see, finally. Thank you everybody in this, you should try and choose one only one of them.

Melanie Golob: Do you want to give the second choice, again, just to make sure we have think it was just too but it was fluctuating? So, if you choose the second choice, please raise your hand. Okay, great. It is two. Thank you.

Jim Kirkpatrick: Can I make one suggestion about what what you could say? Because I think the spirit of this is that consistent with what was said before about use in sort of coronary artery disease and that's the idea of the absence of symptomatic CAD, you shouldn't do it with when the patients had CABG, perhaps, adding the thoughts because it doesn't make a whole lot of sense to see in the absence of symptomatic CAD patients who are requiring lead placement are not covered right those things are generally are not connected. But what you could say is, are in the suspicion of coronary vagus anomalies or something like that, as the thing that would be similar to the idea of absence of symptomatic CAD or you can phrase it negatively so it actually matches but I just think you probably need need something that would be covered under the first thing that we considered the court the vessel anatomy, that you'd be referring to here, similar to the way that you referred to symptomatic CAD in regards to the CABG statement about that, it's it's probably not expressing this very well but it's just that connecting those two things in the same, same thing when you have an out for the first one only doesn't make a whole lot of sense.

Sheila Rege: Jim, the first one is, they have congenital heart disease they cover, regardless of whether they need cardiac lead placement or not, or not. Right, right.

Jim Kirkpatrick: That's true.

Sheila Rege: It doesn't it, they won't even come to this.

Jim Kirkpatrick: Right, so the only the only time though would be when you would suspect that somebody has an a coronary vein that would that has, coronary vein anomaly that would make it difficult to put the cardiac lead in right there be very unusual extremely unusual.

Sheila Rege: But rather, already without conditions, because they would spot so I.

Jim Kirkpatrick: It should be I'm more. The reason the only reason I bring this up is because it's the way it's, it's more of a wording issue. It's also covered if you have symptomatic CAD or, you know, and nothing else has done your. The first part is referring back to that second conditionally approval. Right. So I was just maybe this is, I'm being a little bit too anal retentive but the idea that that having a parallel structure with something in mentioning the cardiac lead placement, because critically placement and symptomatic CAD you don't really. They're not directly related. So, I guess the other thing you could say is just straight out that CMCMRA is not covered for those requiring lead placement or find some other way to, or even put that first maybe and then, and then put the part about CAD and CABG afterwards. I hope that's making some sense is probably not.

Josh Morse: It makes sense to me, Dr Kirkpatrick is. I don't know if I, you can tell me to be quiet. Looking at the key questions. I'm a little confused because maybe the Center can help with the structure here, but it's for adults with suspected or confirmed CAD. You have made a decision. Conditional coverage for that so is the intent of addressing those who have had bypass that if they're suspected with CAD, they should the evidence does not support. That is that how this analysis was structured?

Valerie King: Oh, Josh, this is Valerie, I think that's really meant to be for CABG alone.

Beth Shaw: I would grieve out some of the studies, either excluded people who'd have CABG, all they included. So in the suspected coronary artery disease, or the CABG, and they have further symptoms.

Sheila Rege: Yeah, Josh you want you got a suggestion on how to move us past that concern?

Mika Sinanan: I put some draft language that in the chat might take a look at that, which is uh maybe simplify everything.

Sheila Rege: That's good. It does.

Laurie Mischley: Thank you for posting that.

Sheila Rege: And just because it's late and I want to put something after looking at those key questions. The key question said symptomatic coronary artery disease and we have taken symptomatic out of all our coverage for coronary artery disease. So, let us let us. Everybody in favor of this revised language, rather than what is was highlighted now no longer being highlighted, so I'm going to call the revised language choice number to everybody in favor of choice number two. To clarify our

position on CABG and cardiac lead placement, raise your hand I should ask, Jim. Jim, do you think this addresses your concern?

Jim Kirkpatrick: Absolutely does.

Sheila Rege: Okay.

Melanie Golob: And that's all that's all eight they voted for that.

Josh Morse: Okay, so can I delete this other language here.

Sheila Rege: Yes. And now to my last question because the key questions were all with symptomatic. Um, I'd like Valerie to comment on whether you think we have gone out of the scope of what your key questions were with a coverage decision or are we good. Clint to your hands up, were you looking for a question? for this briefly.

Valerie King: This is Valerie, um, I, I worry a little bit in the second bit about the use of the term stable chest pain, because there may be other symptoms that are presenting for coronary artery disease particularly among women. So, I would just say with symptomatic coronary artery disease.

Sheila Rege: Instead of possible, is that what you're suggesting based on the key question? I'm just looking at input based on what the scope of.

Valerie King: Well with symptoms consistent with coronary artery disease.

Jim Kirkpatrick: I think that's a good point. Although the recent guidelines, tried to redefine chest pain along the lines that you're mentioning the reality is is going to take 10 years or whatever for those guidelines to really dramatically affect how people think about this and use those terms, so I think that makes a lot of sense.

Sheila Rege: So, Jim where would you, where were you thinking about?

Jim Kirkpatrick: Well, I think the suggestion of seeing as as CMRA should not be the first line diagnostic tool in patients with symptoms, consistent with obstructive coronary, what synonyms consistent with coronary disease or stable symptoms consistent with coronary artery disease,

Valerie King: Stable, yeah.

Jim Kirkpatrick: And presumably that will also, that won't mean, people think that it would be covered that unstable would be covered but I think it's, I think we don't have to go there.

Sheila Rege: We've come back to this even though we voted on the language but just when, when the key questions got flashed it just made, give me a little bit of concern that we were not consistent with the key questions, any any discussion on this or would you like to vote on the language? Everybody comfortable with that or one oh look back on it? I'll be comfortable with that change, raise your hand now.

Melanie Golob: And that's everyone Sheila all eight approved.

Sheila Rege: Josh, Melanie from a process standpoint we probably need one vote again for the entire thing as is or are we good?

Josh Morse: I think to be consistent with the fact that you voted on the first, the second and now you have a third statement, I think, a cover, no cover or cover with conditions vote on this seems appropriate.

Sheila Rege: Okay, so how what would that be, would that be a cover with conditions or no cover or what is them the way we've written it?

Josh Morse: The way you've written it is it as of now, you have written on these two are not covered. I think

Sheila Rege: That's I think going to generate some discussion which is why I asked you to answer. Can we make a vote of whether we are comfortable with that language that we have written?

Josh Morse: You just voted on that.

Sheila Rege: Oh, are we comfortable with a final vote to approve? Is that something we can do just approve this document as a final recommendation.

Josh Morse: Yes, you can do that.

Mika Sinanan: Sheila, Mika, I think that if the patient has cardiovascular anomalies, then they fall into the covered first agreement that we have the first line, right? So, we're saying that everybody else has not got it covered has no basis for coverage and just to address the apparent inconsistency internally I think that it. It doesn't drop any patient out. I don't think we have to re crafted as a covered with conditions because we've put a caveat on it.

Sheila Rege: Right, which is why we're going to do a final vote for approval that this is the committee's recommendation.

Mika Sinanan: Right.

Sheila Rege: Based on the key questions on that this is the document, and it'll come back to us so it is not final, we will, you know, we'll have this back so we can talk about it more if questions get raised. If there's no discussion. Let's Melanie, or Josh, if you will, will vote on accepting this as our draft decision. Does everybody in favor of voting now, and actually anybody objecting to voting now? Please raise your hand, wanting more discussion. Not seeing anybody. Let's proceed to voting as this as our draft decision. Everybody in favor of what what is projected there, raise your hand.

Melanie Golob: And that's all eight that approved.

Josh Morse: Great. Thank you all.

Sheila Rege: Um, we, we did have something else on our decision tool. We do have to make sure we have identified all the safety and you know that that little column we we have we need to make sure it's filled out appropriately and nobody else has thought of things. Where is that tool? You know where we kind of what is this, we, we doing it out of order because we're not together and I got myself ahead of my got the horse before the cart little bit this one. Is there anything here we want to put into safety as adverse events based on the evidence we will presented? This would be us CMRA, and I would like to add I mean I've had patients who've had permanent kidney damage because of GAD. So that scares me more than, you know, kind of the CT based because that's at least, sometimes reversible. So, I would like to say contrast. I'm induced kidney damaged.

Jim Kirkpatrick: I'm not completely up on it, there are newer agents which have a much lower risk of the, of the kidney problems, I don't think it's completely gone away but the newer agents should be better I don't know if there's anything in the evidence review that came out strongly in that.

Mika Sinanan: Mika Sinanan, I agree I don't, I think that there were anecdotal listings from the, the registries, from some have some adverse events but we don't have any rate, or any significant information about that. The gist of it was that these. This is a very safe technology.

Christoph Lee: Do you think you know NSF is for specifically people on dialysis and you probably wouldn't order this test for that patient population and cardiac MRI can be done without contrast, without IV Academy.

Sheila Rege: And then every time I send a patient with a pacemaker and ICD, I, you know, it's usually safe but there's a lot of questions so I don't know how you put that. I just want to make sure this is very complete, and you

know that we talked about it. So adverse effects burns, loss of hearing. Can somebody explain that to me?

Jim Kirkpatrick: I would have to defer to Christoph on this but they're really loud, you have to wear a basically headphones. If not, your full-on earplugs, and I wonder if that's some of what has been leading to that.

Christoph Lee: That's my guess as well. It's extremely loud so either patients have noise cancelling headphones and listen to music, or they have earplugs, or both.

John Bramhall: This is anecdotal but just a couple of months ago, I had a patient whose cochlear implants were pulled out because they weren't retrained in an MRI wasn't MRA, it wasn't MRA, but it was MRI. So that's just a one off. But it did affect his hearing.

Sheila Rege: So, so we'll keep that loss of hearing, tinnitus, adverse effects of anesthesia, so sedation, especially in children, um, is there any anything else that we want to do any content? We don't want to put any contrast related side effects we don't want to put; we do or do not? It was anecdotal.

Valerie King: Sheila, this is Valerie. To the extent that a concern about anesthesia or sedation adverse effects which are indirect. They're not the test itself. The procedure itself, they are an adjunct to it. I would wonder if you're treating it the same or treating it more broadly. The, the issues around gadolinium was really the only contrast agent that we saw appear in these studies. There are newer agents were aware, but they weren't in these studies. But if you're going to include anesthesia, you might have to include contrast as well.

Sheila Rege: I would I would say something like, I mean you could be allergic to some of them because I just a contrast related. You gotta say kidney damage but contrast related side of it and leave it at that. So, it's not scary and

Valerie King: Yet, Melanie contrast, not contrasted.

Sheila Rege: Everybody okay with that? In efficacy, we beaten that horse I think we've looked at things and in the cost effectiveness we've, we've kind of discussed that I just wanted to make sure we we looked at this table which we always do and I had not done that, during this meeting. Um, we talked about age. We talked about the fact it was mostly male. Um, any, any thoughts on any special populations that we need to put into this? And I know I'm doing it after the fact, I'm sorry, I don't think there's anything new, going on. Have filled in all our blanks that we have to? And

we've done okay so we just jumped to the unproven because it was virtual and I didn't have a book in front of me, I'm sorry.

Josh Morse: My apologies, Dr Rege, we are learning how to more effectively use this virtual setting and these tools. I think we found a few edges here in the past few weeks and Melanie is leading us leaps and bounds ahead with some of the work that she's doing so. We'll have improvements for future meetings.

Sheila Rege: Now, I should have remembered this but may have actually helped us, but any, any other anything else we have not done before we, I will take a call to adjourn. I know we are over time I'm sorry I think we are.

Laurie Mischley: I just want to thank Valerie for this report. You know this was beyond a review of the evidence you did research on the research, and I just want to thank you for going above and beyond what we asked you to do and I hope you actually publish this in some form because I think other people would benefit from seeing the review that you've done.

Valerie King: The thanks really goes to Beth and Megan, who did all the heavy lifting um and we had an expansive array of peer reviewers whom we are grateful.

Sheila Rege: And now I will tell you, the staff and Beth, Megan and Valerie, I know the virtual meeting seems easy as we can sit and not travel but I know it’s a lot more heavy lifting for the staff, so thank you. Jim, I really appreciate you hanging in there with these difficult issues. Thank you very much for all your help.

Jim Kirkpatrick: Thank you for the opportunity.

Sheila Rege: Thank you everybody else and I am going to say goodbye, unless there’s, goodbye.