



Washington State Health Technology Clinical Committee Meeting

Noninvasive Cardiac Imaging

November 5, 2021

DISCLAIMER

Note: The following is the output of transcribing from an audio recording. Although the transcription is largely accurate, in some cases it is incomplete or inaccurate due to inaudible passages or transcription errors. It is posted as an aid to understanding the proceedings at the meeting.

- Janna Friedly: Christoph Lee?
- Christoph Lee: Hi, Christoph Lee and I'm a professor of radiology at the University of Washington. I, I do not practice cardiac imaging, or nuclear medicine imaging I'm a breast imager, hundred percent of my clinical time. So even though I've performed some of these imaging tests as a resident, that was about 15 or 16 years ago, so I don't have any conflicts there. But I could give some, some perspective from the imaging side.
- Janna Friedly: Great, thank you. And Clint Daniels?
- Clint Daniels: Hi. Good morning, everyone. I'm Clint Daniels, I am a chiropractor at VA Puget Sound, and I don't have any specific conflicts or specific expertise on this topic.
- Janna Friedly: Great. Right. And then, Jim Fitzpatrick, Dr. Fitzpatrick.
- Jim Kirkpatrick: Jim Kirkpatrick I'm a professor of medicine and cardiology at the University of Washington and the section chief of cardiac imaging and the director of echocardiography, and I do practice echocardiography. I'm also the chair of the ethics committee to ethics consultation and I'm the chair of the geriatric section of the American College of Cardiology, so please feel free to take as many conflicts out of those as you think are, are pertinent to it. The one thing that I probably should highlight to say is I do a fair amount with the American Society of Echocardiography. I don't serve on the board of directors or in the Executive Council, but I do volunteer and serve on a number of different things.
- Janna Friedly: Great, thank you so much for being here today. And Larry Birger.
- Larry Birger: Hi Larry Birger. I'm currently a hospitalist at two trios Hospital in Kennewick Washington as well as Samaritan health care and Moses Lake. Many years ago I had extra training that have amounted to an unofficial cardiology, limited cardiology fellowship, with a large cardiology group and I practiced cardiology is my first job for three and a half years have

read echoes over the years and noninvasive stress testing but not the cardiac imaging stress testing. I have since moved past doing that, that sort of work and I'm just doing hospitalist work and educational work so I don't think I have any conflicts, but I do have a fair amount of experience with these different tests.

Janna Friedly: Okay, thank you. And Laurie Mischley.

Laurie Mischley: Yeah, I'm a naturopathic physician in Seattle and a researcher working on metabolic defects and nutritional deficiencies in Parkinson's disease, and I do a lot of patient reported outcomes, epidemiology research, and have no conflicts to disclose.

Janna Friedly: Alright, thank you. And then Mika Sinanan?

Mika Sinanan: Hi, Mika Sinanan, I'm a GI surgeon, based at the university. My primary care physician says that despite the fact I'm a surgeon, I do have a heart and I expect that I'll be needing some of these studies at some point in the future, so that's my principal conflict. And the fact that apparently I have a heart that's, that's my only expertise.

Janna Friedly: Thank you. And then Chris, are you, is your microphone, working now. Or are you still having issues? [pause] Not yet. Okay, maybe in the chat you can you can just write, if you have any particular conflicts or expertise related to the topic that would be helpful. Is there anybody that I have missed? I think I have got all of the committee, the committee, the committee members. But if I have missed anyone please, please let me know. Okay and Chris has said no, no particular conflicts or, or expertise to disclose. Great, well thank you everybody. I know, Josh is going to, in a, in a moment, go over some housekeeping items. I just wanted to mention, as you all know, in this in this topic and with every topic that we review. We're really going to be evaluating the evidence related to the effectiveness, safety and value of these of these diagnostic interventions. And so we'll, we'll keep that in mind throughout a little bit later in the morning, we will be having public, public comment, and assuming that time allows, we are going to be allowing for up to four minutes per speaker today. And so we'll, we'll try to gauge how many public comments that we have to make sure that we, we have enough time to hear each of those. I think those are those are all of my items so. Josh, do you want to do you want to take it over from here.

Josh Morse: Yeah, can we quickly do introductions from the Health Care Authority?

Janna Friedly: Oh yes, absolutely.

Josh Morse: And other agencies. So I'll start. I'm Josh Morse. I'm a section manager here at the Health Care Authority in Clinical Quality Care Transformation

and the direct, program director for the Health Technology Assessment Program.

Janna Friedly: Great. And then, before we do the rest of the introductions, Conor, looks like he is here. Conor, do you want to introduce yourself briefly and then just mention if you have any conflicts, specific conflicts or expertise in this area.

Conor Kleweno: Yeah, thanks sorry again for being a few minutes late. My name is Conor Kleweno, I'm an associate professor of Orthopedic Surgery at the University of Washington Harborview Medical Center. I have no current conflicts with the topic related today, and as an orthopedic surgeon don't have specific expertise in the topics discussed today.

Janna Friedly: Great, thank you. And then, Josh, do you want to lead us through, make sure that we get everyone else—

Josh Morse: Sure. We'll go to Dr. Zerzan.

Judy Zerzan-Thul: Good morning, everyone. I'm Judy Zerzan-Thul, I'm the Chief Medical Officer at HCA.

Josh Morse: And Linda.

Linda Liu: Hi, good morning everyone, I'm Linda Liu, I'm a chief resident at Harborview Medical Center for the inpatient internal medicine program. I'm also working as a policy fellow with the HCA and the CMOs at the HCA.

Josh Morse: Chris?

Chris Chen: Hi everyone, I'm Chris Chen, I'm a hospitalist and work as a medical director for Medicaid at the Health Care Authority, and I'll be presenting today's agency medical director comments.

Josh Morse: Emily?

Emily Transue: Hi, I'm Emily Transue, also an internist, and medical director primarily with the PEBB and SEBB programs for HCA.

Josh Morse: Thank you. Ian?

Ian Zhao: Hello, I'm Ian Zhao, I'm a research specialist at the Department of Labor and Industries.

Josh Morse: Thank you. And Melanie.

Melanie Golob: Okay. Hi, I'm Melanie Golob, I'm the Health Technology Assessment Program Manager and Fee for Service Operations Manager, and I work with Josh at the Health Care Authority. Nice to meet everyone.

Josh Morse: Great, thank you. Okay, Melanie, can you confirm, we're seeing--

Melanie Golob: We can see all your slides, but if you want to put the slide—perfect.

Josh Morse: There we go.

Melanie Golob: Yes. You're good.

Josh Morse: Okay. Thank you. Okay, so our introduction here, as you know we're doing a webinar today, and if you have any issues or are unfamiliar with the controls, please scroll around and you'll see there are various settings for raising your hands and chatting and entering the Q&A if there are any questions. We also have some instructions for if anybody, by phone you can use star six to mute or unmute yourself, and star nine to raise your hand. Some important reminders, this meeting is being recorded, we started the recording here a few minutes ago with the roll call. We will create a transcript of the proceedings. And that transcript will be available on the Health Technology Assessment Program web pages. If you are participating today in discussions or providing comment, it's helpful if you can please state your name and of course use your microphone for that. A little bit of background about this program, the HTA program is administered by the Health Care Authority, the Washington State Health Care Authority. This program is designed to bring evidence reports to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures and tests based on the evidence on safety, efficacy, and cost effectiveness. Multiple agencies participate to identify topics and implement the policy decisions that come from this process and they include the Health Care Authority, that administers the Uniform Medical Plan, and the state Medicaid program, or Apple Health, the Department of Labor and Industries, with the Workers Compensation Program, and the Department of Corrections uses the decisions here too. These agencies implement the determinations from the clinical committee, within their existing statutory frameworks. The purpose of this program is to ensure that medical treatments, devices, and services paid for with state healthcare dollars are safe and proven to work. The HTA program provides resources for state agencies that do purchase healthcare. The program develops scientific, evidence-based reports on these medical devices, procedures, and tests for the clinical committee. And the program supports the HTCC to make the determinations for the selected medical devices, procedures, and tests based on that available evidence. There are multiple ways to participate in this process and with the program and the committee. We have a very robust website that has all of the decisions, and the documents associated with each decision on the Health Care Authority web pages. Anyone can sign up and receive program notifications. And you can find links to that through the web page. There are public comment periods, on proposed topics, key questions, draft and final reports, and draft determinations or decisions from the clinical committee. Anyone is welcome to attend these HTCC meetings, these are

public, and anyone may present comments directly to the committee. We also have a petition form to nominate technologies for review or re-review through this process. So public comment: attendees who wish to provide public comment today. We have some that are scheduled to provide comment, and will be temporarily reassigned as a panelist, and provided the option to unmute and turn on their camera if they desire. A pop-up window will ask you to rejoin the meeting as a panelist. Please limit your comments to four minutes. When you're finished providing public comment your role will revert back to an attendee, there will be a brief pause in the meeting, while you rejoin. If you are not signed up in advance, and you wish to provide comment today please indicate your interest to us by providing a comment, using the chat function prior to the comment period. Volume of signups will determine the available time for each person. We typically have 40 minutes available for public comment. And we have I think this morning three scheduled public comments. If you can please disclose any potential conflicts of interest prior to making your comment, it is appreciated. The agenda today is noninvasive cardiac imaging, this does include updates, or re-review of two previous topics, and that includes cardiac imaging and computed tomographic angiography. So these decisions will be subsumed into the decision from today, and the topics combined on our website at some point. So on the agenda, we have after this presentation will go through previous meeting business which includes minutes from the September meeting retreat and the July meeting that the committee had. That will be followed by the technology review for today, the noninvasive cardiac imaging, it will go in the following order: the agency medical directors' presentation, followed by the public comment period, the evidence report presentation committee question and answer around the evidence report, and then the discussion and decision period. After today's meeting, the program will publish any draft determination. That draft determination will be open for public comment for two weeks. And I'm happy to entertain any questions if you have any at this point. Thank you.

Janna Friedly: Great. Thank you, any—I'll give a couple more moments for any questions for Josh. Okay. So with that I think the next item on our agenda is to review our previous meeting business, and that includes our, as Josh mentioned, our July and September meeting minutes. And these are available with the meeting materials, in the past business section. And why don't we approve those or discuss those separately, so we'll first start with the July meeting minutes. Do I have a motion to approve the July meeting minutes?

Mika Sinanan: So moved. Mika Sinanan.

Janna Friedly: Great. And a second?

Conor Kleweno: Second. Conor Kleweno.

Janna Friedly: Okay. And then, Josh, oh, there we go. Okay, and so we will be using polls for each of the things that we're going to be voting on in today's meeting, so if you could please make your vote on the poll-

Tony Yen: –apologize for interrupting, but it says that the host and panelists can't vote?

Melanie Golob: Yeah, let me and relaunch it. I think I need to select something. There we go. Alright, let me relaunch it. Okay, let me know if that works.

Tony Yen: It works. Thanks.

Melanie Golob: Thanks for letting me know.

Janna Friedly: And, and then will that pop up with the results in a moment?

Melanie Golob: Yeah, once we end it. I think we have 11, so I can end it and share the results.

Janna Friedly: Okay, Great. So those are approved. And then the next item is the September meeting minutes. Can I have a motion to approve?

Mika Sinanan: So moved. Mika Sinanan.

Janna Friedly: Great. And a second?

Christoph Lee: Second.

Janna Friedly: Okay. And then we'll open the poll. [pause] Great. So those, those were approved. 82%, one, 18% abstain. Okay, so that is all of our previous meeting business. And so with that I think we can move to the agency report.

Josh Morse: Great. Dr. Chen, will you be sharing your slides, or would you like me to share them?

Chris Chen: Yeah, I can share them Josh.

Josh Morse: Great, thank you.

Chris Chen: How's that look for you guys.

Josh Morse: Okay. Great.

Chris Chen: Great. Great. Yeah, so again I'm Chris Chen. I work as a medical director for Medicaid and, and also am a hospitalist and have taken care of patients in the ED and inpatient setting for suspected ACS mostly, but today I'll be presenting our agency medical director comments with Linda Liu, who is our CQCT policy fellow, as well as a budding cardiologist who will be entering fellowship next year so we're excited to have her work with us on this topic. And Linda will start us off with a little bit of background, and then I will review our prior decisions, or comments on

the evidence report and then some proposed recommendations for today. So Linda, do you want to kick it off?

Linda Liu:

Yeah. Thanks, Chris. So good morning everyone. So just a little bit of background to give context for the discussion today. So we're discussing noninvasive cardiac imaging, and I think the most common scenario that will encounter these cardiac imaging modalities is within stress testing. And so, in brief, stress testing is to evaluate heart function and anatomy under stress, and it's a very heterogeneous topic with multitude of indications, I think the most common indication that we will find is coronary artery disease evaluation, and this is in a variety of settings, whether that be evaluating angina, acute coronary syndrome, a patient with known CAD and changing syndromes, or a patient with a history prior vascularization. While that's the most common indication, several other indications for stress testing are also present, including valvular heart disease, cardiomyopathy, arrhythmias, and pre-operative evaluations as well. Stress testing with noninvasive cardiac imaging can also be used found in a variety of settings both inpatient and outpatient. Go to next slide? And so these are the stress modalities that we'll be discussing today. Just please know that we're not going to be discussing stress MRI or coronary artery calcium scoring. But in brief, just looking at the stress modalities, specifically looking at stress echo, which is ultrasound technology, as well as PET, SPECT, and CCTA which all use computed tomography scanning as part of the PET basis for their, their use but with different radio tracers for PET and SPECT. Next slide. So, kind of putting this all together, so when, when using noninvasive cardiac imaging and, and evaluating for stress test. This is oftentimes placed in the background of assessing patients at risk for CAD. And so there's a multitude of scoring systems out there as well that categorize patients along with low, intermediate, and high-risk CAD, depending on the kind of indication or setting that they're in, so unstable outpatients there's again multiple listed scoring systems there you can see the Framingham General Risk Score. And then for suspected ACS, so patients presenting with anginal type symptoms, there's the TIMI score, the heart pathway, and many more. And so just to kind of characterize that there's just so many different scoring systems for patients who have chest pain. Next slide.

Mika Sinanan:

Linda, Mika Sinanan. I'm sorry, on your previous slide. You know one of the things that shown up in, in this presentation and in the agency, or not agency, but the, the academic presentation is FFR, and it is could you make a comment about the role of FFR and what we are assessing about that today.

Linda Liu: Yeah, so I believe we will be discussing CCTA with FFR. I'm not an expert in the topic, unfortunately, so I'll let Dr. Chen, expand on that a little bit more when we get to that.

Chris Chen: Yeah, and Dr. Sinanan and so the so FFR that we'll be talking about today specifically is CCTA perform, so for performed with CCTA rather than FFR performed during invasive coronary angiography, and typically what's done is that the CCTA is initially performed, and then preliminary really concerning lesions are identified on the scan. And then those images are kind of shipped off to a vendor that can simulate FFR on those images to further kind of characterize those. That's kind of typically how it's done from my understanding, it's only one vendor that currently does that at this time.

Mika Sinanan: Thank you.

Linda Liu: And so, kind of reframing this idea of evaluating patients and the risk for CAD, chest pain itself, oftentimes there you know there are very several severe life-threatening causes of chest pain, however, oftentimes chest pain can reflect a more benign condition. And so this is a figure pulled from a Jack paper, discussing about the top 10 causes of chest pain in the ER based on age, and as you can see that within all age groups nonspecific chest pain is the most common presentation, and then trying to elucidate the more concerning causes of chest pain such as acute coronary syndrome is the purpose of stress testing and those risk scores that we talked about.

Chris Chen: Great, thank you so much, Linda. So I'll talk a little bit about the previous HTCC decisions that have addressed parts of this topic. And again we're focusing mainly on four modalities today, being stress echo, PET, SPECT, and CCTA. So, there have been no prior decisions on stress echocardiogram. We discussed nuclear imaging in 2013, including SPECT and PET. At that time the scope of the review was slightly broader as it included asymptomatic individuals. The scope of our evidence review today did not include asymptomatic individuals and so, that may impact the scope of the decision as well. In 2009, CCTA coronary computed tomography angiography was reviewed at that time, there was not a decision on FFR. And just a side note cardiac magnetic resonance angiography, coronary MRA will be presented in two weeks. There have been no prior decisions on that, and the scope of that decision is slightly different to addressing more than just coronary artery disease. But, so I'll review some of the prior decisions, just to refresh everyone's memory here, so the previous HTCC decision on SPECT was that cardiac nuclear imaging is a covered benefit for patients with symptoms of myocardial ischemia, yeah, so those were symptomatic, who are at high risk of coronary artery disease, or low to intermediate risk of coronary artery

disease, and have an abnormal or indeterminate exercise treadmill test, or are unable to perform exercise treadmill tests, or EKG abnormality that prevents accurate interpretation of exercise treadmill tests, and it's also a covered benefit for patients who have known coronary artery disease, monitoring for changes and symptoms. At that time, the decision was cardiac nuclear imaging is not a covered benefit for asymptomatic patients, which does not apply to preoperative evaluation of patients undergoing high risk, non-cardiac surgery or patients who have undergone cardiac transplant, nor for patients with known coronary artery disease, and no changes in symptoms. The previous HTCC decision on PET, was that it is covered under the same conditions as SPECT, when SPECT is not technically feasible or SPECT is inconclusive. The previous HTCC decision for CCTA is that CCTA is covered when patients have low or low to intermediate risk of coronary artery disease, and for investigation of acute chest pain in an emergency department or hospital setting, and using the appropriate technology with CT machines with 64 slides or better capability and not covered when patients who are asymptomatic or at high risk of CAD, or for used outside the ED, or hospital setting. And this again was 2009. So the noninvasive cardiac imaging topic was selected for HTCC review and your consideration today, based on the high prevalence of coronary artery disease. And many of us have taken care of patients for coronary artery disease, and the high degree of clinical variation stress test selection. There is quite a difference in diagnostic testing strategies in terms of index tests, follow up tests, patient selection as well. There's high cost and utilization of noninvasive cardiac imaging and I can talk a little bit about our agency experience in upcoming slides. There has been stakeholder feedback on prior authorization for noninvasive cardiac imaging the past, as well as further development of the evidence base since last review in 2009, 2013. Because this is such a broad topic, and people can spend entire careers studying this area, that we wanted to kind of scope the discussion appropriately today and just kind of remind the committee. What was part of the evidence report as well as multiple indications for stress test to try and make this a manageable topic today and, and bring focus to our decisions as well. And so in scope for the evidence report and our discussion today, are adult patients with symptoms of suspected coronary artery disease, those who are have been previously undiagnosed who present with either stable symptoms or acute symptoms and those stable symptoms, typical or atypical symptoms suspicious for coronary artery disease or suspected acute coronary syndrome and emergency departments. And I'll just say as a side comment, you know there's been a little bit of change recently in nomenclature, in terms of using typical a typical symptoms. And, and people are trying to frame it more in terms of cardiac or non-cardiac

chest pain. But for the purposes of our reference report, this is kind of historical nomenclature that we've been using so stable outpatient symptoms or acute symptoms and EDs, and the second bucket is for those who have known or establish coronary artery disease, including those prior MI or revascularization. Scope and not reviewed in the evidence report are asymptomatic individuals preoperative studies, those undergoing cardiac transplant patients with STEMI assess assessment of myocardial viability prior to revascularization for individuals with left ventricular dysfunction and patients presenting for evaluation of cardiac pathologies other than coronary artery disease such as congenital abnormalities, valvular disease, evaluation of etiology for various cardiomyopathies, heart failure, etc. So, overall, these are the highlights of our agency medical director concerns. And with being low for safety, medium for efficacy, and high for cost. And I will say that on reviewing the evidence report, this was a modification of our initial concerns, which were medium for safety but efficacy and cost concerns remain the same. The key questions that were asked of the evidence report include: what is the comparative effectiveness of noninvasive cardiac anatomic or functional imaging modalities, i.e. CCTA stress nuclear imaging, stress echocardiogram, in leading to improve clinical outcomes, such as MI or mortality, with respect to clinical decision making, including additional downstream testing and treatments, and with regard to harms or adverse events, which might result directly from testing or additional downstream testing. Another key question was does effectiveness, or safety, differ in special populations? For example, women, those with co-morbidities, the elderly, from noninvasive cardiac anatomic or functional imaging. And what is the cost effectiveness of CCTA stress nuclear imaging and stress echocardiography for clinical outcomes? The just a brief comment on the evidence report. I think heterogeneity was kind of the name of the game, in terms of the different studies that were reviewed and generally this this body of literature has multiple different comparators, for example, and so, fewer studies with direct modality to modality comparators, oftentimes you'll see one modality compared to either a testing strategy, or a category of tests, such as functional tests which might include a number of different stress test modalities. There's also significant heterogeneity in this body of literature as it pertains to definitions of risk, and Linda shared with you before, the multitude of ways that people can define risk on both the outpatient and the emergency department side, and heterogeneity on the populations that were studied, including outpatient versus ED and hospital settings, and other specific exclusion criteria. So, following up on our agency medical director concerns, a comment on safety despite being a heterogeneous group of diagnostics, noninvasive cardiac imaging is generally safe, and there's rare occurrence of life-threatening adverse events. Stress agency agents, specifically, such

as dobutamine, regadenoson, may be associated with transient side effects that are expected and contrast agent related adverse events and allergic reactions, such as those with CCTA or SPECT, are rare. Radiation exposure is higher for SPECT than CCTA. However, cumulative radiation may change with different testing strategies, for example using CCTA as index study, and repeated testing may subject patients to a greater exposure. And for CCTA specifically as a CT scan, incidental findings are common and they may merit further workup. For efficacy, the thing that struck the agency medical director group was the relative lack of compelling evidence that definitively defined testing strategies in one direction or the other, and that despite multiple, many years of evidence, development, and so I'll just comment here that you know, I, I'd like to try and frame. Given the heterogeneity of testing strategies and, and imaging that we'll be talking about today, tried to frame things a little bit in a, in a hierarchical or algorithmic way in terms of thinking about the lowest complexity cost studies first, and then kind of tiering them up, so starting with exercise EKG, then going to exercise stress echo or stress echocardiogram, and then thinking about SPECT, and then PET. And so, in along that framework stress echo as compared to exercise EKG, there was insufficient evidence regarding risk of myocardial infarction, all-cause mortality, and cardiac mortality, in stable patients with suspected coronary artery disease. It's, stress echo was associated with the reduced risk of invasive coronary angiography and downstream noninvasive testing, the strength of evidence was low. SPECT compared to stress echo or EKG, there was a moderate strength of evidence that there was no difference in risk of revascularization or hospitalization, and no difference in risk of MI, all-cause mortality, or cardiac mortality, with low to insufficient strength of evidence. I'll just highlight there was one good quality trial, comparing SPECT with stress echo, that demonstrated a non-statistically significant difference in acute MI within 18 months of randomization, and also highlight the women trial that focused on, on women in 2011, that was comparing SPECT with exercise EKG, that did not demonstrate a significant difference in coronary artery disease death or hospitalization for acute coronary syndrome, so acute chest pain in women. And then for PET compared to SPECT, there was no difference in clinical outcomes, including myocardial infarction, all-cause mortality, with an insufficient strength of evidence.

Mika Sinanan:

Chris, Mika Sinanan again, before you go off that slide. Did the discussion that you had with the other agency directors, believe that the targets for efficacy were the right ones? I mean those may be the available ones, mortality, cardiac mortality, and MI, but it seems to me that these kinds of tests also will have significant lifestyle dietary and other changes medication changes that may improve the quality of life from a patient

directed, you know standpoint. And I understand that we didn't look at that, that's not part of the evidence report but, was there any discussion around other potential outcomes for efficacy?

Chris Chen: So in addition to MI, and all-cause mortality and cardiac mortality, there was also a number of different outcomes that were studied as part of the clinical decision making. And those included further testing, as well as treatment, generally speaking, such as revascularization. I think there were some studies that addressed medical therapy. And I guess I would defer a little bit to our, Aggregate Analytics will be presenting the evidence report later on, to go into detail there, as well as Dr. Redberg, who can comment a bit further on those additional ones.

Mika Sinanan: Thanks. I just think that for the group of patients that we had, that you had identified as being, you know symptomatic but unclear as to whether the symptoms were related to cardiac disease, a positive test of this nature might have, have significant changes in their life: medications, activity level, diet, and so on that are not measurable by the ones that were principally focused on and so I don't want to lose track of that. That could be a significant potential benefit.

Chris Chen: Great, thanks. So moving on to CTA, coronary CTA. Also, along the same lines, no clear clinical difference on clinical outcomes, there were several randomized controlled trials with similar outcomes, clinical outcomes cost of care, length of stay, including Promise, Beacon, Romicat 2, to Scott-Hart trial is one that's frequently cited and this, I think, was the, the random RCT that is commonly cited as having the most meaningful impact and there was possible demonstrated possible added benefit and stable chest pain in reducing non-fatal MIs and deaths from coronary artery disease. There were concerns about the control arm and kind of being mostly exercise treadmill tests and the control arm as compared to other functional studies. So we'll just highlight that and can, can discuss that a little bit more with review with evidence report and in symptomatic patients, CCTA vs functional testing may pass, may lead to higher in the coronary angiography referral and revascularization would increase radiation. For the FFR portion of CCTA the platform study which is a vendor-sponsored study, demonstrated that FFR CT approximates invasive FFR, and may lead to decreased invasive coronary angiography as well. So, moving into cost ,only a few studies as I mentioned before, really compared one specific test directly over another, especially as it pertains to cost. Most compared testing strategies results for mixed, and many limitations. I'll just highlight that for stable outpatients two systematic reviews suggested that stress echo may be more cost effective than SPECT in patients with low to intermediate risk, and in patients with suspected ACS in the ED, CCTA was found to be the more cost approach, cost effective approach in some studies. Kind of more concretely we'll

share, Medicaid, the Medicaid programs fee for service reimbursement for noninvasive cardiac imaging is as you see on the screen. And so, with stress EKG kind of progressing increasing costs to stress echo, SPECT, PET, and CCTA. I'll just note that this, these are professional fees, does not include institutional claim reimbursement. This also does not include the codes for the radio pharmaceuticals or drugs administered during the stress test, which can add a significant cost, for example the technician that's administered the SPECT test, the dobutamine or regadenoson, or adenosine as well. So—

Larry Birger: Hi, Larry Birger here, just breaking in on that slide unless you're going to make this point in a subsequent slide. How can we do a meaningful comparison of cost, without the institutional component or the facility component? I mean, in my experience that was much greater, far greater in costs than the professional portion. And as far as I could tell it had everything to do with the motivation behind private groups or institutions wanting to be able to have the, the domain of owning the equipment and being able to charge the facility fee. So I look at a slide like this and if I'm understanding it correctly I, I don't know how I could possibly do an accurate cost comparison.

Janna Friedly: And, and do those do those fees differ by, by the, the specific imaging? Those facility fees?

Larry Birger: Yes.

Chris Chen: So I'll just say. So the next slide does include facility reimbursement. I wanted to. It's a little bit complicated, on the facility side, because it may change organization to organization based on the group or methodology that's often used. So, so for technical reasons I didn't want to portray an exact number, because that reimbursement can change. But I will say that on the next slide this is the cumulative expenditures by modality and does include both the professional and the institutional claims. And so you'll see here, these are noninvasive cardiac imaging expenditures, over time, specifically for the modalities that we're discussing today. The, the coding is a little bit complex. And so the stress test codes for example that you'll see on the left-hand side, those are actually nonspecific codes that can be administered with either a stress EKG or a stress echocardiogram or a SPECT so there's a number of expenditures that are kind of lumped into that bucket. And then you'll see expenditures, from 2017, 2020, for stress echo, SPECT, PET and CCTA there. I will just add some other comments on this and data again as in the last one, this doesn't include the codes radiopharmaceuticals or drugs administered during the stress test, and the nuclear imaging codes were actually revised in 2020, and so they were these were not included in our utilization data here. The pandemic, you'll see kind of a general trend

downward on SPECT. It's unclear how much of that was attributed to the pandemic, and kind of just reduced kind of elective evaluations and procedures, in general, across healthcare so. Did that help answer your question, Dr. Birger?

Larry Birger: As long as, if I'm understanding correctly, this slide then would include the facility fee.

Chris Chen: Yeah. Correct.

Larry Birger: Okay, I think so.

Janna Friedly: And may I also just comment a little bit hard to interpret with a graph like this but looking also so it does look like at least for stress test and SPECT. There was a clear, sort of decrease over, over time, and it looks like that's probably also true with, with PET, specifically in 2020, there was a fairly significant drop, and are those. Do we have, I'm assuming that this is related to the pandemic and that makes sense to me but do we also have data on the patient population that is at risk and that would be that would potentially benefit from these, these or, or would have these tests ordered that it's not a decline in the number of patients, but rather availability of the test and other other factors.

Chris Chen: Yeah, I would. I'd have to pull up the data again I, as I recall, I don't remember seeing a stark drop in the number in the volume. But we can, I can look back into the, the spreadsheet and bring that up later, if helpful.

Conor Kleweno: I have a question, segueing from that. You know, are these numbers to be in, I mean one thing I can interpret from this is the relative expenditures between them. I don't have a sense of the expenditures relative to other imaging modalities from the payers. And secondly is the decrease we see, you know, stress testing SPECT based on a decreasing reimbursement classification, or a decrease in number of requisitions by providers?

Chris Chen: So the, the, I don't believe that the fee schedule has changed meaningfully in a way it's a drop again I think some of this, and I apologize that kind of acknowledge that our data is not perfect. I think there's unclear impact at this time of whether or not there was a decrease also due to the fact that the nuclear imaging codes for revised. That was discovered later after the data pool was done. And so I'm not sure what component is also due to change and coding practices.

Janna Friedly: Thanks, and looks like we have a hand up from Dr. Redberg as well.

Rita Redberg: Hey, thanks so much. I'm Rita Redberg, cardiologist at UCSF and look cardiology consultant for this report, part of it. And I just wanted to underline what Chris just said I mean I think his numbers are great but the data on costs is so limited and the other points about causes that

there is a lot of downstream testing that occurs, I would say, particularly after CT because of a lot of incidental findings and those are never calculated, you know when something shows up and doesn't seem important but you end up with another test or another test and those never also get considered. And the other thing is that the numbers depend a lot on sort of the pretest probability of having coronary disease of the population and in general. Those aren't, it's very hard to include those in the cost effectiveness analysis so I think he's done a great job with the data but the data itself is very limited.

Jim Kirkpatrick: I'm Dr. Kirkpatrick. Yeah, the other question I had was, this is taking into account any changes in hospital based versus nonhospital based billing and reimbursement?

Chris Chen: Yeah that's certainly possible especially since this slide includes the institutional claim, I don't have the breakdown of where these were performed. But that's possible.

Jim Kirkpatrick: Yeah. And the only reason I bring that up to show that the committee understands it's even more complex than what we've been talking about in terms of where things are data, whether it's considered hospital based nonhospital based and reimbursement is different. With that, so it is a really really murky and difficult area to get data on and then trying to make sense of that the pandemic is even more difficult.

Chris Chen: Thank you. Any other questions before I move on? So, current coverage criteria in place and again modality by modalities for stress echo. A number of our carriers and MCOs, although not all of them use aim criteria for evaluation of medical necessity for stress echocardiogram, and generally it's covered for symptomatic individuals, and I'll highlight that suspected coronary artery disease and symptomatic patients with intermediate to high risk of CAD, and no and CAD and patients who have new or worsening symptoms. We don't have a current clinical policy for Medicaid fee for service. Other payers there's a Medicare Local coverage determination for patients with EKG abnormality prior equivocal stress EKG or a history of post your wall, MI, and it's not covered if the incremental information and stuff no clinical relevance or if it's performed too frequently. And I'll just say again and I know I've said this many times, but there are numerous criteria and policies out there that address topics outside of those indications. Specifically, including asymptomatic individuals with suspected are known CHG post revascularization, recent MI, Kawasaki arrhythmias, congestive heart failure abnormal prior tests myocardial viability vascular disease preoperative eval pulmonary hypertension, how come that I did not highlight here as out of scope for the decision discussion coverage for SPECT aim criteria are for suspected coronary artery disease and

symptomatic patients with intermediate to high risk of CAD or a commonly coexisting chronic conditions such as and abdominal aortic aneurysm peripheral vascular disease. History of stroke or CKD, or high-risk occupation and known coronary artery disease and patients with new or worsening cardiac symptoms. Medicaid follows the 2013 HTCC decision on nuclear imaging. And there's a Medicare and local coverage determination that requires documentation of medical necessity, per appropriate use criteria or similar standard. And the current coverage for PET scans. Aim has PET scan as appropriate as the initial stress imaging test for suspected or established coronary artery disease in patients who have a relative contraindication to conventional nuclear perfusion imaging and or contraindication to stress testing. Again, Washington Medicaid falls the 2013 HTCC and other payers and policies that cardiac PET is used in places SPECT in those who are not candidates for specter use calling it inclusive SPECT scan and current coverage for CCTA for aim criteria suspected coronary heart disease and symptomatic patients with intermediate to high risk, a CAD Medicaid follows the 2009 HTCC, and for other payers Aetna covers the CTA for symptomatic patients with low to intermediate pretest probability of coronary artery disease with or without a positive stress test and Medicare Local coverage determination covers TCT as an alternative to invasive angiography and stress testing, not medically necessary if pretest evaluation indicates that the patient would require and basic criteria angiography for further diagnosis, or for therapeutic intervention. So understanding, there's a lot of information to process and myself have been rustled a little bit with this evidence before over the last couple of months, I was actually quite happy to see that. On October, 28, and less than a week ago the American Heart Association American College of Cardiology, among other professional societies released a joint statement on the guidelines for the evaluation diagnosis and chest pain at included. I figured that I found especially helpful. And I think and I just want to take some time to walk through this today. As framing up a little bit of what we're talking about. And so again the scope of this paper was for the valuation diagnosis of chest pain on the, on the left-hand side here you'll see acute chest pain. And typically evaluation performed in the ED for suspected acute coronary syndrome. Right hand side you'll see a stable chest pain evaluation that's typically an outpatient evaluation for patients and then, and the pyramid here is categorization of risk. And, and I will say that there are times that people use the term spree test probability at risk, somewhat interchangeably but this, this is focused on the risk of major coronary artery defects, with kind of increasing levels of risk being asymptomatic on the bottom, but low risk on the next tier intermediate risk, high risk, and then, different is acute coronary syndrome on the top. And so, the interesting thing about these guidelines, is the focus on testing for or

avoiding unnecessary testing for low-risk individuals on both the acute coronary syndrome site as well as the stable coronary artery disease side. And this has kind of emerged given changes in practice patterns availability of better in noninvasive tests such as high sensitivity component further defined algorithms etc. so I think this is helpful figure to keep in mind as we're deliberating today. And I think I'll just call out another couple of things. So, in addition to recommending avoiding clinical testing, testing for low-risk individuals. There's an emphasis on anatomic or functional testing for intermediate individuals from the chest pain side and I intermediate to high risk on the outpatient side. And just because we didn't get too much into the technical details of the different modalities here anatomic studies, mostly referring to CCTA for example and then functional testing, mostly referring to things that, You know stress EKG, stress echo SPECT, etc. So, coming on our recommendations. So, the four separate decisions here again by modality. And so, a recommendation for that stress echocardiography is the cover benefit for suspected coronary artery disease and symptomatic patients or evaluation of known coronary artery disease and patients with new or worsening symptoms and exercise EKG is inappropriate or unavailable. And we generally defined this to encompass various degrees of risk. And there are many reasons why exercise EKG may be under inappropriate or unavailable, such as individuals can exercise, or the EKG ever maladies that prevented accurate interpretation such as a left bundle branch block or someone has to be paste, but kind of generally saying that exercise EKG is inappropriate unavailable for a second would be covered. Our recommendation for SPECT is that SPECT as a cover benefit for suspected coronary artery disease and symptomatic patients who are at high, sorry intermediate to high risk of coronary artery disease, or for evaluation of known coronary artery disease and patients with newer worsening symptoms and, and so, and exercise EKG and stress echocardiography or inappropriate run available. My recommendation for PET is that PET is covered benefit for patients under the same conditions expect when SPECT is not technically feasible or SPECT is inconclusive and so this is not a change. This is remains the same from 2009. I'm sorry, 2013. And for our recommendation for CCTA is that CCTA is a cover benefit for suspected coronary artery disease and symptomatic patients who are intermediate to high risk or for evaluation of known coronary's these patients who have newer worsening symptoms and using the appropriate technology. And that's the CTA with that as FFR as the cover benefit under the same conditions, went further investigation of concerns to notice these identified on the initial CCTA is necessary. I'll just highlight here that this is a change what the from from the previous position and, which was restricted to hospital ED settings, and I think many of the randomized control trials were performed in the outpatient setting and

so understanding that there is a utility testing that patient side as well we, we decided to modify that criteria. And, yeah, so for that, I'll just pause and see if there any questions or comments. Hey, sorry, that was my dog.

Janna Friedly:

Thank you very much, Dr. Chen for that report. That was really helpful. I think we are running a little bit behind, about 10 minutes behind, which should be okay. But if there aren't any other questions I suggest that we move to, to public comment. I think we have, at least that I'm aware of, and you can update me, I think we had, we had three originally scheduled, I know there was at least one added in the chat. So we have four to my count, public speakers. I just want to again reiterate that when you are giving your public comment, if you could make sure to introduce yourself and as part of your introduction, if you could make sure to include, to start with any disclosures that you have, including whether or not you have been paid by anyone to present here today. And we'll limit comments to four minutes for each speaker. Josh, did you want me to keep track of the four minutes or do you have somebody who's going to be doing that?

Josh Morse:

Melanie will be keeping track of time. We have, as you pointed out, we have three setup as scheduled to comment, and then have a day of comment so far. If there is anybody who would like to comment, who has not already let us know through the chat, now would be a good time to put that in the chat. As your, as you come up to your turn, we're going to elevate you to a panelist. Dr. Susan Mayer is first she has four minutes; after Dr. Mayer will come doctors Thompson and Yakovlevitch, they will have six minutes combined, they have a slide presentation as well. And then Dr. Lindner and then at this point, Dr. Larry Dean. Okay? So we can start with Dr. Mayer.

Susan Mayer:

Good morning, my name is Susan Mayer, and I'm a cardiologist at the Mid America Heart Institute in Kansas City. And I'm also Chair of Advocacy Committee for the American Society of Echo and the fellow of the American College of Cardiology, and the American Society of Echo. On behalf of the ASC, I would like to thank you for the opportunity to speak with you this morning regarding the evaluation of diagnostic imaging for ischemic heart disease. There are several diagnostic imaging studies available for patients for the evaluation of heart disease is already discussed this morning in the physician takes into account their knowledge, their training their expertise, which might be the best test for the patient and their shared a decision-making process with the patient together, they decide which tests might be best. The diagnostic tests have similar accuracy, and each has their own unique advantages or disadvantages. If one test is best suited for all patients, we would not have so many imaging modalities available. There are many of patient

factors to take into consideration such as claustrophobia, chronic kidney disease, having a solitary kidney or heart rhythm abnormalities. Some patients may like to avoid radiation when deciding on a test coronary CTA can provide information about the coronary arteries, but many times we need more information, such as the significance of disease. And this can be determined by exercise stress testing, stress echocardiogram or nuclear stress studies. For example, a patient may have a 60% stenosis of a coronary artery on CT angiography, but by having a stress Echo, for example, we can learn if significant obstruction is present and if this is the actual cause of their symptoms. We can learn if medical therapy is effective, or whether a coronary intervention is necessary. Another very important consideration is the local expertise of physicians performing and interpreting the imaging studies, and also the test availability. Not all hospitals in the US have dedicated CT imaging for coronary arteries, especially rural areas, and community hospitals. In conclusion, the best test for the patient is one that is best suited for that particular patient, based on joint decision making, test availability, and the local expertise.

- Melanie Golob: Thank you so much for giving those comments, Dr. Mayer, we appreciate you, you taking the time to do that. So next on the list we have, I can promote these people, Randall Thompson. Dr. Randall Thompson, and he's speaking with Dr. Marco Yakovlevitch. So you will have six minutes together.
- Randall Thompson: Thank you, I had some slides, do you show them or shall I share my screen?
- Melanie Golob: Josh, do you want to display those?
- Josh Morse: I'm happy to share the slides here, just give me a moment.
- Melanie Golob: Great, thank you.
- Randall Thompson: My name is Randall Thompson I'm a cardiologist in Kansas City. I'm a multi-modality imager and nuclear and CT. I'm also the president of the American Society of Nuclear Cardiology, and I don't have any disclosures, any financial disclosures other than I have authored some articles on the concept of keeping the patient first in decisions on cardiovascular imaging. With me is Dr. Marco Yakovlevitch, who's a cardiologist in Seattle, nationally known very reputable cardiologist who among other things, he founded the nuclear cardiology, first nuclear cardiology laboratory in the Pacific Northwest. And among his many accolades he's been named best doctor and one of the top doctor in Seattle for nine of the last 10 years. Next slide. So the points we would emphasize, and this was a very comprehensive review that you all, Commission, the randomized controlled trial data indeed showed no major advantages of one diagnostic test compared to another one for patients with suspected

CAD and the various subgroups. Next, the logical conclusion is that providers shouldn't be allowed to use all the modalities and the diagnostic toolbox based on appropriate use. Next. And then many, including our organization have long pointed out that patients are variable. The decisions about which test orders nuanced and the local availability and expertise are very important, as Dr. Mayer said. Next. The one place where there seem to be a bit of an advantage in the text of that report is that CTA is dominant cost effectiveness, but the study also pointed out that the data are mixed, comparators are varied, and there are important limitations across studies. That's indeed the case, in fact of the largest trial that was looked at, the PROMISE study, the CT actually had higher costs because of downstream testing. Also, a number of those trials, there's a certain expert center bias in the issue. So for example when someone puts together a trial of CTA versus nuclear, they recruit CT experts, and expert centers with the top equipment. The CT scanner at my center is a \$1.5 million CT scanner, it's much better than the one we used to have, it's much better than most of the systems in the, in the area, and the number of downstream tests we order is less than it used to be in that other places are because we've got a lot more confidence and expertise we have high quality equipment. And as you go, when you move from that type of expertise, the number of downstream test number of follow up cardiac catheterization becomes higher. Next. So I'll just hit briefly, and for the sake of time, on these is a, this is an editorial of us, some colleagues with us. Next. One of the things and that they pointed out was just how many of the comparative trials did show downstream testing, especially extra cardiac catheterization following a CT first approach and patients without known coronary disease, next. So what's not in the report is how to test patients with established coronary artery disease. Most of us have concluded that nuclear has a real advantage over CT in this setting, or patients have stents of heavy coronary calcium and so forth. And that there is that there is a lot of absolute contraindications and relative contraindications were not really discussed. And then I will also just touch briefly on what we do with, in our centers. We combine coronary calcium scoring with my, with microinfusion imaging. We think it makes a lot of advantage and I would like not to see restrictive protocols or algorithms for things like this that are emerging and our new, next. This just speaks to some of the discussion you all had earlier. This is the Medicare or rock database of number of tests knows the three breakpoints along the vertical axis, the number of spec cases, the United States is probably about twice this but half my patients are over age 65. The number of cases probably less than twice that number and the number of coronary CTA is is probably more than twice that number but you can see that the number of spec cases national is about 10 times the number of coronary CTA as PETs are

probably up twice the number of coronary CTA is this speaks to availability expertise is Dr. Mayer was saying, which is quite variable and very important. Next, go ahead and skip a little bit further if you all want to get more chance to speak. And just as Mayor says all these demands have contraindications here so for CTA, next. The not many for nuclear, next, next, and this is what we do it by combining these tests we improve more. The prognostic value, next. Next, the diagnostic accuracy next, and it changes, next, next, it changes, physicians behavior. Next. So I would summarize with saying the right test for the patient the right time is a nuanced decision. Patients have considerable variability there's considerable variability local expertise and availability, and all these modalities are advancing, and the providers and appropriate with appropriate expertise in the context of appropriate use you should be able to utilize the best tool available for optimal patient care and not be hindered by restrictive algorithms. Let me say thank you and invite Dr. Marco Yakovlevitch to say, what do you like to say.

Marko Yakovlevitch: Thank you Randy. Hello everyone Dr. Sinanan, Dr. Kirkpatrick, I'm Dr. Yakovlevitch, a general a nuclear cardiologist in Seattle, have written articles on nuclear stress testing and on the subject of reducing radiation exposure and coding nuclear imaging I have no other potential conflicts of interest. I fully agree with Dr. Thompson and with Dr. Mayer, you know, as Dr. Liu described there are multiple reasons for doing stress testing, and as Dr. Chen described your mother, many different types of patients, the studies that are used to develop these guidelines look at large groups of patients and then average the outcomes, and there's a distribution of individual outcomes in those studies. So if we were to say we're going to have one treatment for every kind of breast cancer, then a study like that could say, this is the treatment everybody should get, but we would never do that for breast cancer because we know different cancers respond differently, patients presenting different characteristics and so we allow providers to have as Dr. Thompson puts it, a nuanced decision making process regarding what is best for this patient in front of these Patient Centered imaging. You can provide the optimal treatment without achieving the right diagnosis and achieving the right diagnosis requires a different test in different patients so at the same time that we are obliged to manage the skyrocketing cost of medical care. It is imperative that we don't compromise the quality of care because then we would lose that precious thing that we are trying to control the cost of. Thank you for giving me some time.

Melanie Golob: Right, thank you so much Dr. Yakovlevitch. So next up on the schedule we have Dr. Jonathan Lindner so if you want to go ahead and give your public comment you have four minutes. Okay thank you.

Jonathan Lindner: Thanks for allowing me to talk to you guys in terms of background I'm down at Oregon Health Sciences University. I'm a Professor of Medicine there by way of conflict of interest and disclosure I'm a multi-modality imager with expertise in echo and nuclear. I'm a former president of the American Society of echo of know die was a reviewer for this process and I was also an expert reviewer one of two on the HR q document. A couple of years ago looking at the same thing I was a reviewer of the ACC ha guidelines which were just released which you guys have reviewed and also an author on an upcoming multi-modality document that's being put out by all of the imaging societies on evaluation of stable coronary syndromes, so I'm, I'm kind of knee deep in this whole process. I really want to just, you know, the previous speakers have really kind of gone into some of the rationale. The bottom line, the thing that I really want to kind of explore the topic is this this topic of nuance, the, you know, if you take a look at the literature, the literature is only as good as the patient selections in these trials, okay and the processes that were done. And so the trials that are done with kind of the broadest allowance of usual, you know, state of the art practice are probably the most valuable and those have essentially shown that there is no advantage of one technique over another, but there's so much nuance to everything that we do in selecting these tests, and for an example, for example, people said that there's new ones here's just some examples. So, I consider and I send patients for CTA when they are younger, when they're more likely to have better quality studies that are not in a fib they're not tachycardic. If they're suspected AR tauopathy, which is a good test. But FCT is not really good for the elderly where sometimes I've had patients who have had disease detected by CTA have had PCI, and intervention and their symptoms didn't improve one bit. It's also not really good for people who are in in irregular fast rhythms like atrial fibrillation, and it can't detect small distal disease. Functional Tests are extremely helpful, not just for, you know, determining patients functional response and having high risk versus low-risk features, but also for determining whether things like a pericardial disease, aortic stenosis, exercise arrhythmias are responsible for the symptoms, but also for this thing, micro vascular dysfunction. An anatomic test can tell you nothing about the fact that somebody has micro vascular dysfunction, which is something that is extremely important as overlooked, health care disparities, a women's care issue more than than men's as well. But it's not perfect as well. It has problems with sensitivity, specificity. Not everybody can have every pharmacologic test. So the bottom line is there's a tremendous amount of nuance to what we do in cardiology which tests that we we select and the ability, you know, if you take away that choice and the ability for us to be able to use our knowledge and our experience for, for correct test for the right patient, it'll just, it'll just lead to patient harm.

- Melanie Golob: Great, thank you Dr. Lindner, appreciate you taking the time to speak to this group. Next we have Dr. Larry Dean. And as a reminder, if there's anyone else that had intended to give public comment, please send a message in the chat. Dr. Dean.
- Larry Dean: This is Larry Dean. Appreciate the opportunity to speak to the committee. I'm currently at the University of Washington, and a professor of medicine surgery UW. Background in invasive interventional cardiologist, a master interventional cardiologist from the Society of Cardiovascular Angiography and Interventions, and former, and the past president of that society. As far as sort of disclosures I'm not so sure it's a disclosure, but there's going to be a publication but they use the appropriate use criteria, looking at multi-modality imaging, which sort of speaks to this discussion from the ACC/AHA, etc. that will be published soon as well and I'm on the rating panel of that you see, otherwise have no conflicts and I'm not being paid for my presentation today. I just like to sort of echo what others have said, particular Dr. Lindner, just spoke a moment ago. I think the major problem that I have with the document is this, this notion of worsened symptoms that drive these different modalities. That's a very broad term worsen symptoms can be someone who has no symptoms and all of a sudden has unstable angina. It can be someone who has class one symptoms, who now has class two symptoms. Or it could be someone who has class one symptoms who now has class four symptoms, and the modalities that are used in the approach to these patients Isn't the last one is driven by those symptoms. So, someone presents to the emergency department with an acute onset of chest comfort or has worsened significantly worsen symptoms than the pathway that we would follow is different than someone who presents with mild symptoms for example, I think the fact so that's the major concern with the document is is trying to is trying to lump together too many patient populations in the decision-making process which can be quite nuanced. I think that I was, I was happy to see that. Dr. Chen went over a little bit of the currently recently published a document. At this point from the ACC ha and other societies around this particular topic. And I think following that document that guideline is what I would recommend for the committee from the standpoint of how patients should be tested. I think it very nicely outlines that. And so if you have a high-risk patient who presents the emergency department with prior history of coronary disease and has unstable coronary syndrome, unstable angina, for example, you're unlikely to do a non-invasive studying on that patient. Patient is much more likely to have an invasive study. And I know that's not the point of this particular guideline, but that nuance is very important in the standpoint of management of these patients. And so I think those are primarily my comments. The only thing

I would say about see coronary angiography by CT, is that I'm all I'm looking forward to the ability to have an anatomic test a heart catheterization and angiography is an anatomic test. I'm looking forward to the time when we can take a noninvasive anatomic test and combine that with FFR which measures the significance of what we're seeing on these anatomic test to really guide our therapy, but that that technology is not ready for prime time at this point. It was pointed out a moment ago there's a single vendor in that space. It's somewhat cumbersome to have an analysis done, it doesn't really suit. Except for perhaps an outpatient dialysis patients who are in the emergency department. And with that, I'll go ahead and close my comments and again, thanks very much for being allowed to participate in the conversation.

Melanie Golob: Right, thank you so much Dr. Dean. Dr Friedly, back to you as we do not have any more public comments.

Janna Friedly: So thank you very much everybody for those, for those comments, those were incredibly helpful. We, at this point, are a little bit ahead of schedule, and we have a scheduled five-minute break. To start with the report at 9:40, which is 15 minutes. Should we, does anybody have a preference whether we take a little bit longer break and start at 9:40 or should we try to shorten that to 10 minutes and come back at 9:35 to get started.

Larry Birger: I'd prefer a longer break.

Janna Friedly: Okay, so let's let some stay on schedule then, and start the, start the next section at 9:40 so if you could please come back at 9:40. And when you come back if you could turn on your video, so that we can make sure that everybody is back, and we'll know your back, that would be great.

[break]

Janna Friedly: Josh, before we get started, I have a question I don't know if Dr. Chen is on but he had in his presentation. The slide from the with the graphic, with the asymptomatic low risk medium risk high risk from the recent guideline that was, that was just published and referred to, I'm not seeing that in the, the, the slide deck that is on the website, was that added after that was published, and if so, is that something that can be shared with the groups.

Chris Chen: Yeah, the, you know that those guidelines actually just came out on Friday of last week, or Thursday thanks so the, the, those are new edition and all the shared the link in the chat.

Janna Friedly: Okay. Perfect. Thank you very much. That's really good. Can...

Josh Morse: We have the more recent slide from Chris, and if the committee would like I can email that to you. The next few minutes.

- Janna Friedly: That'd be helpful. Yeah, that that would be helpful I think for me in and and also the link to the, to the guideline. As since that was just published I'm sure most of us have not had a chance to review that ok for aware of what we're aware of that. Okay. So, it is it is 940, now, and we are scheduled to review the evidence report at this time. For committee members if you could just at least momentarily, when you were here turn on your, your video so that we know that everyone is back it looks like most, most people are. But I want to make sure that we are all back. Okay. So why don't we go ahead and get started with the evidence report. And thank you for the length Dr., Dr. Chen, and we'll go ahead and get started with the evidence report. Dr. Skelly and her team.
- Andrea Skelly: Okay, thank you. Josh, Melanie, do you want me to try to share my screen?
- Melanie Golob: Yeah, if you're comfortable. If, if there's any issue we are happy to do it.
- Andrea Skelly: Okay, we'll give it a try it seems like when we practiced the the, it was the PowerPoint thing that we wanted.
- Melanie Golob: Yeah.
- Andrea Skelly: Okay, let's give it a try. And let's see, so I assume you all can see my screen.
- Melanie Golob: Yes.
- Andrea Skelly: And let's see we needed to, figure out which way to do this in terms of allowing you to see the slides but me to see the notes. So let me, let me go to the presentation. I will start the presentation from the beginning. And do you see, do you see just the presentation or do you see the notes?
- Melanie Golob: It showed for just a second. Maybe try hitting the from beginning again.
- Chris Chen: Actually I think Andrea, I think if you select monitors on the top right there...
- Andrea Skelly: Okay, so, so what do you guys see? Do you see just the slides or do you see the notes?
- Melanie Golob: We see your, your whole PowerPoint, with the. Okay.
- Andrea Skelly: So does that?
- Melanie Golob: There we go.
- Andrea Skelly: Okay, perfect. Oh yay, thank you. I have other talents, mastering Zoom is not one of them so thank you for your patience. So you see the slides, and I have my notes. This is great. So, I would like to first start by thanking everyone for their attention. I know this is a long record I've tried to put some breaks in it, and some logical areas to take a breather. I

would like to acknowledge the team. This almost 400-page report would not have been possible without their assistance. And, Erica wrote was a project manager for this is on the line with me as well. And I'd like to acknowledge Dr. Rita, Redberg for her assistance with the topic refinement and also clinical questions related to this report. So we'll go ahead and go on to the next slide if I can figure out how to do that. There we go. Alrighty. Dr. Chen has already reviewed the previous reports, as you know that this report is an update to two previous health technology assessments. I won't go through the nuances of the report on the previous report, other than to say that at the time of the CCTA report in 2008. There was only one available RCT and the focus of the report was both mostly a diagnostic accuracy and eyesores modeling of cost effectiveness. With regard to the update for this particular topic. We now have 22 randomized control trials over 46 publications, as well as we included one perspective cohort nonrandomized study for CCTA FFR which is a new adjunct modality that was discussed by doctors Chen and Liu. And I just want to draw your attention to the fact that in terms of the effectiveness. Again, there was some differences maybe between that review and what we will be sharing with you. I would like to point out that in terms of safety the radiation risks they considered to be small but high enough to obviate the need, or the benefit when they were applied to very low risk patients, and that incidental findings were not infrequent. Moving on to the prior report for nuclear stress testing as already pointed out, there were differences in scope and differences and key questions. We did not evaluate asymptomatic patients whether they had known, or did not have known coronary artery disease. And again, I won't go over what their findings for their effectiveness or in detail, other than to say that the load intermediate risk patients SPECT was considered a better or comparable to exercise treadmill testing, but comparable to echo, and in high-risk patients. There was considered to be maybe an incremental benefit over ETT. But comparable to echo, and in patients with known coronary artery disease, there was insufficient evidence to make a conclusion, and all of the information related to PET was considered to be insufficient. was considered to be insufficient. This update includes six RCTs, three of which were included in the prior report, and one new PET or CT. Oh, let's move on. Okay, just as a loving reminder, there's a continuum of types of studies and ways to evaluate medical testing. It's, they tend to fall along this continuum and related to this update, and the report that you have before you, the prior report, like I said, primarily focused on accuracy and clinical validity and those types of questions. All of these modalities CCTA in particular have matured substantially since that prior report. And so the focus for this report is basically on the clinical utility, the ability of a test to direct management and improve patient outcomes and be cost effective. So

again, just a little loving reminder of that continuum. By way of background, you're already aware of and understand the public health and cost burden to ischemic heart disease coronary artery disease. I do want to point out a couple of different aspects to this that are important to the testing. First of all, it just because one has atherosclerotic plaques in a, an artery doesn't necessarily mean that it's obstructing the vessel, such as would compromise, receiving substantial flow and impact function. And the symptoms don't always correlate with lesion presence or severity and as Dr. Linda Liu pointed out, if you look at some of the patients with really just all disease ischemia may be present, but there may not be an observable obstruction. And so this kind of gets at a little some of the the, the, the question aboutatomic versus functional testing, to some extent to just to keep those things in mind. If we go into the next slide, as was pointed out chest pain can be a variety of different types. This is from the new ACC as a guideline, and the probability of ischemia varies based on the patient presentation, And there may be very different origins to the chest pain. This is just a nice graphic to add a little color. As I mentioned before, the traditional cap classifications of angina, have been well described and because most of our literature, many a bunch of our literature, use as many of these traditional normal nomenclature pieces. We are I'm giving you this background and typical angina generally meets these three categories. A typical engineer would be two of the above, and non-angina chest pain would maybe meet one of the above. And again patient history and presentation are important to understanding, whether it's stable or unstable and stable angina. Basically, the patient may be present with very predictable pattern of pain. And it may be brought on by physical or mental stress and subsides generally with rest or appropriate medications. It is associated with stenosis, but often without plaque disruption, or plaque associate associated thrombosis, which would be that a harbinger of myocardial infarction, again. Classically, the Canadian cardiovascular society classification of angina has been used and you'll find it in the literature, many of the pieces that we've reviewed and basically, the bottom line is that it kind of evaluate the extent to which the angina. Maybe induced with physical activity. And so, again, along the lines of background and some definitions of terms acute coronary syndrome represents a spectrum of conditions a spectrum of a constellation of symptoms that may be compatible with acute myocardial ischemia. It's divided basically into three areas. One is unstable angina, which, as you can see, is defined as a new onset of at least class three or greater of the Canadian cardiovascular society classification. And it may be a short, short, there are other divisions of it, which we will not go into. And then there are the non-STEMI and the semi myocardial infarctions, both of which are considered serious and important. The STEMI and the possible risk of

death are generally indications to take the patient to cardiac catheterization and possible revascularization whereas the SME that may not be in this setting so these are the patients that would be presenting to the emergency department they would receive testing for cardiac biomarkers biomarkers particularly troponin and that based on based on that and the EKG evaluation would click categorize patients along the spectrum of acute coronary syndrome. Let me go on. And so one thing I would like to point out is that in terms of this evaluation and any HTA it needs, we need to bear in mind that the value of a medical test really relates to its ability to identify the people for whom there is appropriate and effective treatment. And when we look at the studies we need to remember that the outcomes that we're looking at the cardiac morbidity and mortality outcomes, as well as the decision-making outcomes are basically a function, not only of the test but the outcomes, especially the clinical outcomes are in combination with whatever treatments are received, or the decisions that are made on the basis of the test results. And as pointed out many of those decisions could relate to decisions to initiate or change medications and those changes. They also then impact a clinical outcomes that are also considered indirect. For the most part, clinicians and clinical guidelines consider the imaging modalities described in this health technology assessment to be superior to exercise treadmill testing, and in the US my understanding is that generally usual care would encompass some form of imaging. Again, as many of the public commenters pointed out, it depends on the pretest risk of ischemic disease, and the presentation of the patient. And in looking at the literature and discussions with clinical colleagues. It appears that there really is a lack of consensus or clear superior or clear superiority for one of the noninvasive images test versus others, and that's influenced by many, many factors. In addition, patient presentation and history and pretest risk. The acuity of the symptoms, but also is pointed out the availability of equipment and appropriate expertise to perform interpreted tests, what are the goals of testing and then consideration of patient exposure to radiation, and the patient's needs and preferences. This was a slide that was shown by Dr. Chen and it's in the new guideline. He's already gone over it. I'm not going to go in detail, other than to say that there are a variety of decisions that need to be made, and those decisions related, related to whether anatomic or functional testing or is the best way to go. Again, there doesn't seem to be a clear indication in some instances for this. What is clear in this guideline compared to the old guideline is that asymptomatic patients have low risk patients. There really doesn't seem to be a recommendation that testing be done at all so I'd like to just point that out in this pyramid. This kind of says the same thing in some respects, in that gives you a flow from what happens when we have a patient comes for suspected coronary artery disease, whether

that's acute or stable. The initial evaluation using physical exam the patient's history and presentation EKG then leads to a risk stratification, and then further decision making about how and what kinds of tests should be employed. The guidelines have often considered low to intermediate risk to be a very broad group of patient pretest risk. And that's a 10% to 90% risk of an event within five years. So that's a very broad range so when you see that in the literature that we're reviewing, you might want to keep that in mind for the low pretest risk individuals, there's always a balance of, do you need to make a diagnosis, and in low test Hello pretest risk individuals. There may be a lot of false positives that require follow up, and the events are often very rare so there's always that balance. As pointed out patients at high risk for ST elevation MI or death are likely to go on to invasive coronary angiography and revascularization was necessary. And those individuals are not included in this technology assessment. In terms of treatment, everybody is going to have some form of optimal medical therapy guideline directed medical therapy which includes lifestyle changes, education, maybe pharmacologic agents lipid lowering agents, and that's going to apply to all patients with coronary artery disease, and the higher risk individuals revascularization may be considered. It's beyond the scope of our report to really discuss those options, but just wanted to lay out the lay them out for you, for completeness, in terms of background you've already heard a bit about all of the modalities so three modalities that we are focusing on our CCTA , stress nuclear imaging, and stress echocardiography. And as you know CCTA involves ionizing radiation and I had donated contrast materials to evaluate the coronary artery anatomy and visually estimate obstruction, and the advantages that you can see, potentially the obstruction and moderate to larger hospitals likely have CT have it available to them. And it may help also identify causes of chest pains that are not related to the heart. Some of the potential disadvantages does involve radiation. It does require specialized equipment and expertise as all of these do. It does not provide functional information however and cannot confirm ischemia, as a standalone test. As with all of these imaging modalities, some of the tests may be an interpreted under certain circumstances for CCTA. If there's a lot of coronary artery calcium, if there are arrhythmias rapid heart rate or the presence of previous stent placement, there may be a lot of artifacts that would render these images and interpreted as mentioned, there seems to be a lack of consensus on the effectiveness of CCTA vs functional testing as one or the other beings superior. There are some newer adjuncts to evaluate attempt to evaluate function related to CCTA one has been mentioned, is the, the fractional flow reserved derived from CT data or FFR CT, and the other is a CT profusion which is the usable pharmacologic stress. As mentioned, I think by Dr. Dean there's only one

approved method for doing FF RCT so they take the CT data, and use hemodynamic modeling to evaluate this fractional flow reserve the data, and the equipment is related to a single vendor. The images get sent to the information gets sent to this vendor. And then there's a little bit of a turnaround. And then, the results are then sent to the clinician, in an acute setting there are concerns that this delay may delay decision making that may be important for the patient. We'll talk a little bit more about the FFR CT as we go through, but it is detailed war in your report. In terms of nuclear stress testing, it's often called bio cardio perfusion imaging, small amount of radioactive material is used to evaluate physiologic function, and as already mentioned there are a variety of agents use SPECT and PET both effect and PET do also incorporate the CT aspect of a visualization so sort of a hybrid test. In some ways, and the potential advantages are that you can evaluate perfusion or wall motion based on the distribution of coronary arteries, you can evaluate the segments that may be impacted by an obstruction. It may be preferred in patients who have a left bundle branch block, and it's used for for patients for home echocardiogram echocardiography is, is very difficult. And PET may be preferred and women and women individuals who are obese. Again, this is a modality that exposes patients to radiation from the radio nucleotides that are included. Patients may experience claustrophobia, the SPECT can incorporate either pharmacologic stress or exercise stress but PET would be limited to pharmacological stress and there are potentials for allergic reactions, etc. And again, there's substantial expertise required for interpreting the, the aspects of SPECT or PET image.

Mika Sinanan:

Andrea, Mika Sinanan and just, just to emphasize the point you made earlier about anatomic studies sometimes not showing an obstruction, but they're being micro vascular disease. So this test is the one that shows micro vascular disease and effect on muscle, where there may not be an anatomic obstruction right? That's an event.

Andrea Skelly:

Yeah, so SPECT, and maybe in many respects the echo might be able to do that as well. So you can see the function, you can only see the anatomic aspects, with the CCTA.

Rita Redberg:

I would say there's a lot less evidence for the clinical value of, you know, imaging for micro vascular disease and, and whether the treatment as an entry have pointed out, the important thing is, is this going to lead to a treatment that's going to help patients and center is the test needed for that. I think that's not well established for PET and micro vascular disease.

Jim Kirkpatrick:

And it is an area of very active research right now probably the biggest advantage is sort of in in sort of at least realizing that if you don't have

obstructive disease you could still have coronary artery disease that of getting back to your point earlier Mika the patient sort of being blown off and said well you don't have anything wrong with you that actually there. There is a recognition and this can lead to substantial improvements and patient quality of life as they no longer feel ignored and marginalized.

Rita Redberg:

They actually say I've been, you know, looking at women and hearts of youth and doing research in the area for 30 years now and I see a lot more women who get labeled with something they don't understand and then have a lot more recurrent symptoms and feel worse than and feel better. And, and the data, when you look at the follow up it's you know once you start telling someone they have a disease, they then worry about every twinge and every ache and pain they get so I am really not convinced that there isn't a real advantage for women to tell them they have micro vascular disease, and you know it's not predictive of MI and. But I don't want to get Andrea off topic.

Andrea Skelly:

I appreciate you, providing the clarification on the micro vascular disease. As a non-clinician, I'm grateful for it for that clinical perspective. Thank you.

Larry Birger:

Larry, Larry Birger here, could I interject as well and I don't maybe this isn't the ideal place to mention it but it did come to my mind, the difference between an anatomic and a functional test. And then the accuracy of the CCTA as an anatomic test and the subject of downstream testing, I think is huge and easy to, you know, not realize if you're not in the midst of this kind of ordering these tests. It's been a number of years since I've had access to CCTA the cardiology group that I worked with. They coordinated as far as I know, the, the satellite hospital that I was working at an upstate New York having the first Community Hospital in the nation with the fancy GE, you know CCTA capable scanner. Number one thing I noticed that was kind of disconcerting was a pretty significant discrepancy between the degree of stenosis being called on the CCTA, and the you know what we would find on angiography or functionally or whatever and if you could just, I don't know if that those discrepancies that we saw the technology has improved over the years, or is that still a big factor because I could definitely see that muddying things even further.

Andrea Skelly:

We will, I will show a slide of some of the accuracy and the like, all of the modalities have improved over the years. In many ways for their accuracy, one of the points that came to mind when you mentioned that is that most of the accuracy information is comparing the test, to invasive coronary angiography which is also an atomic test. And so when you're comparing and anatomic tests like CCTA to invasive coronary angiography, there may be a different correlation a better correlation

related to quote accuracy than when you compare a functional tests like a stress of nuclear test, or echocardiography. And although there have been many advances in the use of invasive coronary angiography, there still are some inaccuracies, and difficulties with interpretation, is my understanding, and again, Dr. Redberg or Dr. Kirkpatrick may be better able to speak to some of that. But, yes, that there are there are all of these have some accuracy issues and some inter-rater and intra-rater reliability issues, again coming to the idea that expertise, can be very important in these settings and I'll defer to Dr. Redberg, Dr. Kirkpatrick if they want to add, add to that.

Janna Friedly: And I'm just going to stop for one brief, brief moment. There was a comment in the, in the chat that reminded us that we did not, in our disclosures, obtain disclosures from Dr. Redberg, our any financial support, or

Rita Redberg: Did you want me to comment now--

Janna Friedly: --make sure that the. Yeah, if you could just do the address that now, that would be great.

Rita Redberg: So, I have no financial conflicts. I have research support from NHLBI for evaluation of chest, low risk chest pain project, and research support from Arnold Ventures and Greenwall Foundation, not related to this topic.

Janna Friedly: Okay.

Rita Redberg: I'm editor of JAMA Internal Medicine.

Janna Friedly: Great, thank you very much for doing that. And then, in the interest of time, we can we can certainly address this, this question by Dr. Skelly, but in the interest of time, I want to hold the remainder of comments until the end of the presentation so that we can make sure that we get we get through the content.

Andrea Skelly: So, Dr. Friedly, did you want Dr. Redberg or Dr. Kirkpatrick to respond to, to Dr. Birger's question, Larry Birger's question?

Janna Friedly: Yeah, that's fine, that's fine to do that, but ok for the rest for the remainder let's let's, let's hold off until the end.

Jim Kirkpatrick: I would just agree with you that all of the techniques have both scanning and interpretive issues with them, and it does require some degree of expertise and some of it is explained, the discrepancies early on might have been explained by technology and experience and everything else, and that things are better, but they still are dependent on the interpretation.

Andrea Skelly: Okay, well then, why don't we go on most of you already know that medical imaging is probably the largest controllable source of radiation exposure in the US and cardiovascular related tests comprise maybe about 40% of all that medical radiation exposure. So it's not, not in consequential, and as over the decades, there has been increased concern about the cumulative ratio radiation exposure across all tests across the lifetime, and there is a lot of variation in what's reported for all of these procedures. In terms of the average radiation dose and table for in your report on page 23 provides you a range for that. In general, SPECT is a higher radiation dose from CCTA echo doesn't give you any radiation, and again there's a wide variety of doses of radiation anywhere between three millisieverts to 20 up to 20-minute millisieverts depending on the source and the registry. I would also like to point out that naturally over the course of a year, we are probably exposed to somewhere around three millisieverts just naturally and that'll be something to consider maybe a little bit later on. I think we'll go ahead and move on. Here, stress echocardiography does not involve radiation, it's an established modality for the evaluation of CT coronary artery disease, and based on the coronary artery distribution. You can stress the heart, either by exercise or pharmacologic agent to see what was the move similar to SPECT in that you can see that the segments of the heart that are potentially impacted by decreased blood flow. The advantages are that you can again find functional information via wall motion analysis. You also have the opportunity to look at diastolic function when the muscle is compromised the filling of the heart may be compromised, as well. You can look at the integrity of the cardiac structures such as papillary muscles etc. which may also impact function prior infarct it's widely available, it's inexpensive compared to the others it's portable. And as other with other imaging modalities, again it doesn't involve radiation that the others do. And there are established protocols differences disadvantages are that it may be very difficult to perform. It's very operator dependent. And it's an interpretation is also important expertise in patients who have pulmonary disease or who are obese echo can be very difficult. And, again, there have been advantage advances in all of these modalities, the stress echo does not evaluate the coronary arteries, specifically in terms of being able to visualize them again referring to the coronary of the new guidelines from the AHA/AAC. They have a bunch of algorithms, based on individual patient pretest risk, and whether or not there is known or not known cardiac coronary artery disease and this is the one for interface intermediate risk patients with no known coronary artery disease, not going to go over in detail, other than to say that the new guidelines do indicate that in patients who have not had any prior testing, both the stress testing and CCTA are given a level one or class one access, one strong recommendation. So there doesn't necessarily

mean that there's a preference for one or the other, based in the algorithm here but again I would add that there is some controversy and lack of consensus regarding what the optimal energy modality approach, maybe for a given patient. Similarly, and so the one, the one that I just showed this was in patients who may be presenting with acute chest pain and presenting them to an emergency department. If we go to the next one. It's for stable chest pain and again I would just point out that level one recommendations or class one recommendations for stress testing and CCTA, are, are noted in this particular slide as well. Let's go on to the questions and scope, again, we've looked at contextual questions related to diagnostic accuracy of the different modalities compared with the traditional reference which is again in basic coronary angiography and looked a bit at the types of reliability as well. This is detailed in excruciating detail in the report, we're not going to go over a lot of it here. The key questions you've already been made aware of so I'm not going to discuss them in any detail. I would like to point out a couple things about the PICOTS, we again focused on symptomatic adults with suspected coronary artery disease. That could be in an acute setting for suspected acute coronary syndrome. Again, primarily unstable angina or NSTEMI, but also we did look for studies in known or established coronary artery disease, which would have included patients with prior MI or revascularization. So we did look at those three patient populations. And we'll talk a little bit more about that. You already know the imaging modalities that we're looking at, and comparators that we sought were no testing usual care, and then comparing the different interventions with each other and then against coronary angiography. I would like to point out that the strength of evidence was confined to primary outcomes for each key question, as, as follows. So for the clinical key question clinical question of efficacy, myocardial infarction cardiac death and all-cause mortality were the primary outcomes for decision making. We looked for referral for treatment and referral for additional testing and safety and harms, again we try to make as inclusive again as possible. And then for cost effectiveness, looking at full cost effectiveness studies and looking for intermittent, looking for ICERs and incremental cost-effective benefit. If we go ahead and look at the PICO scope again, it's pretty straightforward I would indicate that we did focus on RCT evidence, given the maturity of these modalities, and we focused on the highest quality studies that we could. And let's go on. So in terms of methods, just a couple of very brief reminders. First of all, we did follow the AHRQ guidance for systematic reviews and rigor for systematic reviews. And once we evaluated the studies do only for inclusion and exclusion we took a look at the risk of bias of each individual study, you're familiar with. Most of the algorithm, I would like to point out for testing. Two important pieces are whether the test were blindly assessed

and whether or not there was a pre, pre described pre-specified threshold for a definition of a positive test again by way of loving reminder that risk of bias is only one of the price but only one criterion that goes into evaluating the overall strength or the overall quality of the body of evidence. Consistency directness precision and publication reporting bias are also components that go into the overall strength of evidence as we call it, or quality of evidence, I would like to point out that we follow the AHRQ way of evaluating strength of evidence, which is a little bit different from what grade does. And so, by way of review again, we do a review citations and studies for inclusion, assess risk of bias, and based on the quality decided whether it was good fair or poor based on those algorithms, and then across the studies of a given outcome, we looked at the overall strength of evidence, again using the arc approach to evaluating strength of evidence. And so for each outcome. we then made a rating of whether we had a high confidence moderate low confidence in the estimates for effect, or if there was insufficient evidence to make it a conclusion. So let me take a deep breath here and say this slide is to give you an idea of how we're going to present the results will talk a little bit very briefly about the contextual questions, then for each of the individual testing modalities, we will address questions one through four because cost effectiveness evaluations, were basically across test. I'll reserve that for last after we've gone through the all of the modalities, I would like to note that the evidence on the advocacy for the CTFFR was considered to be insufficient. And I will not present it in detail but it is discussed in detail in your report in two places, first of all in the section of the report that that discusses it, the main report but also there is a rapid review by Mark health and at the for the VA system on CTFFR, that I would draw your attention to. We did not find any prospective comparative studies of CT perfusion, so there was no evidence for that. As I mentioned, the sensitivity and specificity of the tests, as well as the other other parameters are based on a comparison to invasive coronary angiography which is an anatomic test. It's not a perfect gold standard. And you can see that the ranges that I've highlighted in bold for the top level relate to government sources, systematic reviews that may have been of higher quality and incorporated higher quality studies, but you can see that there is a range for all of them. And, you know, none of them are perfect. And I don't want to spend a lot of time on this. Most of them are considered to be reasonably sensitive and specific as you know predictive values are related to the prevalence and the ranges of prevalence across studies that these data from vary from, you know, very low prevalence of coronary artery disease to very high prevalence of coronary artery disease. We did not identify any studies of differential accuracy by the subgroups of interest in terms of the FRC TMC perfusion there is much

less data. You can see that for the CT FFR, there's a range for sensitivity, but the specificity ranges is quite a bit different, is has quite a range. And again, there's a limited amount of data on this based on the reviews systematic reviews that we had available to us, and the coronary artery disease prevalence ranges are quite high. Let me then talk a little bit about the inter-rater reliability in general for CCTA SPECT PET and echo. There is very good inter-rater reliability and intra rater reliability. FFRCT, the data suggests that the range maybe from fair agreement to almost perfect again for inter rater. And again, this is based on unless evidence that we have for the others. And I think we'll just go ahead and move on. So our literature search was very broad it encompassed over 16,000 citations from which we were able to include any one studies across 212 pop, pop, publications. Most of the evidence is in CT CCTA that's where a lot of the most recent research has been. And we have as the main evidence base 36 studies across 66 publications. Again, we always do a very broad reach for supplemental information on safety which includes observational studies. And then we had a fair number of sources for a cost effectiveness. So I'm going to start with CCTA versus quote functional testing and talk about the first four key questions. There's a lot more detail again in the dependencies and in your report regarding the different characteristics of the patients in the studies. And one of the comments earlier this morning, is that we didn't include patients with no coronary artery disease. That was not by design, we sought studies of that. We are at the mercy of the literature when it comes to reporting, the pretest risk probability, and how the studies report, the different patient populations and I'd like to point out that if you look on the left-hand column patients with suspected acute coronary syndrome. Again, we made these, these bins, based on how the literature was reporting things. You can see that eight of the trials looked at patients with quote low to intermediate risk, and I believe it was Dr. Liu and bought Dr. Chen pointed out there are a variety of ways of looking at pretest probability that was evident in the studies that we included. There were a lot of different ways of doing it and a lot of different ways that it was reported. It would have been impossible to harmonize into specific bin for how things were reported. And you can see for the stable outpatients we have fewer studies but more patients in those studies, and again there was a wide variety of priests pretest risk for those patients. You can see the age ranges, you can see the cardiac risk factors that were represented again a fairly broad range across study so. As pointed out previously there's a lot of heterogeneity in the patient populations and our, our goal was to make this as high level as possible for that. If we take a look at the study characteristics for patients with suspected coronary acute coronary syndrome, most of them were based in the emergency department or similar setting. There was some inpatient settings in one where patients

were evaluated and more of an outpatient setting, outpatient settings in stable outpatients with suspected coronary artery disease. We just classified as stable outpatient settings again. There were some nuances and differences and how people determined the pretest risk. Most of these studies, did not include substantial amounts of individuals with known coronary artery disease. There is a table in the report that discusses what patients populations were mixed and not really pure suspected and have some mixed known coronary artery disease, but again you can see the types of tests, I would like to point out that we have a category of any functional testing and that's how it was described in the studies. The studies may not have given us information about what specific test or what proportion of tests in the functional testing category, were used. And you can see the rest of that. I'm going to spend just a little bit of time on this particular slide I won't spend as much time on a lot of the forest plots but it's important to orient you. We attempted to describe the patients who may be presenting to the emergency department with acute suspected acute coronary syndrome, to an emergency department or similar setting. And then also the stable outpatients, there was no interaction between statistical interaction. When we pulled these studies together so most of them we will take a look at the bottom line, the, the, the pooled estimate. You can see that there are more studies in the acute population than in stable population but again there's a higher number of patients in the stable population. And as was previously discussed we discussed by Dr. Chen, there was one study the Scott Heart Study, where 85% of the patients received exercise treadmill testing. And that was considered the standard of care in that system in the UK. And so it's not necessarily a pure CCTA. vs functional type of test. And so, that raises the flag of clinical heterogeneity, that we may want to consider. If we go ahead and take a look at the rest of the plot here you can see that we have listed the competitors for CCTA as described again by the test, the level of follow up in terms of time. And then you have the number of events and total population and the like. When we excluded the Scott Heart Study because of this concern over clinical heterogeneity. You can see that, in contrast to all studies, there was no strong clear definite association with decreased risk of myocardial infarction or decreased observational observation of myocardial infarction. When that study or other studies that compared to exercise treadmill testing specifically were excluded. Based on this, we felt that there was no clear difference in reduction of MI related to these tests that the strength of evidence was considered to be moderate, partially because some of these are fair quality trials, some are poor quality trials. And then also the stability of the, the exclusion is here as well. So, this led us to that conclusion of no clear difference in myocardial infarction, by testing strategy. With all on to all-cause mortality, this

one's a little more straightforward I would like to point out though that six of the trials had no events in either arm. There were no myocardial infarction events in three other trials in the previous slide, but this probably speaks to the fact two issues, potentially, one maybe the sample sizes of the individual studies involved, but also the, the low pretest risk, and of the studies that were involved as well. Across the studies that could be pulled we can see that there is no difference in either the absolute absolute rate of black heart of all-cause mortality, or when the Scott Heart was excluded. So across populations, there was no difference in all-cause mortality and the strength of evidence was moderate. If we look at ICA referral consistently ICA referral was more common with CCTA versus the other tests, you can again see how that parsed out when we excluded Scott Heart, there was a little bit of an increase in the, in the relative risk not huge, but in the heterogeneity did decrease on we, when we exclude that trial. If we take a look at the use of additional noninvasive testing you can see that across both populations. There was no difference in us, and the strength of evidence was low. There's a lot of unexplained heterogeneity particularly in the stable outpatient population, but again across the populations, there was no difference. We did attempt to look at whether imaging, or, ETT may have been used as additional functional testing was very difficult to do that again. It was not well reported in stable outpatients that appeared to be mostly stress imaging involving radiation, specifically SPECT with regard to those patients presenting was suspected acute coronary syndrome. There was no difference on the use of any noninvasive tested any timeframe after the index test. And you can see the data here for the different timeframes, there was also no difference between CCTA and functional tests for referral for stress imaging, in particular, across time frames we did not do SOE on this. We also attempted to look to what extent testing involved radiation, but this was so inconsistently prescribed, it was not possible to really evaluate. If we look at again key question to relates to clinical decision making, revascularization again was consistently higher and more frequent with CCA is index test. And if we continue along that thread per cutaneous coronary interventions, again we're consistently associated more frequent with the CCTA, and the strength of evidence was moderate again excluding Scott Heart Study reduced reduced our heterogeneity. But didn't really greatly impact, the, the conclusions didn't really change the conclusions. If we look at hospitalization CCTA versus functional test, there are a couple of things to point out in the patient population because patients was suspected ACS may differ from those with stable. In terms of their need for hospitalization. We did not pull these data. So these data, here are for patients was suspected acute coronary syndrome. And you can see there's a lot of heterogeneity partly based potentially by comparator. So,

for those studies that did not give us exact information about what the comparator functional test was, you can see that CCTA appears to be favored with lower rates of hospitalization. If, however, you look at studies that compared them to specific functional tests, the SPECT studies suggest that, that decrease that SPECT may be associated although not significantly was less hospitalization, but stress Echo, maybe slightly favored again not significantly. So, but there's a lot of heterogeneity and we didn't feel, we could make any from conclusion about hospitalization at index testing for this population. If you look however after index testing and patients was suspected acute coronary syndrome, you can see that there's really no difference at any time, following that index test. Similarly for patients with stable outpatient and stable outpatients and suspected coronary artery disease, there was no difference in hospitalization, in that population. I'm going to go briefly through safety. Basically most test related adverse events were not considered major, and many of them were considered to be maybe related to the function of the test itself. The stress test in particular, we'll get to that in a moment, but suffice it to say that these may be rare events, and some of the studies may not have been powered sufficiently to detect some other rare events. If we take a look at and contrast related things, again, there may not have been sufficient power to detect rare events in some instances, many of the types of reactions or things related to contrast were fairly rare and transients, there was only one study that reported on contrast inducing nephropathy, but because of the sample size and the risk of bias, we didn't feel there was sufficient information to draw conclusions about that. As mentioned previously, stress test related symptoms were generally rare but most likely expected related to the pharmacologic agents used, and not due to ischemia or major adverse events, radiation exposure is potentially a more important consideration with regards to safety is very ugly reported across our included studies. And so some of our estimates are very rough, and the exposure generally is less with CCTA versus fact that the index test. But interestingly, among those studies that looked at cumulative radiation, it may be higher in patients who have CCTAs index test versus others. It's unclear what goes into that whether it's strictly use of the functional testing or a combination of that functional testing, plus ICA and or revascularization which would have associated radiation, as well. And again, it's unclear whether some of these range ranges may impact, decision making on whether to have a test that involves radiation or not. So again, our estimates are very very rough I would not put a lot of stock into them but they may range at the index test for 1.3 millisieverts to 11, almost 12. And then for cumulative radiation 1.9 to nine millisieverts. And as I mentioned, again we all are exposed to about 3 millisieverts as a course of daily life, annually. So again, I just make that disclaimer that

these are very rough estimates, and it's unclear whether some of these ranges would impact clinical decision making. One of the other issues related to downstream testing relates to follow up with incidental findings. These are very common in CCTA patients receiving CCTA as you see, even if we take a look at those findings that are potentially significant or clinically significant or requiring follow up, that's a fairly large range and denotes increase utilization may be in increased radiation exposure for follow up testing, and of course, there the patient psychological factors that go into all of this as well. If we take a look at differential effects, there's a lot more detail in your report. And before we go into there, I know that with your in service that you had with Dr. Guyatt, I think a month or so ago, he talked a little bit about subgroup analyses. And what we look for when we're looking for differential effects is effect modification or what's called heterogeneity of treatment effect or hereditary heterogeneity of testing effect here, and basically we're looking for, whether or not the effect of an intervention on an outcome varies by levels of a different variable. And if you can look at the left upper side of the slide, we can have an average effect across populations and across factors that shows no difference, but a small population with different can one characteristic or without the characteristic may show a different effect, and then lead us to a conclusion or lead us to at least a suspicion that there may be a differential effect, based on whatever that characteristic is. It sounds simple and straightforward, it isn't. There are a lot of things that need to be considered. And they include whether or not there's a hypothesis about why a characteristic may or may not modify the effect within the role of chances to be considered. The number of analyses that are done, whether there's evidence biologically or from prior work that might suggest there are differences sample size, etc. Bottom line is, these are really hypothesis generating findings, not definitive findings. And I just wanted to point that out as we go to the next slide, and look at the differential effects. Again, there's much more detail in your review. Overall, we don't have a lot of confidence in these in these findings. There are some suggestions that for some outcome sex and diabetes may modify the testing results for some of the outcomes but again, these are hypothesis generating and would require some verification. There is some indication from the studies that age the type of angina and raised did not substantially modify the effect of testing on the outcomes. But again, findings we considered the very low confidence and most of them were considered insufficient. In summary, then for CCTA versus functional testing, the impact on clinical outcomes, we didn't find any clear evidence that there was a difference between testing strategies for myocardial infarction, or all-cause mortality. Cardiac mortality was very very rare, and there was insufficient evidence to really evaluate its frequency, oops, didn't mean to go, or where are we are

sorry I. Where are we. Sorry, I. There we go, clinical decision making. There is evidence from the studies that there is increased use of or increase referral for invasive coronary angiography, and for revascularization CCTA is the index test. There were no differences in downstream testing based on the data available. We did try to take a look at medication initiation and change, but as discussed in the report in some detail, there was so much heterogeneity across studies, it was not possible to make any definitive conclusions about what did change how that changed, and whether or not the extent to which the testing was really responsible for that change so the evidence for that was insufficient. With regard to hospitalization at the index testing stage for patients with suspected acute coronary syndrome. We found that the evidence was insufficient we discussed that there are no differences after that index testing in either the stable. Patients are those who was suspected ACS in terms of safety again test specific adverse events that are serious are very rare radiation is important, an important consideration and there's appears to be a little bit of difference between whether you're looking at the index test or the cumulative radiation incidental findings again are common and require follow up. And again, the differential effectiveness or safety, again, we don't have a lot of confidence in the information that is available. Not going to spend a lot of time talking about this, but we did look at other CT related studies. One was a prospective nonrandomized study on FFRCT, that was conducted. There were two different cohorts of patients, one cohort was a low-risk cohort of patients, there was a hot other was a high-risk cohort of patients. The high-risk cohort was scheduled for invasive coronary angiography the lowest cohort was scheduled for noninvasive stress testing. And because of the way the study is reported and the design, although it was a reasonably good study we felt that the evidence was insufficient to draw conclusions. One of the reasons is that not every patient that that wasn't either of those groups, and so was subjected to the FF RCT. We did find that there was some evidence to suggest that when you combine the FFR with the CTA that there may be a cumulative radiation that is as high them versus a noninvasive testing strategy. Again, we did not find any prospective comparative studies for CT perfusion in your report again, we did compare CCTA strategy versus direct referral to ICA briefly summarizing it here for the clinical outcomes, there was no difference in myocardial infarction, all costs are all cause mortality again cardiac mortality was not evidence to make any sort of conclusion about with regards to key question to the clinical decision making, CCTA was associated with a decreased risk risk of having ICA without obstruction and of PCI for any revascularization but there was an increase in overall testing. Again, safety, not a lot of information to hang our hats on two major adverse events related to bleeding, with the ICA, and again fairly

rare events. So we're going to go on to SPECT quickly. There are fewer studies for SPECT and echocardiography, partly because these have been established and there hasn't been as much funding or push, or impetus to do big, randomized control trials, as there has been for CCTA. So we have four studies, two studies, looked at SPECT versus echo two studies look at SPECT versus exercise ECG and you can see again there is a broad range of patient pretest risk associated described in the studies. And you can see again, some of the patient characteristics and distribution cardiac risk factors will move on. So looking at the clinical outcomes myocardial infarction versus all versus testing you can see, we've again divided up versus Echo, and the studies versus exercise EKG across all these studies we felt that, because of the low risk of myocardial infarction, there may have been lack of power to detect that combined with risk of bias concerns. The study, we felt that the information was insufficient in terms of the overall strength of evidence. With regards to mortality, there was no difference at all-cause mortality across these studies, but the strength of evidence was low, again, for cardiac mortality, we felt that the information was insufficient. Looking at SPECT vs functional testing in terms of use of ICA a referral for ICA, we see that there's no difference, but there is some inconsistency when you take a look at some of the individual studies, versus echo in particular. So that contributed to our overall strength of evidence being low for that outcome. Looking at any additional testing, we felt that there was so much variation in the data inconsistency and imprecision combined with risk of bias that we felt that there was insufficient strength of evidence to draw conclusions. Looking at revascularization, there was no difference in revascularization across four studies, and there was no difference when we looked at PCI or CABG separately. In terms of cardiac related hospitalization and subsequent emergency department visits the cardiac related hospitalization, you can see that there was no difference. The strength of evidence was low with regard to emergency department revisit again the strength of evidence was low. And you can see that there was no difference between testing, testing arms for one RCT. There were two interesting studies that we included, I'm not going to spend a lot of time on them. One was a study looking at SPECT as a first line of testing versus what was called nice guideline directed care. The nice guideline directed care is interesting from the standpoint that they use predefined testing pretest risk categories to determine what test patients got. And so patients who were in a pretest probability pretest risk probability up, I apologize. My cat jumped up here and I tried to pull him off. And it's one of those, one of those fun parts of trying to work from home, virtually so I apologize. So the nice guideline directed care, like I said the pretest risk categories that were used patients receive specific test, based on their pretest risk. So those at lower pretest risk received cardiac CT, if they

were in the 10% to 29% pretest risk, and from 61% to 90% they went directly to ICA, and then the people in between, basically got SPECT. That was compared to SPECT as the primary test. And when we take a look at the data there was another one, another study that looked at clinical assessment only versus SPECT, and unfortunately we felt that the because of the unknown consistency and lack of precision, for some of the outcomes, we could not draw any conclusions about the clinical outcomes of myocardial infarction or mortality. If we go on to looking at ICA referral ICA referral was lower with SPECT, and to have this in these two studies again they are very different, both in their comparator, and there's a lot of, there are some heterogeneity in terms of the point estimate. And so we gave this a risk of overall strength of evidence of low. And they're both kind of saying the same thing. Both suggests that SPECT may reduce ICA. That doesn't lead to a clear diagnosis of obstruction, one talks about it in terms of ICA not showing obstruction, and the percentage of patients that didn't show obstruction for each testing strategy. The other refers to it as unnecessary invasive coronary angiography, but the strength of evidence is low for that. In terms of revascularization, there was no difference across the studies for each either study across the testing arms but the strength of evidence was low with non-additional noninvasive testing and hospitalization, again, there appeared to be a decrease frequency was SPECT for both of these outcomes on the risk, the strength of evidence overall was low compared to expect with ICA, we felt that the evidence was insufficient for the clinical outcomes. And with regard to noninvasive testing we felt it was also insufficient. And we noted that with regard to any revascularization there was no difference that the index test but, but there was some indication that there was somewhat lower revascularization at the longer timeframe. There was no difference between the testing ours with regard to cardiac specific hospitalization. However, if again look very briefly at the test related adverse effects again they seem to be rare, and many of them are related to the sort of expected responses to the pharmacologic agents used for stress. So in summary, across SPECT versus either echo or exercise treadmill testing. Again, the impact on clinical outcomes, was really insufficient for mortality and myocardial infarction. There was no difference in all-cause mortality, but the strength of evidence was low. With regard to clinical decision making, ICA referral, we didn't notice any significant difference again strength of evidence was low insufficient evidence for additional testing, and no difference in revascularization or in cardiac hospitalization. And again, there was insufficient information on radiation, and the test specific adverse events appear to be very rare. When we look at those other two competitors, just very briefly, you can see that we felt it was insufficient evidence with regard to the impact on clinical outcomes ICA referral may be very may be different in this. When

we compared to the nice guideline directed care and the clinical assessment, it may be lower with SPECT in terms of additional testing again, it may be lower with SPECT compared to clinical assessment only, but we could not draw inferences from the studies, comparing the for ICA, and for revascularization again when we compared the nice guideline group, and the clinical assessment group there was no difference. There may be in the comparison with ICA less revascularization respect. And again, with regards to hospitalization, there was no difference when compared comparing a strategy of SPECT versus ICA. And there was maybe some suggestion that clinical assessment along a spectrum there was lower risk of hospitalization with this with the SPECT as a first strategy. Stress echo I'm going to go over very quickly. Overall, across the five studies that we had, partly because of sample size and risk of bias we felt that the strength avoidance was insufficient with regard to risk of MI for all-cause mortality. Similarly, it was considered to be insufficient and for cardiac mortality as well. Looking at ICA referral, if we look at stable outpatients, there may be a little decrease risk in our say referral was stress echo based on one RCT in patients presenting acutely to the emergency department, there did not appear to be a difference but as you can see there are there are some heterogeneity here, and one for quality study has a lot of variation. We felt that the strength of evidence was low in these in these in this setting. Regarding...

Janna Friedly:

Dr. Skelly I just wanted to make sure you're aware we are a little bit over our scheduled today. And we are scheduled to have a break now so I just want to make sure that you're aware I think we can continue with the slides but if, if, if you can maybe keep that in mind and.

Andrea Skelly:

Okay, last year. Okay, I will I will cut to the chase. With regards to any additional noninvasive testing, it was insufficient evidence across the patients with acute suspected acute coronary syndrome, and there may be less testing with stress echo but the strength of evidence was low. There was no difference in any revascularization or hospitalization across the studies of stress echo across populations. And when we take a look at the stress eco versus direct coordinator coronary angiography referral, the evidence was insufficient. And also, for any noninvasive testing versus the ICA stress echo versus ICA was insufficient. We do know that there was no difference between test. Testing arms for revascularization or hospitalization. There was only one poor quality versus standard care and studied the evidence was insufficient. Again, as with the other stress modalities, test related adverse events are rare and may actually most of them be related to the stressors that are used on the strength of evidence was low for that. So in summary, with regards to impact on clinical outcomes, again insufficient evidence, we just talked about the

ICA referral, maybe being a little bit lower, with stress echo but no difference in stable outpatients but no difference in acute ACS patients and noninvasive testing, again, maybe a little bit lower frequency with stress at one stable patients but there's not sufficient evidence for the acute patient population, no difference in revascularization hospitalization and again adverse events are rare. In summary, then for the standard of care and ICA, again, I'm not going to go over it most of its insufficient evidence. distress echo versus ICA, there was no difference in any of the outcomes for revascularization or hospitalization, but the strength of evidence was low. If we look at PET. This one's fairly straightforward the one new study which was a high-quality study suggests that ICA, maybe not different, at any time frame. Same thing with any revascularization in patients with known coronary artery disease, there was the only the one study and it was insufficient to look evidence, with regard to those clinical outcomes. The one study that was a poor-quality study included in the prior report was a mixed patients with patients with population that was mixed those with suspected coronary artery disease and know coronary artery disease, and neither of the studies provided information on safety. I'm just going to quickly go through cost effectiveness, giving a bottom line that current conclusions are really very difficult, because of the difference in testing strategies that were evaluated. And there are a number of limitations across the studies, there's a lot of heterogeneity in the data sources, how things were wobble clinical pathways and the assumptions around those that lead to variability in the. I service incremental cost effectiveness ratios and across many of these studies the pretest risk probability and the assumed accuracy of various tests, including coronary angiography varied across, and these things impacted the cost effectiveness and you can look at the the other limitations listed here as well. And I put a lot of detail in the report on some of the shortcomings. So in summary, when we look at CCTA versus any functional test with regard to advocacy for key question one, we felt there was no difference, clear difference in an MI the strength of evidence, all-cause mortality. Moderate evidence of no difference, again, CCTA was consistently associated with increased a referral for ICA and revascularization for hospitalization, again we did not will across populations, but there was no difference at any time frame after index for hospitalization for either the acute ACS patients suspected or the stable patients and subsequent emergency department visits there were no differences in patient population in testing arms for the acute ACS patients with regard to other modalities, the versus the ICA again, there were no differences in clinical outcomes. there may be some evidence to show that ICA. Maybe there's, there's not as much inappropriate use blacks maybe not the best word but there's less opportunities of not showing obstruction with SPECT, and then any

revascularization maybe lower with SPECT versus direct referrals ICA. Again, related to the FFR, we felt that there was insufficient evidence for all the clinical outcomes, and that the radiation exposure may be increased with the combination of CCTA with the FFR for any functional testing, again, the safety, compared with CCTA. You can see here again, the primary issues related to exposure to radiation and incidental findings are the, maybe the primary concern as there are no adverse events. There's very rare adverse events to the testing , as you, as we saw before. For safety versus ICA again, the most events related to the ICA not noninvasive test. And with regard to SPECT for efficacy we have all three comparator sections here. And you can see that in general, there's no difference between SPECT, and any functional test in the key question one outcomes, or the key question two outcomes. The nice guideline directed therapy and the clinical assessment, you can again see that there's maybe some low strength of evidence for some of those outcomes, however, again these may not be very common clinical scenarios in the US, and then you can see versus the ICA that SPECT may be associated with lower risk of any revascularization. And again, safety adverse events are rare, and many may be expected, due to the evaluation, due to the medications used for stress. Stress echo again very briefly, I see a referral maybe less when you compare it to exercise EKG in stable outpatients but maybe similar in the acute care setting. Use of noninvasive testing, similarly, maybe decreased compared to ETT and revascularization that remote differences, and we'll go on. So stress echo safety again bottom line is some of the symptoms are mild transient and serious adverse events are rare. And for PET, again, very limited information as you see on the slide here, cost effectiveness again from conclusions, we don't feel are possible. And I'd like to leave you maybe with some considerations. I know this has been a long discussion. I think one of the issues that I'd like to come back to regarding pathophysiology is that the identification of an obstruction or the degree of an obstruction may not necessarily correlate to the patient's symptoms and the presence or degree of a ischemia or functional impact. And again, ischemia may be present, without overt observation of an obstruction. And it may not be evaluated by an atomic testing of the patient pretest probability and other factors may impact the choice as terms in regard to applicability there is a lot of heterogeneity across these studies in both patients and their pretest risk, but the equipment and testing and study methods as well. All of these tests require substantial expertise, and this is reflected in the RCT to the same level of expertise may not be available in all clinic clinical settings and state of the art equipment may not be available in all settings. I would like to point out that, yes, there are fewer studies specifically comparing stress Echo, and SPECT to other modalities, you know, other than those CCTA. This is in part because they are, these

are maybe more established proceed at diagnosis and. Some of these may also as you notice, reflect older studies and older technology and research methods. And so the fact that some of the things may be insufficient may not necessarily reflect the state of the art and there's been differences in research funding opportunities for CCTA again all of them require clinically are all are considered clinically better than exercise treadmill testing. So that, in a nutshell, my little Gecko friend is asking if there are questions but we may want to reserve those till after the break.

Janna Friedly: Yes, thank you so much for that I'm Dr. Skelly, and we are running a little bit little bit behind schedule. So, if it's okay I would like for people to be back by 1110 which is a little bit of a shorter break. So I apologize, but we have a lot to discuss so I want to make sure we don't get too far off track so we'll hold questions until 1110.

Andrea Skelly: Okay, great. I will end my slideshow.

Janna Friedly: Okay. It is 1110. So, Welcome back everyone. Sorry for the short break. We will have another break for lunch time, very quick lunchtime. After the next section, the agenda. At this time, we have, we have about a half an hour for question and answers from the committee. Regarding the evidence that we've just reviewed. And then after that we will have our, the beginning of our discussion and and really framing the the decision. So now's the time for people to, to ask questions of either Dr. Skelly or if you have questions for the clinical experts as well. That can be done now. If you would like to raise your hands. I can monitor the, the chat box for hands that's probably the easiest way to do this. So I see Tony has a question for..

Tony Yen: My question for Dr. Redberg and also Dr. Kirkpatrick because I am not a cardiologist, is how good is CCTA was FFR? That's the part that I don't really quite understand very well. From my understanding from what the presentation is showing us, and a little bit about the literature is is that that's really just a post processing sort of thing that actually occurs. And that's CCTA with FFR not like CCTA with a pharmacologic stressor, am I correct about that? Just really trying to understand these different modalities, a little bit better.

Rita Redberg: I can comment Jim or did you want to first that's fine.

Jim Kirkpatrick: No, go ahead.

Rita Redberg: And maybe Jim has more details that CCTA with, you know, FF R is supposed to be a way to look at the sort of functional significance of the CCTA. I mean, I think. At this time, a lot of the questions besides the technical questions which I think Andrea and Chris mentioned like the processing time you know the images, generally have to be sent to

Redwood Shores, in California and sent back so not really good for quick decisions but then it's in general I would say for CCTA for people where I think that the really important question is should do they need any tested at all because it's a low risk population. Now we have a tendency to do. We're going to do an atomic testing do use invasive coronary angiography for people that you think have a serious chance of having obstructive disease because of this predilection again not based on evidence of going to the Cath lab right away with those patients so this, the CCTA is is additional processing additional time and I think I would say investigational. To me, the real question is going to be, should there have been any test in this population where I see it us now. Jim they have more comments.

Jim Kirkpatrick:

Yeah, certainly the FFR is sort of an additional issue to try to overcome the limitations of an atomic only test to try to say what is the significance of this legion is approximating what we actually do in the Cath lab or I don't do it but other people do in the Cath lab in order to try to test functional significance and there is some benefit sometimes in in doing that we think but, but that's when you are sort of already in the Cath lab with catheters and and then you've got illusion that's kind of borderline and you want to know whether you should do something about it. Usually at that time, from the CCTFFR is really sad it is something that's not super well established in, and just by the nature of having seen the images off it's not exactly available in the same way that we think of it up and available and there's obviously an extra cost, as I understand associated with that as well. And the evidence base I think is Andrea went over very nicely is, it's really not there quite yet. So, it may have some promise in the future but I don't know that that we sort of could look at that as an equivalent thing to a functional test, and it's certainly not invasive FFR at this point. The thing that I believe and I'd have to check on this but I think that there, there's a lot of different ways to do coronary CT imaging and there's some faster modalities and so much radiation during parts of the cardiac cycle and contrast and all of that sort of thing whether or not you have to give extra medicines and some of that depends on how fast your scanner is, I believe that even with those faster things you do have to have more information, or the coronary FFR would for just looking at the coronary arteries themselves.

Tony Yen:

Thanks.

Janna Friedly:

And I, and I see Christoph Lee has a question, so.

Christoph Lee:

I just had a follow up question to Tony's also for Rita. Quickly glanced at the new ha guidelines and just looking at the numerous workflows for test choices. It looks like they mentioned FFRCT in several places in in their algorithms for acute chest pain and intermediate risk with known

CAD. And I'm wondering, are there scenarios where, you know, patient will get a seat CCTA, and then you would send for the FFRCT to avoid the Cath lab? And that's what looks like in the New Age a guidelines I'm just wondering if you guys could comment on that.

Rita Redberg: And I mean reason I could think of to do that is if you don't trust the CCTA I mean if you believe someone has coronary disease, why wouldn't you just treat it you know if they had, we're assuming they have symptoms now you think they have obstruction I would start them on medical management, I can't see a reason you would want to do an FFR.

Jim Kirkpatrick: Yeah, I think that the thought behind some of that and I was involved with it so it's hard to say that I think some of it's a bit of expectation that this is going to potentially take on the role that's currently in the Cath lab of finding a lesion for whatever reason and then trying to figure out the functional significance. And then whether or not you should go to the Cath lab and get it opened up. I don't think there's any question that the patient should be started at medical management in that setting and if that's the goal then I would agree with that that's kind of not all that important because you already know they have chest pain or some kind of symptom that is suggestive of what's going on but is this you know revascularize or no, I think is what they're getting at. I think that they are showing a lot of optimism about the technology in that and that has been controversial in the cardiology world.

Tony Yen: Thank you both.

Janna Friedly: Quiet group today.

Rita Redberg: With a comments if people are thinking of other questions, please. I just, I mean obviously Andrea, is like, four reports in one which was an amazing but just on radiation risk I just wanted to note that in particular because some of those tests people were suggesting for micro vascular disease which tends to be a question and younger women that there is a clear as radiation risk and increased cancer risk associated with medical imaging, and that that risk is most greater for women than for men and greater for younger people, and for older people so it's, I mean, the IOM report on breast cancer a few years ago said that medical radiation was the number one reversible causes the breast cancer. And so I just think it's something to keep in mind. in the overall picture of looking at these tests.

Mika Sinanan: I may concern and I had a question for, I guess, Jim, I would anticipate that the availability of these noninvasive tests would mean that patients who eventually make it to an interventional cardiology test to having an angiogram would be more selected and then the rate of positivity would be higher. I don't think that was really captured in the information the

rates of doing them were present but the rate that they were positive that they found a lesion that either would change diagnosis or management or require a stent was greater. Can you comment on that I read as well?

Jim Kirkpatrick: Yeah, this is a really interesting question and it's in evolution, quite a bit so we have a number of different factors that play into this one was sort of what I was going to bring up in part of the other discussion to is the fact that we do not really have super firm evidence that trying to revascularize somebody who has not had myocardial damage is actually going to help long term. So a lot of what we do in revascularization at this point is for symptom control if our medicines have not worked and and do that now that's controversial and people who, open up a lot of arteries would say that just because the study it hasn't been shown that way just because of study technique and all that sort of thing but that's sort of currently where we're at with that so there is even at this disconnect between finding a stenosis and then what to do about it and search and certainly some kind of functional assessment is generally felt to be important in some of those cases. But you know it traditionally it's been what read up to 40 50% of invasive coronary angiography that has not found any obstructive lesions at all. And that's kind of considered just basically the way you do business, and obviously that has spurred a lot of the development of the noninvasive testing to try to figure out if we can get that number down, select patients better, even though it's low risk what we're doing the cath lab nonetheless. You know, we can if we can avoid that avoid the costs avoid the small risk we should do that with a more noninvasive imaging techniques so I think we're still in the midst of data generation despite many many trials and and reports and everything else in the literature on that I'm not sure we still have a good handle on being able to answer your question.

Rita Redberg: Certainly I agree with everything that Jim said, I will say, I did my cardiology fellowship that Presbyterian Hospital in New York in the 80s. And at that time, it was a 10% normal rate in the Cath lab and I think that was pretty standard. You know that number has crept up quite a lot like quintupled now and for a lot of reasons, but a lot of it is that a lot more people who shouldn't get any tests are getting a test and then if they have anything they end up going to the Cath lab and as Jim said, you know that's not an evidence based practice people who have coronary disease, do equally well on medical management there's no, you know, there are several randomized control studies the latest thing ischemia that show that but multiple studies. I'm showing that and one only one of those was blinded the orbit of trial which actually showed no benefit on symptoms for students as well as no benefit on quality of life or treadmill time. But having said that, you know, I think part of the generation of the

appropriate use criteria for the American College of Cardiology was that payers wanted to start using percent normal calf, as a quality measure and that was opposed by the Society for cardiac angiography and intervention and they came up with this idea of doing appropriate use criteria. Instead, but I think so I think that is, it's a really important question, but I think you, you would get a higher percentage of you stopped referring all these low intermediate pretest probability people for invasive cardiac angiography, because they should. They can be treated medically. And a lot of them don't need the invasive testing.

- Mika Sinanan:
- Thank you that that's that's a helpful perspective. My, my second question is, we talked about invasive testing and noninvasive testing and we talked about anatomic and functional testing. So there, but they're not exactly the same they overlap in both directions. Right. So there are anatomic noninvasive and their anatomic invasive and there are functional, like the FFR functional in base. So, my point is, my question is, can you characterize the role between functional testing, and anatomic testing? What, what are we looking for that's different between those two groups, both of you?

- Rita Redberg:
- So I would say the real distinction and you're absolutely right. You know, like everything we have more and more options and that includes for testing now. But the real still no overlap between functional testing or an atomic testing so anatomic means you're essentially just looking at pictures but you don't know what that means. And that's actually I think what Jim was saying why they've now added the FFR to give you a functional component, in addition to the anatomic component, but basically anatomy is you're just looking at the coronary anatomy doesn't tell you, so there are people that have findings, you know, even have obstruction in their coronaries they have no symptoms. There are people that have symptoms, they have no obstruction in their coronaries. And so functional testing allows us to say, particularly with the imaging, is that chest pain the angina says, the more typical it is the more reassuring it is but is that just pressure that you get with exercise correlated to an area of your heart that is not getting blood flow at that time. And that's the functional part, so you can look at for a treadmill echo you look at the ECG. You see, ST depression, you look at the echo you see this a wall motion of the validate and the person had chest pain, then you can say very confidently that chest pain is due to a blockage in your coronary artery and atomic test, you can feel blockage but you're not going to see, you're not going to know whether that person has any symptoms, or if they do have symptoms, is it related to that or is that true true and unrelated. I hope that answered your question and again I'm sure Jim has more comments.

Jim Kirkpatrick: I think that's a great, great way to look at it the one other component to this is prognosis, that if we do have certain findings either on a noninvasive tests or to some extent on invasive tests that does change our assessment of what's going to happen to the patient. And a lot of times the prognosis is not necessarily going to I mean depends but it doesn't necessarily say well we're going to do something different from a medical standpoint, and depending on the situation we may even revascularize something that is a symptomatic but it looks really really bad like a left main lesion and something like that. But, but I think in many ways we still kind of have to think of those as two separate reasons why we do these tests, and the information that we get out of it are there, they might overlap and they might actually inform what we do but sometimes they're also distinct, you know, if you have a normal treadmill stress echo for instance and you've reached a very good heart rate and you've done well on it you don't have anything at all no EKG findings no echo findings, nothing, then that's actually a really good sign. Even if you have some chest pain it does suggest the chest, we may not be doing a coronary disease but that is your prognosis is kind of even independent of that coronary disease, to some extent, doesn't mean that you're going to say well you don't need to take a statin, you know do you know that those are going to be determined on other sort of risk scores, potentially, but, but it can actually be helpful to know that information going forward, especially, I think in the geriatric population when, when we do things to people we tend to have more complications.

Larry Birger: Would it be fair to draw an analogy between the functional and anatomic testing here and something, maybe a little less exotic like, what somebody knee films look like on an X-ray versus how well they can hike or mount stairs.

Jim Kirkpatrick: Yeah. Yeah, for symptoms absolutely that I don't know if you know so if you see something bad on a knee film that means that you're going to end up with a knee replacement eventually, and there's a prognostic component to it that's quite the same but, yeah I think, I think that does make sense from the standpoint of symptoms.

Mika Sinanan: We've heard a lot about the heterogeneity of patient populations and the need for customizing management, especially from the outside commenters, do all, do both of you use all of these modalities in certain situations or are there some of the modalities that you pretty, pretty much find redundant, not useful, or not cost effective?

Jim Kirkpatrick: But I think that's a good question and there's, you know, all of us have our biases so I directed Ecolab I don't do nuclear so most of my stress test tend to be echo. When imaging is involved that said if I have a patient who I'm worried about going in the can't exercise worried about going

into uncontrolled a fib, and you know that I need a functional stress test, certainly makes sense to go for nuclear and I have absolutely ordered nuclear testing and it no longer shocks the fellows when I do that, I think you everybody kind of has the thing that they're familiar with the one thing that I do think it's important not just from my particular standpoint and I've ordered CT and you have ordered them all basically, I think part of the thing that needs to be remembered is what is the local expertise and all of this, I think we've touched on that before but you know if you have confidence in the scanning and the interpretation and the reporting, you're going to be ordering that test or at least going to have it in your arsenal. If you don't have confidence in that for whatever reason, your local people just are not don't pay attention to it don't do a good job have all the equipment, have bad scanners, whatever it is, and you really shouldn't be using that it shouldn't be in, in your quiver, and you should be going with the thing that actually is working the best at your local institution.

Rita Redberg:

No, I agree with everything Jim said, I did train in nuclear as well as an echo, I do when I order an imaging test tend to favor echo because I don't like to subject patients to the radiation it's also a little bit faster but certainly if you're feeling more comfortable with nuclear, you know, locally, that's fine. I would say for cardiac CT, I think, as I said, a lot of those patients to me didn't need any tests at all, they're in a lower intermediate, you know, very precise probability and I think the functional data is so much data really want to know what does this mean to the patient. And you get the functional time, how much did they have, where did they go on the exercise test you know somebody who can do nine minutes on a boost protocol is much better safe and someone who can barely walk a minute, no matter what you see. And so the functional testing is just a lot more useful to me, the one time I have occasionally tried to use cardiac CT but have been disappointed is in pre opt patients who I'm sending for valve replacement and there is this non evidence based feeling everyone who's going for over placement should have an angiography and so at that point, that would be the only reason to subjects like a middle aged person should coronary angiogram and I've suggested to the surgeon well how about a cardiac CT, and the surgeons of generally at least, where I work, don't want us cardiac CT, because they don't trust, they say it's not reliable enough and they want to have an invasive coronary angiogram. So, and I rarely use that a PET scan it's a lot bigger deal and not generally necessary. So I hope that answers your question.

Mika Sinanan:

Thank you very helpful.

Janna Friedly:

And can I ask a sort of related question to that because you've, you've now said it several times about the local expertise and variability but but

yet in the data least the we're looking at the inter-rater reliability of these different tests seems to to be fairly consistent and high. Is that is that just because these were controlled studies with, you know, very set protocols and experts in those those studies versus in an uncontrolled environment is that, is that how you explain that difference?

Rita Redberg: That is probably true.

Jim Kirkpatrick: Yeah, yeah, some of it depends on how you're looking at the data so generally when when these studies are done across multiple institutions which have maybe varying degrees of excellence and doing the imaging said. Well first of all I think a lot of the studies are actually done a places where you kind of know they can do it to begin with, so I'm not sure. They really are testing everybody, but then oftentimes they're actually read centrally by a core lab and that core lab is at least using experts interpretation, if not the expert scanning. And of course there are sometimes studies that are thrown out for bad image quality and, and that sort of thing so you know be sort of a secondary analysis to be able to answer that question from some of the larger trials, but but I think it's a really good question to ask and having seen some of the studies that come through even from reputable places they're not always the best quality, even in these these big clinical trials so that that would be the other thing that kind of mitigates against that.

Janna Friedly: I have another question. And again, I have just had time to skim through the the clinical practice guidelines that we just got access to it was published on Friday. But, but I think for me, a lot of the sort of crux of the discussion is, you know we're trying to look at each of these different imaging test functional and and atomic tests, and look at their comparative sort of effectiveness and think about coverage decisions related to each one of those specifically. It looks like in the, in the clinical guidelines that there's as you have all pointed out that there are, you know, sort of advantages and disadvantages and different patient populations and scenarios for each one of those different tests and you've just said that, although you have preferences for one there are there are circumstances for each, each one of those different tests are those clinical guidelines that came practice guidelines that were published do those have in your mind, if everybody were using those clinical guidelines as as written, does that go far enough to answer those question or to help direct people to which tests to use under what circumstances and, and, and have sort of a rational approach to using those the various tests?

Jim Kirkpatrick: Well if we're in a bit of a complicated situation because there are some appropriate use criteria that are going to come out and have not been out yet and that kind of addresses that question a little bit more

specifically, then the guidelines, the guidelines is I sort of read it. We're kind of a return to, let's actually figure out what chest pain is and how to treat it and so it's kind of a, it looks like they kind of started at square one and with the very basic building blocks and then they said, the imaging parts actually sort of a smaller part of that, and how to use that and they seem to the big change I think was, you know, bright along the lines of what has been saying this whole time, is that if it's low risk don't image. You don't need that you can do a risk assessment if you want to image for risk assessment, that's fine, and doing the coronary calcium score or the, maybe the exercise treadmill but you don't really need to do that you have to wait until it intermediate when you actually order that test it's putting a lot on those clinical risk scores and risk predictors not only a bad outcomes but also having coronary artery disease that that really should be the first step. So I is, and then they don't really get into much other than they do make the point that, as has been mentioned before, older patients tend to have a lot of current calcium to me but since before this really complicates the use of coronary CT, and then younger patients generally they don't have as much and so that might be a better test and those patients. And then the point so we've just been making before about local expertise and everything else. But, but I wonder if kind of the appropriate use criteria might be the next sort of thing to consider in comparative testing.

Janna Friedly:

And those the appropriate use criteria that are going to be coming out is that, did you did you mention when they were coming out and I don't know, that's a good question in the, in the next few months or year to year is it. Do you have any ballpark of what what kind of timeframe?

Jim Kirkpatrick:

We're not in I know so I don't really have a good sense I shouldn't speculate. Okay, and...

Janna Friedly:

Well it's it's helpful for me it's helpful to know that that those are coming because that, that definitely, to me, is important to our discussion. And also, it would be helpful to know if maybe there's, there's no way that if there and I'm assuming that those those appropriate use criteria are going to be based off of the exact same evidence and literature that we were reviewing there isn't anything additional that's being used to create those that we have not that we have not been evaluating today. I don't know if there's any way to know that specifically if you're not part of that process.

Rita Redberg:

And they more or less the same I would say you're not going to find a more complete evidence review I don't think that was the one Andrea and Erica did the appropriate use criteria generally use expert consensus, as well as evidence so the variability would be to to that been seen. Let me just make a quick comment on the evidence report.

- Andrea Skelly: There are things and we have not had the time or ability to look at all the references in the new guideline. I would point out that for most of the made that we are not aware of any major study that was not included in our report, and there are studies that are report that are not included in the guideline. And I would remind people to that the purpose of a clinical guideline is going to be very different than an evidence report that used here. And there's in the making of guidelines and Dr. Kirkpatrick and Redberg can probably speak to this better than but in my experience with some guideline work in the past, is that there is more interjection of political perspective and discussion of the evidence in ways that are probably not going to be reflected in and evidence report like this. So a one to one correspondence between even an appropriate use criterion, or the guideline itself would not be expected. So, again, doctors Redberg, Kirkpatrick they have different intake input on that.
- Jim Kirkpatrick: I can't say it any better than you did, that's excellent.
- Mika Sinanan: Janna, question for Dr. Chen, from the agency reviews is that something we should talk about now or should we hold that till after the lunch break?
- Janna Friedly: Now I think now would be a good time to do that but we don't have a lunch break until after our sort of initial discussion about decision, so.
- Mika Sinanan: Okay, thank you so you're getting back on video. But my question is could you just summarize what the key differences in your current recommendations are relative to the old recommendations coverage recommendations?
- Chris Chen: Absolutely. And so to do that and might just share my screen again. Because this was a myriad of changes and kind of anticipated this discussion to so my screen. So, can you guys see this okay? Yeah. Okay, so the stress echo there was no prior decision. And so this is all de novo new SPECT. The old decision was for symptomatic at high risk of coronary heart disease, or low to intermediate, and you can't do an exercise treadmill test. And then for those who have known CAD so this top one is for undiagnosed. If you have for the old one was for for patients is known monitoring changes and symptoms. And then, not a cover benefit was basically the opposite of that. With the exception of these asymptomatic patients and preoperative evaluation undergoing high risk non cardiac surgery and we did not include this in our condition since it was out of the scope of the evidence report. And so the difference, and then new proposal would be. Sorry, this was changed. So the suspected coronary artery disease and symptomatic patient score intermediate to high risk of coronary artery disease so intermediate to high-risk evaluation of known coronary disease where exercise EKG and stress echo or inappropriate are unavailable. And so the, the new proposal was not just exercise EKG

being inappropriate or unavailable, also stress echo being inappropriate or unavailable. We there, there was no change in the language and the proposed recommendation for PET. And then for CCTA, sorry I was contemplating differentiating between acute coronary syndrome versus outpatient but did not feel that ultimately that was helpful. But for CCTA, the prior decision was low to intermediate risk of coronary artery disease, and this, the new recommendation is intermediate to high, and the prior was for just the ED or hospital setting and the new does not restrict to setting. And then the CCTA with FFR is also another new decision. Is that helpful?

Mika Sinanan: Thanks that that is very helpful. Jim, could you comment on how those recommendations would impact practice in the state?

Jim Kirkpatrick: They jive pretty well with the new chest pain guidelines to what it does say about the imaging in the chest pain guidelines. I think that the difference would probably, and I you know first of all I should mention that I know the University of Washington Medical Center, and I don't have a firm handle on exactly how stress testing or coronary evaluation with anatomic test happens all over the state. But I think that the difference would be in opening this up to outpatient coronary CT, that there would be in places where this is available and hopefully done well. Another option that people could actually pursue under the right clinical scenario. The other thing that it, it seems to indicate would be that stress echoes preferred over SPECT and PET and, and that would sort of be the decision tree is, as you go. You know if you, if you need this test and you need a functional test. Can they have exercise echo or exercise treadmill. If not, then you would go to SPECT, am I, am I reading that correctly?

Chris Chen: Yeah. Yes, that was the proposed recommendation and kind of trying to tear preferential tests in terms of being exercise treadmill. And then stress echo and then SPECT and PET.

Larry Birger: Could I ask a question of our consulting experts regarding the definition of the word symptoms. In my experience, and I think this echoes the colleagues that I've talked to as well, including those in cardiology. You know, you may have a suspicion that the patient's got something going on, particularly let's say with insidious. You know, maybe they're having insidious symptoms but they're not good enough historians, and they deny symptoms, you know, for example, I would have the, the farmers or people that would manage their property and they're out there active all the time and, you know, sure you know I'm an actor guy and so far to get them up on the treadmill and they have dreadful functional capacity, and they've been slowly self-limiting for probably months or years without realizing that that would constitute a symptom and it seems to me that proposes a difficulty for the workup and, you know, comprises patient set

that could benefit from imaging that might not be covered under some of these guidelines so could you maybe even expound my concerns or articulate them better and then address them.

Rita Redberg: But I will just say, I think you're pointing out the advantage of the functional testing is that you can correlate symptoms, um, you know imaging, you wouldn't necessarily need imaging in that circumstance because with a normal EKG you can still read treadmill ECG changes that you would see whether there was a correlation between fatigue reduced functional status, just pressure or whatever it is, with signs of the ischemia on the treadmill test, I mean imaging always does add more information that question is when, when it's that extra information going to be useful for patient care.

Larry Birger: Accepted some of those folks also have enough orthopedic issues that you may not be able to get a good treadmill test even though they can walk around, you know on flat services and so forth so to me at muddies. So that's where a nuke might be nice.

Jim Kirkpatrick: Now the other issue you're bringing up is it actually is addressed in the guidelines, is the typical what I think are best called a typical but really they're not really typical they're just not symptoms that middle aged white males tend to have with coronary schema. And there's increasing recognition that women do have other symptoms they should probably not be labeled a typical anymore, and certainly not non cardiac, but they should be watched for and obviously this includes things like this via, but there's also mentioned that the fact that older individuals may have something may present with just an unexplained fall, and that may be pretty much it no chest pain or real shortness of breath and maybe the summer that's because they're too frail to get around. And that may be their first manifestation of coronary schema that is important to, to know about, and again just to come back that may be that you don't actually open up any arteries, but you will actually think about treating it and sort of preventing things in the future from a medical standpoint. So I think those are all really good points and, obviously, part of the whole thing that the guidelines are trying to do, and what I think a good clinicians have done for a long time is sort of having your index of suspicion appropriately raised, and in considering some of these other things and not just using what sort of the thing that we're all taught in medical school because that is not appropriate and every patient

Rita Redberg: Yeah, I'm just add again, you know, in this time, I haven't been working on heart disease and women since the early 90s I was part of the American Heart Association's Go Red campaign. I have to say I don't think that message is actually very useful that women have a typical symptoms because most of those women with a typical symptom, don't have

coronary disease and they're not going to have heart attacks and I just see a lot of women who come in with a lot of funny symptoms and they don't have coronary disease and, you know, everybody has funny symptoms and everyone has shortness of breath sometimes. And most of the, you know, and so unfortunately I think it was a well-intentioned but not a useful message most you know the biggest symptom predictor of whether you have obstructive coronary diseases still typical chest pain you that pressure with stress that goes away with rest for women and for men, is to set the prevalence of coronary disease and middle-aged women is pretty low still compared to men.

Jim Kirkpatrick: I think we have to look at the whole picture for all the women and certainly this idea of how old the patient is is a major issue and then part of the problem here is you know you are you setting your sensitivity bar, do you want to not miss things, or are you sort of looking at, at, rational testing considering the prevalence and everything else that's that's going on and you're, you know, I would agree with it's probably been a bit of a backlash and the pendulum is gone the other direction for a lot of this but, but I do think we have to kind of recognize in the guidelines to mention this that chess it's not just all about chest pain. And, and it really requires a holistic view of it and it's also not all about coronary disease, there are plenty of other things that could be going on to cause symptoms and occasionally, there's an maybe frequently there's nothing really that we're going to find anatomically or functionally.

Larry Birger: Well, and I would just say I'm speaking from the perspective of a clinician who has ordered quite a few of these tests over the years and had to deal with the aggravation and the staff time consumption and so forth, because we can't pigeonhole our clinical suspicion into the existing terminology or categories. And so that that's really more broadly what I'm what I'm addressing and I you know I know at least one esteemed cardiology colleague who has said similar things, so that was kind of what I was looking at fleshing out, I agree I think the holistic thing. And as far as I'm concerned what the, what a couple of our public commentators said about nuance really resonated with my own experience, and

Chris Chen: Others that Dr. Birger, it was the same as far as our recommendation went, we considered asymptomatic individuals out of the scope of the evidence report and out of the scope of the recommendation which doesn't necessarily preclude a future decision regarding asymptomatic and, and we're not in the recommendation to prescription for what symptoms would be defined us.

Janna Friedly: And we have three people who were patiently waiting for comments so Christoph, we'll start with you.

- Christoph Lee: And based on the level of evidence comparing the different imaging modalities and, particularly, covering SPECT only if stress echo is not available or inappropriate. I think what we're seeing from evidence is that stress echo and SPECT and nuclear imaging, are all somewhat equivalent in terms of clinical outcomes. And there's only lower insufficient evidence for any minor differences and decision making. So, I'd be careful about being too restrictive with the language for SPECT coverage.
- Janna Friedly: Okay, and thank you for that comment, and then I think Connor was next.
- Conor Kleweno: Yeah, thanks. I think maybe as a follow up to that question to Jim and read as as as you look at what's written kind of help us understand what the most controversial languages there, you know I see that PET is dependent on SPECT. But otherwise, a lot of it seems somewhat open to me but I don't order these tests you know we've mentioned symptoms and that can be vague but whenever there's something vague it doesn't always make it easier for the physician to order the test I just want to understand what aspects of what's written to be really kind of focus our efforts on in terms of what is controversial and as we actually get to the pen on the paper for this stuff.
- Jim Kirkpatrick: That's, that's a very good question. I think some of it depends on the question of what what inappropriate means and how that's defined.
- Conor Kleweno: Yeah, exactly. I mean it's the way it's written to me would seem that if I sit and appropriate then we're good to go so I feel like there is some openness to it but I also don't order these tests and that's them not being declined they're having patients get declined for them so you know I, I've come across it in orthopedics with trying to get MRIs CAT scans etc. Just don't have the clinical experience here where some of this language would be problematic we mentioned symptoms as being somewhat vague but I, you know, I would be interested in any other aspects that we should also focus our attention on or otherwise it's just you know per clinician recommendation is that would be the end result of taking all the vagueness out just saying if the clinician says they want it then it should be approved or any of those fourth modalities should have any sort of considerations, or qualifications met prior to it being approved.
- Jim Kirkpatrick: Yeah. How would this, and I don't know the answer to this how, how would this be translated into clinical practice or clinical denials I guess.
- Janna Friedly: So is that, is that a question for Dr. Chen, perhaps, I think, I think it sounds like what we're struggling with a little bit as is. The reconciling the need, or the, the potential need to be to allow some, you know, flexibility, and clinical judgment, with the practical implementation of that and what that actually means when you look at those words that

when you use words and that decision decisions that are somewhat vague.

Chris Chen: Yeah, I think they generally trying to, I think we understand that there are nuances in this technology, and I think that's why we tried to intentionally be very intentional about the scoping of the decisions and so, you know, at a at a very basic level, keeping stuff out like heart failure or comet Kawasaki disease, cardiac sarcoidosis etc. then kind of focusing on coronary heart disease and then tricking that next to, you know, Unknown, Unknown and symptomatic not asymptomatic. And then, And then within that understand that because of the various considerations when it comes to selecting an appropriate test, and the various criteria that generally. Our goal is to avoid inappropriate testing, and to use equally effective less costly alternatives one available. And I think, I think, you know, most doctors want to do what's appropriate and what's right. but from our perspective we do see times when that inappropriate utilization does occur. And so we wanted to focus on that rather than be overly prescriptive about specific criteria, which would also require maintenance and kind of also understanding the dynamics of HTCC decisions and, you know, maintaining a list of things to add and remove as time went on,

Janna Friedly: Thank you. And then I want to make sure Chris has a chance to ask his question.

Chris Hearne: Um, yeah, that my question was exactly on this on this subject of what the word inappropriate means on the slide that you put up Dr. Chen. It sounds like what I'm hearing from you and just correct me if I don't understand is that HCA would rather lean on a, a little bit less, less prescriptive and and not spell out what inappropriate means, at least in the beginning and kind of make that a little bit more open ended. To begin with?

Chris Chen: Yeah that's that's the initial approach that we took and of course if you know there's room for discussion I will say that Medicare's local coverage determination, kind of, use a similar methodology in terms of not covering tests that don't offer any additional meaningful information. And so I think we're using language around. To that end, but I also want to pause because I saw that Dr. Transue came off camera on to see if she had something to add from the MTG group, the dangers of coming off camera

Emily Transue: To sort of emphasize what we are creating here is that is the coverage policy. So it is ultimately what will be used to say yes or no to people who are. We're making a request so I guess I just sort of wanted to emphasize that a little bit and if there are. Yeah, if they're kind of clean lines that you see in where they do that and not do that that's a possibility.

- Janna Friedly: Um, and then Mika.
- Mika Sinanan: Thanks. This is a question for Andrea on your slides, and I should have asked this earlier, perhaps, but your slide 97, which is a summary of stress eco efficacy? At the very bottom it says it has the down arrow decrease risk with CCTA up arrow increased risk with CCTA. This is a summary of stress echocardiogram related compared to exercise EKG EKG standard care and ICA. So is that just a typo. Did you mean decrease risk with stress echocardiography and increase risk with stress echocardiography, you see that you're on those summary slide?
- Andrea Skelly: I think my slight change the slides a little bit last night so
- Mika Sinanan: There's a legend at the bottom. Oh, okay. Arrows Down Arrow have decreased risk with CCTA increased risk of CCTA, you see that.
- Andrea Skelly: Oh, yeah, that is a typo. I'm sorry.
- Mika Sinanan: Alright, that's fine because that yeah knows use the same template for a number of the slides and that shows up on them. I just wanted to be sure because I didn't understand his slide otherwise. Yeah, well, you're correct and should be echo in my question around that, for either Jim arena is. It would seem that the data suggests dress echo is a better test or has with a low strength of evidence but some increased value over stress EKG. And yet the agency recommendation is only if an exercise EKG is inappropriate or unavailable. So, so basically they're recommending it seems to me as an exercise EKG is the first line treatment, and then only go to stress echo if it's inappropriate or unavailable. My question then it should it be if exercise EKG is in determinant inappropriate or unavailable. What do you think?
- Jim Kirkpatrick: I think. I think most of us would, in many cases, prefer the imaging component and, and it depends on the patient population obviously there's some obvious things that the EKG changes to make it an interpretive or can't get on the treadmill and and other things but, in which case you'd need to have a pharmacologic functional test. And those are performed with imaging. I, I think that, you know, this has shown up in the guidelines for a while, I don't believe they're in the most recent one so this idea of think first of exercise travel to a second can tell you that's really not the way most people do things. Most people just order the imaging test. And in part because there is a certain rate of false positives and false negative that you use kind of think you're going to end up with an energy test anyway so you might as well just go for that. It's relatively rare that we have difficulty in getting that approved. And I think it's because there's sort of a widespread recognition of that strategy as well. So if this would represent a, a difference, and that. Now, a lot of requests for imaging tests would be denied until there's kind of an

exercise treadmill. I think that would change how things are actually done pretty consistently, but I don't think that was changed from the prior iteration. Is that correct or that I misread that?

Chris Chen: The this specific component. And thank you for trying attention to this to send it out, because it might be worth spending as much time on the decision as itself as what's out of scope for the decision, or what may not be in the discussion for today so I actually interpreted, because the evidence to focus on, on the modalities and their utility as follow up with that normal testing. And so, kind of it hearing again to the scope of the evidence report and Andrea could correct me if I'm wrong on that, but I did propose scoping abnormal follow up of abnormal studies out. And the other reason is just knowing the different permutations that occur in terms of like the sequential nature of some of these tests that that was one of the reasons why I removed the or proposed removed move off the language of indeterminate a prior test.

Andrea Skelly: Your question is asking whether or not we could follow the pathway of a, of a test. If it was in determined or not that was very very poorly described in the studies that we included.

Mika Sinanan: So thank you I what what Jim just said was, if we were to adopt this as a policy then stress echocardiography would not be a primary option for patients with subset suspected CAD until they had been evaluated for an exercise EKG, and it was either inappropriate or unavailable. Dr. Chen, that's my understanding is that correct? And he's saying that that is different from our current prop from current practice out there I just want to be sure that that is what your intention was that we change current practice.

Chris Chen: I'm, I'm sorry. Can you can you clarify for the clerk care, sorry, clarify that one Dr. Kirkpatrick. How's that deviate again?

Jim Kirkpatrick: We have only one cardiologist at the University of Washington Medical Center, who, who sort of directly orders EKG only stress tests for ischemia. And it's a big to do every time he does everybody tries to sort of say, do you really mean that because the normal practice for just about everybody is to order a stress echo or another functional imaging test and more rarely because it's not covered in the outpatient setting a CT. And I think that that's that's kind of the way things are generally done. Because there everyone has this this sort of suspicion that a lot of exercise treadmill testing is is fraught with with inaccuracies, and that you know you come into a situation where you're pretty sure that there's coronary disease and it's normal even at a good heart rate and then you end up ordering and imaging test or sort of the opposite things happened and it's, it is abnormal and then you're really not sure about it and you you don't go straight to Cath from that. So and and for some reason I,

again, this has been sort of the way it's been suggested is that that is the first time test in a lot of the documents that we don't seem to have a lot of denials from any insurance companies, saying that you should have done an exercise, only first, and occasionally happens but for the most part, when people order a, an imaging stress test that generally tends to be okay. And again, I don't see the denials for new studies at least enough for echo but that seems to be the, the dominant paradigm is that it is okay to go straight to a, an exercise particularly exercise imaging study without doing an exercise treadmill first.

Chris Chen:

Okay, thank you for that clarification. So yeah, I think this specific component about having for echocardiogram being the recommendation for coverage in the instance where exercise treadmill tests was inappropriate or unavailable that kind of mirror some of the previous language that what that is in the current spec decision as well. So not a major deviation there but, yeah, this is very much the committee's decision to make. So,

Janna Fiedly:

In fact, Christoph have to do have a.

Christoph Lee:

Oh no. Just to follow up I just wanted to double check with Jim, in terms of talking about going directly to imaging study. Is there any differentiation in terms of saying echo should be got going to first versus a nuke med test, or is it really dependent on what's available locally, and you would basically say that someone should be able to go to any of those first?

Jim Kirkpatrick:

I'm very biased and in my echo position here. And I can, I'll just lay out some of my rationale for that, but then understanding and I'm very biased. You know I echo does give a little bit more information in terms of the fact that we can get what is generally considered to be a more accurate ejection fraction at the same time as the stress test, we can see even if it's a stress only we're not actually looking at the rest of the heartbeat, get some sense of whether it might be your next to gnosis or cardio fusion right ventricular size and function, some views so the, there's this a lot of different I could go on and on but there's a number of different sort of extra things that that we can get as far as extra information now of course extra information is not always good. And that can lead to, you know, incidental finding problems but that that's one sort of aspect and some of those things extra pain. just me too so it's kind of helpful. I think the other thing is, does take less time and, and it, it has, you know, as was pointed out, there are some problems with obese patients and those with lung disease in general, all of those can be overcome. At slightly increased go up some increased costs, with the addition of non-iodinated contrast agencies or microbiology don't hurt the kidneys. And that generally we don't have that problem anymore. So

that's sort of some of the rationale is behind my bias it had nothing to do with the cost situation.

Christoph Lee: Thanks for the double or echo definitely, I guess that other institutions.

Thanks for the double or echo definitely, I guess that other institutions where they don't have a great echo lab, but you know and

Jim Kirkpatrick: I would absolutely agree that you have to go with what's good and, and you're, you're absolutely right, if, if, if the Ecolab is known not to produce a high quality product have trouble to end the stress test early because they want to leave, whatever it is that ends up making that test not a good one, or even just in comparison with other modalities or with outcome studies, it's not good, then I would absolutely agree you need to go to another test. And I would also really strongly advocate for this idea that the other testing, really should be available and encouraged because they're always going to be patients that really that is the most appropriate test and I think this idea of finding the right test to the right patient is really key.

Larry Birger: That certainly echoes my experience over the years we had one physician a hospitalist who oversaw the stress tests and the, the cardiology group finally reached out to me and said could you talk with him because he kept ending the tests, really inappropriately early based upon heart rate as opposed to getting a better physiologic stress test. So I just wanted to reinforce the ideas that are being laid out here.

Janna Friedly: Okay, and I don't see any, any hands up are there. Are there any other questions or comments, I?

Clint Daniels: This is Clint as I put a quick question about where the public health comments are not public health, I'm sorry public speakers. One of them mentioned that there may be some access issues and availability, is that like one specific test that's less available, or specifically rural areas, or are several of these less available, can anybody comment on that?

Jim Kirkpatrick: Oh, it could be any of them. And some of it is, you know, echo is pretty available all over the place, but stress echo is not necessarily because it depends on a lot of them you, if you're going to do dobutamine stress echo for instance, really you should have a nurse administering the dobutamine, and sometimes nurses are not, especially not now, not sort of been in plentiful supply. And the technicians are not always available and sometimes you can only have it during certain hours and then there may be limitations on the scanners that you have. And all of these really kind of depend on the local area. And what is actually being offered so I believe the comment was made in in relation to CT scanning, but it's kind of true for everything you got to have the equipment you got to have the

technicians on first, and you got to have the people know what they're doing and reading it.

Janna Friedly: I think I'm sorry I was just gonna say as a follow up to that I think one of the things I struggle with is if if in the, in the language of the decision you say, you know, if, if, you know, stress echo isn't available as part of the criteria for another for an alternative test that that interpreting that is, it can be challenging because I'm not sure who would who would know whether it was available and what does availability mean does it mean available within a specific time frame or, you know, or available within a certain mile radius or, you know, so availability can be interpreted in so many different ways so just from a practical implementation standpoint, does that, is there a potential for that to be problematic and, and actually implementing a coverage of decision. It's more of a comment I guess it's not really a question to anybody but that's that's what I what I struggle with. I think Christoph, you were going to say,

Christoph Lee: I was just gonna make a comment to follow up with Jim's comment that accessibility for nuclear med studies is tough to write. You need a nuclear medicine department that could deal with radio pharmaceuticals and not all facilities will have that and urgent care ED settings, CT maybe prevalence ultrasound may be prevalent but nuclear medicine may not be.

Conor Kleweno: I kind of go back to my question I might not have articulated a well when we're actually writing this down and it says, if SPECT is unavailable, than us PET, you know whatever way you want to phrase it is the issue that the criteria to meet any of the tests is controversial, or the restriction on which test is allowable more controversial or both, Jim.

Jim Kirkpatrick: And they both could be controversial depending on the situation.

Conor Kleweno: Again, I guess I read what you know besides the PET being dependent on a SPECT scan, much of what's written there seems pretty open to the provider choice but maybe I'm not understanding the restrictive nature of the languages as well since I don't order those tests maybe Larry you can comment.

Jim Kirkpatrick: I guess practically what what would happen I mean I this is sort of what my question is the same really is, if this were to, would this be basically a situation in which you know pretty much all of my stress echoes are going to be denied because I haven't done an exercise treadmill first or haven't somehow documented very clearly that an exercise treadmill can't be done and how much documentation burden would that entail and I is that what what you're asking? Because that, that's certainly what I'm concerned about.

Conor Kleweno: Yeah, well I mean one thing is that what your comment that you know we don't do exercise treadmills anymore we just go straight to stress echo I didn't realize that is part of clinical practice but when I read what is, what was written, it seems like there's a lot of choice if I say okay well this is not appropriate. We're going to do that. I totally agree with you know, what does that mean in terms of what do I have to document or appeal to say that it's unavailable or inappropriate. And so I just didn't know what part of what's written is problematic for you or even some of the, the open public comment personnel that called in.

Jim Kirkpatrick: And I don't mean to say we don't cover do them and we certainly do them and can do them, to be honest at university we do them mostly just looking for rhythm disturbances and electrophysiology patients not really assessing ischemia but a lot of those three to infinity to.

Mika Sinanan: So Jim biggest thing that I, I guess I interpret and I appreciate Connors question, as if you're teaching a cardiology fellow or resident about this, are there a list of well accepted criteria for which exercise EKG is inappropriate, that we should be listing or is it in his question is, is that so clear that we don't have to list them? Or we should list them? Or is it in the mind of or in the opinion of the provider? And when we say that if if we just write the, the comment in the medical record, exercise EKG and appropriate refer for stress echocardiography, is that going to become sufficient explanation?

Jim Kirkpatrick: That's really good question. It's a little bit of both. There are definitely criteria that are, that are set out for an interpretive EKG pretty obvious with that one. But there are different character. There are different qualities that he did make an interpreter stress test. We don't have to get into but then there are sort of these patient level factors which are kind of hard to quantify or put down why someone might want to, to have increased sensitivity for instance, that is offered by an exercise, treadmill test and some patient populations, increase specificity as well. And in some of this as I was very much struck by Andrea's presentation and one of the things I took out of it is there's just not a whole lot of evidence that supports and and really makes it very, very clear what to do and so it seems like having a little bit more wiggle room allowed in the face of evidence, not pointing in particular directions and and being a little less prescriptive I think in my mind, sort of makes sense based on the evidence review but I certainly would would be happy to be proved wrong.

Larry Birger: Well I'm concerned that we're trying to reduce something to an algorithm that is in the nature of the case doesn't lend itself to that. And again, as somebody who has spent a lot of time over the years, wrestling with people on the other end of, you know, who's going to be approving

payment or whether the test is going to be scheduled I feel pretty strongly that we do just what you said, and not be so prescriptive but allow wiggle room nuance clinical depression or whatever because I think this is a really complex topic that it could not be reduced to something more simple. At this stage without it becoming simplistic and thereby inhibiting patient care. And there's a fallout from that too I mean if your staff is having to waste inordinate amounts of time with you know trying to track down approvals and so forth. That's not without its really significant impact on the staff and on the provider but that doesn't really get accounted for in these sorts of, you know, discussions, I don't think so.

Conor Kleweno: Larry, how would you have, you wrote it?

Judy Zerzan- Thul: Can I interject for just a minute because I think this will, this will help the discussion this is Judy Zerzan-Thul , I think, based on the evidence that we've seen, we're not really trying to restrict stress echo and it, it seems that in terms of advocacy and cost, either stress echo or an exercise treadmill or, or good first step. So, if that helps we currently don't have stress echo on prior authorization. And I, you know, I don't know, based on the evidence of effectiveness and costs that we would need to do that so if, if that helps. I, I just don't want to get too far down the rabbit hole because there are a lot of options here and this is a complicated topic. But, but yes that's, that's sort of what I think.

Janna Friedly: Right, thank you that's that's helpful clarification Christophe, do you have a another comment.

Christoph Lee: I guess, a question for both HCA and for Jim. The difference between PET and SPECT. It seems like a lot of the literature and the guidelines lump that together into nuclear medicine scans. And I know PET is certain information that SPECT doesn't right like blood flow reserve for instance, so you get some more functional information. PET says lower radiation dose, but obviously it costs a lot more. So, in, in your minds, why is PET, a separate decision point, compared to just nuclear medicine in general? We have a different decision for that.

Jim Kirkpatrick: Why I can't really answer that question per se but I think you've captured it really really well my understanding also is that it is considerably more helpful in patients who are on the larger side and tend not to have really great SPECT images and their sensitivity and specificity for detection coronary ischemia actually goes up with PET scanning and larger individuals, but other than that I don't other than cost I'm not sure I would know why that is either.

Christoph Lee: Thanks. Is there anyone on the HCA side that could discuss why PET is differentiated?

- Chris Chen: So I think generally this was reflected in multiple appropriate use criteria, as well as some of the evidence in terms of yes, I had being a reasonable option where speech was not technically feasible in the situations discussed around body habitus. But, there, there is a very very significant cost difference there. And in the interest of kind of stewardship of resources I think that does get mind its way into, not just coverage discussions, but also appropriate use criteria. So, yeah.
- Janna Friedly: We have just a few minutes before our scheduled lunch break. Does anybody have any sort of other related comments or questions that haven't been asked of either Dr. Skelly or clinical experts at this time? So, I think, not hearing any new questions or hand, hands up I think what I would recommend is that we, we take our 15-minute lunch break. And then when we come back, then we can start going through our decision tool to help us start framing framing the decision. And, as you all remember from previous decisions. we will go through each of the different tests that we're going to be talking about separately. And we are our decision tool that we that we use will go through evidence related to safety efficacy and cost and will we will do a poll of where we feel the evidence lies on each of those. And then after that we can have a little bit more discussion about the decision and and sort of take a straw vote in terms of decision. And, and talk about wording of decision if appropriate, so I think that's our plan for when we come back from break. So anybody have any either content questions or operational technical questions about how we're going to proceed?
- Conor Kleweno: Just just remind me that it does the clinical experts remain throughout for that decision and in case we have questions on phrasing or I don't know Jim if you're available or leaving or Rita.
- Jim Kirkpatrick: I'm happy to stay, that would be helpful.
- Josh Morse: Yeah, this is Josh if I could just say so Dr. Kirkpatrick is a member of the committee today he is a, he has full privileges as a member with the, aside from voting. As a clinical expert. So thank you again Dr. Kirkpatrick for being here and Dr. Redberg is part of the evidence review team and I am. Maybe she can speak for her availability this afternoon for the next few hours but I expect that aggregate will remain with us at least for a couple more hours.
- Andrea Skelly: Yeah, we will be with you I think Dr. Redberg had another meeting that she needed to go to.
- Janna Friedly: Okay. Great. Okay, well it's 12:30, why don't we return at 12:45, to start talking about the decision. Thank you, everybody.

[break]

Janna Friedly: Okay, welcome back everybody. Very short lunch. I, so, it is it is 12:45. And at this point, we are going to start talking about the decision so I do want to make sure that we have everybody from the committee back, because we will be doing some polling [indistinct]. So, before we get started, you know, and yes I just. Chris, are you here?

Chris Herne: Yes, I'm here, sorry.

Janna Friedly: Okay, no, that's okay, and I don't see up there we go, I'm losing people, there's something going wrong with my video. OK, and then Larry I think is the only other person on the committee that I don't see, are you here, Larry. Yeah. And then Larry I think is the only other person on the committee that I don't see, are you here, Larry?

Larry Birger: Yeah.

Janna Friedly: Okay, perfect. Okay, so I think we have everyone on, on the committee. And I know that this, we have a lot to cover. Essentially, you know, multiple different tests to talk about. So I do want to jump in and and start going through these. The individual tests with our with our decision tool so what I would recommend is that we start with the stress echo first and then SPECT hat and CCTA if that works for everybody, in terms of the order. And, okay. So we'll do that, and then we will, you know, the first thing that would be helpful to do is to go through safety efficacy and cost effectiveness and, and as you remember, and maybe, can we can we pull up the decision tool so that everyone has that in front of or at least the sort of an unproven last equivalent more and more and all, which are our choices. Perfect that's helpful. So, as you know, we'll go through each of those for each of the different tests and then once we once we have done that, then we will start having a little more discussion about the decision itself. So, with with safety. And let me just pull up so that the stress echo is the is the first the first test. And, and the, sorry, I'm just pulling up the compare, make sure that we have the right wording for the comparator. So, in this and maybe we can clarify, you know, so there in the, in the report, you know there were there were different competitors. So, does it make, does it make sense in this to when we're considering stress, echo to consider it in comparison to the treadmill test EKG or versus standard of care versus ICA separately or all all together as one? I think there's there is, we saw there's there is in really very limited data with standard of care, or standard care and ICA comparisons, so I'm assuming we would be comparing to exercise EKG unless somebody has additional thoughts teaches a reasonable? Okay, okay, so let's, let's think about safety outcomes. First, and we have here a list of our potential safety outcomes. And it was there additional discussion that people want to have about specific safety outcomes that we should be considering other than the ones that are listed here. Okay.

- Andrea Skelly: So Dr. Friedly I'd like to just point out that some of the ones on the list are not going to be applicable to stress that go.
- Janna Friedly: Yeah, so I think what we are for the purposes of this, this part of the vote, we are, we're really sort of looking at safety as a whole so we're not we're not going through each specific safety outcome is that that that's how I'm framing this. So, radiation exposure, you know, for example doesn't apply. But some of the other ones well, or, okay.
- Tony Yen: So I think that by going through each one actually still be relevant because, well, for example when we're comparing stress echo to say for example, SPECT scans and then they'll be differences right there right in comparison to what another less well
- Janna Friedly: I yeah so I was thinking just specifically for the comparison of stress echo to exercise EKG to start. So these are relevant safety outcomes for sort of the the whole group of tests so for this one and this one particular comparison there may be some on this list that don't that don't apply. But I think for the purposes of the this poll that we're going to take, we're considering, and any of the safety outcomes that are relevant to that particular test.
- Larry Birger: I guess I just have a question you know we're covering an awful lot of material an awful lot of comparisons on multiple levels, how is it that we are doing this in what seems to me to be a pretty short amount of time?
- Janna Friedly: Well, I don't have a good answer for the relative amount of time. We want to make sure that we have a thorough discussion. I think this part of the, the decision process is really just to help us to frame our sort of group thoughts about each of the different tests in terms of these different outcomes. It's not, it is not making the decision itself it's really part of just the decision, the process or the tool to help us. And what we found in the past is that it's helpful to go through this exercise for the test on each of these three different categories of evidence that we're looking for safety, efficiency and cost. And then after we do that then we can have additional discussion about, about the decision and wording of the decision which I think is going to be the more time-consuming part of the process.
- Larry Birger: I understand I guess I'm, I'm really speaking more broadly. I mean I could see as many things as we're having to cover here it seems to me that this was such do subjects really is what they are, it's a composite could take multiple clinical committee meetings. I guess that you know to be honest I'm, I have a fair level of comfort with all of these studies having used him over the years and trying to accomplish what it seems like we're supposed to accomplish in one meeting. To me, I'm just not comfortable with.

Josh Morse: So the committee agenda if I could jump in for a second, please. So, your process here, well, they just go high level first. If this is too much to digest, today, as a topic, the committee does have the ability to form an ad hoc subcommittee. That's at the chairs discretion to call that we have some very specific language around the composition and what that would do. And the committee has used that that mechanism once or twice before, and to be honest it was related cardiology topic because tend to be more complicated, I think. So you do have that you don't have to rush today and get this done if if you find that there is a lot of detail and you think you need to go that avenue, certainly, you know, one of the tools that you have that you can do and I think that's in the should be in the decision document here, some language about that but I can, I can pull that out here in a second. I think the other thing is, so, you know, as I've observed how you do this section, you typically go through and make sure that these are the outcomes that you saw some evidence on. And then the committee at the retreat discussed ranking these outcomes, thinking a little bit more about which outcomes are most important to you on these topics so I you know you could do that on these for modalities. This this is all of the outcomes that we pulled from the aggregate presentation so they don't all apply to each necessarily to each technology. This is what they found in the literature. But these may not all be of significant, the same importance to you. And then how much you trusted that evidence so, and then to come after this would be that vote on this is what we call the straw poll. I think, you know, what is your sense of the evidence supporting each of those compared to the alternative that you were just discussing what you want to use as the comparator, or what was your comparator so I think Melanie is ready to, you know when you're ready for this she has polls ready so that you can vote on each of those modalities, because it's going to be, I think, what is it four modalities times three different boats in different ways. So hopefully that information is helpful.

Janna Friedly: So I guess I would recommend that we continue with these this part of the, the, the, the straw poll, and then after that when we have discussion about the decision, if it looks like, we want to have more discussion about whether or not we can come to a decision today, or need additional information or additional time and then we can we can discuss that at that time, but I think it would, to me it seems like it would be helpful to go through this now and, and see where we, we, we started bland as a, as a group on these polls in terms of the, the safety outcome. So, for rent ranking of these outcomes for each of the different is the suggestion to rank, each of the safety outcomes for each of the different tests, each of the four different tests in terms of importance.

- Jose Morse: I think that would be a way to go about it. Yeah. What other groups have done in this regard that we were talking about at the retreat is identify those topics where they think they're the outcome. The critical outcomes were you hope that there's evidence, because that's where you're going to make your decision. But in some cases you may not have the evidence on the outcomes that you hope for. And this list may not include all the outcomes you really want to know about because it didn't show up in the literature and try not to make this too murky. So, yeah, if it helps your conversation to rank these outcomes or to identify ones and I just mean high low, medium, I think, is how we talked about this, which are most important.
- Janna Friedly: Okay, I'm just trying to think through operationally how to do this with the group to come to consensus about the importance of these, these outcomes.
- Christoph Lee: I have one thought. If we looked at the documents today, the analytic tool summary tables that Aggregate Analytics put together for safety. It might be easier for each of us to just look at that document, look at the summary tables for safety for each modality. And then have a straw poll, rather than trying to go through every safety outcome for every modality. Because those summaries tables are really good.
- Janna Friedly: Yeah. Yeah. And that's, that's what I was using and I'm, I'm looking at those summary tables as I was planning on going through this, so that's how I was framing it in my mind so this using this tool to me is sort of straying from, from what seems to make sense with how the data was presented.
- Christoph Lee: I agree.
- Josh Morse: And if that's the case, if that's a better example, you know I can switch and share those tables.
- Janna Friedly: I think that would be really helpful. So starting with safety. So that's slide 98, I think is the summary table for stress ECHO.
- Melanie Golob: Josh, I think I also put them in the, at the end of the decision aid.
- Josh Morse: Oh that's right thank you. I think we did think about this. Melanie did.
- Janna Friedly: Okay, great. So, so looking at, at this table it, you know the safety data for stress echoes included. Any complication in one trial dobutamine-related adverse events, dipyridamole, and adenosine-related adverse events and then the contrast, contrast related adverse events. There we go. I guess the question one question is are there any additional adverse events that we're not reported on that we would that we would have liked or that we think are important that we do not have data on from the reports.

- Tony Yen: I don't think we have data on radiation exposure necessarily but that's mentioned and I think the decision tool.
- Christoph Lee: Yeah, no, no radiation for echo.
- Janna Friedly: Yeah.
- Tony Yen: Sorry, picky about all the tests combined.
- Janna Friedly: Yeah, sorry we're looking just it's written right now just invest echo yeah vs EKG. Yeah. Okay.
- Janna Friedly: Okay, well, do we, let's, why don't we then move to the straw poll for safety for stress echo. So if we could pull up the, the pole for safety. And so remember the choices are unproven. There are, it is less safe, equivalent and safety, more safe and some of the studies are more safe and all of the studies.
- Christoph Lee: To show the comparator, because I think this report is with a comparator of ICA, should we be kept comparing the safety of each modality to ICA rather than each other?
- Janna Friedly: Yeah, so that's a, that's a great question because that that does make more sense I think from a state that as a sort of gold standard comparison to, to the test. Maybe it would be worth just stepping back for a moment and talking about the comparators as a whole, for for safety efficacy and and and cost for for each of these different categories because you're right, or each of these different tests to make sure that we are clear about how we're approaching this. Given that the studies were done in different ways. in terms of the comparators.
- Christoph Lee: Are doing analytics to clarify how they put these tables together in terms of their comparisons?
- Andrea Skelly: Sure, um, what we did is we went strictly by the studies, and what the studies compared to what. And there was not an attempt to look across all the studies across all modalities, to put together a one big table. Although I would put forth for consideration there is some consistency across the different comparators so for CCTA versus the functional test. There is some information about those that looked at stress ECHO specifically, or stress testing in general. But by and large, we just went by what the study, compared to that specific comparator. We did not have lots of studies that compared to invasive coronary angiography for any of the the primary tests. So I would, I would point, that, that out, if one that answers your question, Christophe.
- Christoph Lee: Yeah no, thank you. I'm just wondering, in the straw polls, right, what our comparison should be so this is a common point of struggle, identifying those.

- Erika Brodt: So yeah and all this is this is Erika from aggregate. Particular, since we're starting with this one. Only one of the RCT is the one that you know that any complication at the top there compared stress ECHO with exercise ECG and that's the only or RCT that reported complications, for whatever reason, complications just really weren't reported by by a lot of these studies the stress echo the SPECT studies the PET studies. So that's why we dive when went to K series cohorts registries to kind of see what are the common safety issues with these studies so for instance with some of the stressors there isn't a comparator, they're just looking at, at echo and what's the what's the rate of either major or minor adverse events, when you're giving patients these pharmacological stressors. So, for some of these there aren't comparator tests, if that's helpful.
- Janna Friedly: Yeah, I think it is it's just the way that this, I think what we're struggling with is the way that the word, the wording of this poll is worded in such a way that you have to compare it to something here.
- Erika Brodt: So, okay, is there.
- Janna Friedly: So the question is, is there sufficient evidence that it's safe. And, and, but it has to compare it to something. So I think in part makes sense if you're thinking about a coverage decision, if it's if you are if you hypothetically made the decision to not cover a treatment what would be the all or test, what would be the alternate that a person would be receiving to be able to compare it to. And that's, in this case that's even that is a little bit challenging to think about. So does anybody have any specific thoughts, other than to a I think the choices are to think about this in comparison to ICA or in comparison to a treadmill test, and those are two very different, different things as comparators show to be considered in?
- Mika Sinanan: In the real world, they would be to exercise treadmill test. Mm hmm. And that's what the coverage discussion we had earlier is about. It doesn't seem to make sense to me to compare it to something which is. It's an anatomic versus a functional tests, it's radiation versus no radiation. Doesn't seem to make sense to compare it to the ICA.
- Andrea Skelly: So I'd also like to point out that some of the, the safety issues are going to be specific to a given modality. Like contrast with the CT, etc.
- Janna Friedly: Right. Right. Okay. Okay, that makes sense. Thank you. So let's let's proceed with thinking about this, you know with echo versus the exercise, EKG treadmill test and do the straw poll that way. So if you could, everyone submit their poll and then as soon as we have.
- Jim Kirkpatrick: Right. I don't mean to be a complicated this issue but there's also the issue of pharmacologic stress that go vs exercise stress Echo, unfortunately.

- Janna Friedly: Unfortunately, yeah and it's the data is not not easily broken out that way. Although you can think about the risks of pharmacologic stress. Okay, do we do, we have a. Is that, is the poll been completed or, we still.
- Melanie Golob: We have eight eight votes I think we have, what is it nine, nine members today.
- Josh Morse: Yes. Okay.
- Melanie Golob: Do you want to wait for the one more to go ahead and close it?
- Josh Morse: Does everybody remember abstain from voting on this. We can go to a voice vote here if we need to. Is it easy for you to see who's missing.
- Melanie Golob: Not yet. I think if I export it once it's finished, I can, I can go ahead and end it.
- Janna Friedly: Okay. There we go. And I think that is, that tells you, just how complicated that question is. So, we are pretty evenly evenly split there. And I think that reflects the ambiguity of the, of the question and the comparator and the different ways to look at it. Okay, let's, let's move on to efficacy see if we have any clarity, there and again, comparing to exercise, EKG. Can we have a poll for that pulled up? Has the poll been released? I don't see it. Oh, there we go. Perfect. We'll give that a moment, and then let us know when we're up to hopefully nine, this time.
- Josh Morse: There we got to nine.
- Janna Friedly: Great. Okay. Ok. So, also fairly divided split. I don't see it and flashed up quickly so I didn't say about it look like no, no one had indicated less but there is a split between equivalent equivalent unproven and and more in some and more and all. Okay. And then how about for cost. Let's go through this exercise with cost. If we could put the poll up for that. Okay, little less, a little less than maybe divided in categories, but still divided. Unproven 56% equivalent. Yes, 22% and more and some 22%. Ok. Okay, so that was stress echo. Any, any comments before we move on to the next, to the next one? Okay, so the next, the next one that I have is SPECT. If we could pull up. We have the summary table, and they, and then the poll. And...
- Mika Sinanan: What's the comparator?
- Janna Friedly: Yeah, that's what I was just pulling up I want to make sure we're, we're clear about that. So, sorry, I'm having a little technical difficulty here
- Mika Sinanan: In the summary slide just above it, it's SPECT versus any functional test. Yeah. SPECT versus NICE guidelines directed care, SPECT versus ICA.
- Janna Friedly: Yeah, sorry, so it you know I the way I'm thinking about this and maybe, maybe, maybe this is just driven by the, the proposed coverage decision

that Dr. Chen had presented. Thinking about them in sort of a stepwise fashion, with respect versus stress echo, or treadmill test. So, so that would be one comparison or or SPECT versus any of them which would also include PET. So, I think that that, to me it makes sense to consider those sort of separately. You know, Echo stress I go in and and the treadmill test versus considering PET as well but but I'm open to suggestions. When the group is, this is complicated to frame these. Hearing no discussion should we just do it just as I have in the, in the table here, where it's SPECT versus any functional test, so that would include stress ECHO, EKG treadmill and PET. Does that sound?

Tony Yen: So Janna worry about efficacy that you're looking at or we talked about a safety for now.

Janna Friedly: Well, we have to make that decision for each of them. So, so I was thinking that the comparison should be the same for efficacy or safety but

Josh Morse: Don't disagree and I don't know if this will be helpful, Janna, but, you know, if you were offering this test to me. I and it was you were concerned about the efficacy for the decisions you needed to make, I would want to know, compared to the other functional tests that you could offer to me. What, what is the safety difference, that would be the question I would be asking, compared to the alternatives, and I think I know where this is where my vote would go, because I assume it's more in some in, in less in some others but. So I, but I'm guessing it that but I'm thinking about it from the perspective of a patient how you would explain it.

Larry Birger: Well as a diagnosing physician if I could just jump in, I think that's a good, good point Josh but you know if I was talking with somebody, I'm not going to have a whole spectrum of tests that I'm going to be considering I'm probably going to be considering one and only one or maybe two tests. And so I think an argument could be made and it would probably make this process simpler as well, at least in one sense, test vs know test I mean those the test itself. You know when I'm going to think about coronary angiography. You know the primary thing I'm looking at is the the benefits of diagnostics and possible PCI outweigh the risks of something like contrast nephropathy. And there I'm just considering a test or no test. Now that's an invasive example but to me, I would say, in my, you know, years in the clinic, it would look something more like that. Rather than saying I've got five tests in front of me that I could choose from because the other thing is locally. You may not have that option. Now there were many times where we didn't have sufficient stress ECHO setup, for example, so it may have been just a new curve, or not, or whatever.

- Jim Kirkpatrick: I think this is really difficult if I think it depends on where you start from if the idea is the need to test and which one that's very different than, you know, sort of, considering it in a more global sense. The if it is compared to the exercise only that might make for some still complex but a little bit easier comparisons. You know there are certain risks to an exercise only test. And basically, you're going to be exactly the same for a stress ECHO without anything else. In other words, an exercise stress echo. And then it's going to be a little bit different. If you use the echo micro bubble ultrasound enhancing agents, there's a slightly increased risk of certain things of that. And then if you do a dobutamine, that's going to be instead of the exercise that's going to be a different risk profile, and then switching over to the nuclear studies obviously there's radiation, and switching further over to the CCTA you're going to add contrast plus radiation. Would that be a way to, sort of, consider it, because the question is, what is the safety, compared to the exercise test or, or is it more of that, this more global sense of what is the risk in general of doing the test.
- Janna Friedly: Yeah, and in my mind it's a comparator, compared to exercise test or what the what the alternative test is not, not the test in general versus nothing but that's that's the way that I that I think about it, and perhaps we're spending too too much time trying to focus on these, these specific questions that may or may not be ultimately helpful in terms of us making the decision. And so I don't want to belabor it too much, and put too much weight on, on this but, Uh, Joe.
- Mika Sinanan: Janna, Mika my, my takeaway from all of the evidence we've seen is that although the evidence doesn't seem to be terribly good. The decision to offer these tests is not based on the safety of them. It's based on efficacy and cost primarily, There may be some differences between radiation and non-radiation and functional versus anatomic, but it's private, it's probably not a safety issue. There are hundreds of thousands of these done nationally and people are dropping dead from them or having serious problems so I think you're right, is it this is we have to answer this question but it is not the main decision.
- Janna Friedly: Yeah, so, so why don't we just just given that, that framework, I think that's helpful. Let's, let's just do this poll in comparison to to exercise. As the comparator for this. And then, and then move on. And then we can discuss a little bit more the other the other outcomes that I think are more relevant to the discussion. So let's let's submit the poll, and then we'll, we'll move on.
- Melanie Golob: Okay, I think we have eight. If there's one more person has yet to go ahead, if not I can poll.

- Janna Friedly: Okay, great. So, pretty evenly split between less than equivalent. Okay. And then in terms, in terms of efficacy.
- Josh Morse: You want to see this slide again or do you want to stay on the voting questions?
- Janna Friedly: If you could show the summary slide would be helpful. Okay. And then, let us know when when we have. There we go. Ok so, again, a little bit of separation here, equivalent 67% more in some 22% on proven 11%. Okay and then cost. cost effectiveness.
- Melanie Golob: Okay, and then wake up.
- Janna Friedly: Okay, thank then fairly evenly split unproven more in some less than equivalent. Okay. All right, let's move on to that again similarly, comparing to just as we did with SPECT, I think so. Although this, this safety data presented is safety compared to SPECT, and the summary. In my mind, it made sense to consider it similarly is fact, in terms of comparing to size. first Western equivalent 89% less 11%. Okay.
- Josh Morse: And does that does that vote? I just want to make sure that everybody understood the question, interested in. This was compared to an exercise treadmill test PET is thought to be equivalent safety. Or was this a comparison to SPECT? So, and I apologize, I was using exercise as the comparator for all of these even then, even though this this table is compared to SPECT, so that we could have a common reference point for each of these. If anybody didn't answer that question in that way, let me know so we can.
- Mika Sinanan: Yeah, Let's do it again please. Okay.
- Josh Morse: Thank you all. Alright, that's fine.
- Janna Friedly: Okay, Okay. And, and then, yeah, so, efficacy or effectiveness. And again, compared to compared to try to exercise.
- Melanie Golob: I'm waiting on one more and then I'll end it up.
- Janna Friedly: Okay. We're seeing a consistent theme of being split unproven and 11% equivalent 56% more in some 33%. Okay. And then how about cost effectiveness. Okay, again similar similar split 30% 6% unproven 22% equivalent more in some 22%. Okay, so we have consensus that we are split with each of these. So, the next, the next one is CCTA. And, for, for this one. Again, this is CCTA versus any functional test. So, so CCTA versus exercise test, I suppose. And I'm assuming for these that this is just CCTA and not with a FFR is that are we considering those two separate decisions is, does anyone have clarification about that? Or we can affect our...

- Mika Sinanan: Discussion forum if a far as it's essentially the same test except the cost more, and there's some post. Right, thing analysis so what the patient sees is the same.
- Janna Friedly: Well for safety but for in terms of effectiveness I'm thinking about these points, right. So, I think from a safety standpoint it doesn't matter if we, if we lump them together but it might in terms of effectiveness or cost effectiveness.
- Jim Kirkpatrick: Right so that that's probably true. I do think there's a bit more radiation and, and possibly more contrast but it kind of depends on so many different factors, I don't think it's entirely unreasonable to consider them to be somewhat equivalent just from the administration of radiation and contrast but just this be where I think they have to image more of the cardiac cycle. Then, then with some of at least the CCTA alone.
- Janna Friedly: Okay. So, are we can say so then does it does, does that make sense then to? I'm still struggling with whether we should include them or or or do them two separate ones. Does anybody have strong feelings about whether we should just put those together or separate those out?
- Tony Yen: A do wonder if we should split out FFR because from the discussion I heard before it seems like for is almost, almost investigational, that is not completely mainstream, right.
- Janna Friedly: There's only okay so let's let's do just straight CCTA here then.
- Josh Morse: So, Melanie may not, I may not be prepared to split that out is that right
- Melanie Golob: Yeah I could probably lower voting on this maybe come up with other ones. So, one would be CCTA by itself on one would be CCTA plus up, FFR Yes. Okay. Yeah, we can start voting and I can see if I can put that together as a...
- Mika Sinanan: Comparator is exercise stress test that right?
- Janna Friedly: Yeah, I think for the four. Yes, I think we should be consistent. Just across the board with, with a comparison of recognizing that these, these choices are somewhat arbitrary. Okay, everybody submitted.
- Josh Morse: Two more.
- Janna Friedly: Okay. You can submit your..
- Josh Morse: That's fine.
- Janna Friedly: Okay. Little bit more consensus less 67% and equivalent and 33%. Okay, and let's move on to efficacy. OK, so again, somewhat split train unproven less equivalent and more in some. Okay. and then cost effectiveness. Okay, 56% unproven 11% percent equivalent 33% more inside. Okay, so I think our last, last one, and it will be CCTA with FFR.

- Melanie Golob: Everyone me one more minute I can pull that up.
- Janna Friedly: And just to clarify with a comparator, does it still make sense to, for this particular one to compare it to exercise, exercise, as a comparator, functional test vs?
- Mika Sinanan: I think so for consistency.
- Janna Friedly: Okay. Sounds good. Thank you all for bearing with me through this part of it. This has been a little challenging to fit our discussion into these, these polls with this particular topic. Okay. Okay. Again split between unproven less and equivalent, 11%. Okay, now move on to efficacy. split between unproven 44% equivalent 44%, and more than some 11%. Okay. and then cost effectiveness. Okay, so unproven 89%. Probably the most, most agreement we've had in any of the polls, so far. Okay. Well, now that we have, we have done those polls, I think, I think that was helpful and at least two to help us to think about what we're comparing to and, and some of the challenges with coming to consensus on those particular things. At this point, I would like to open it up for discussion. I think one of the things that I would welcome input about is whether we have enough information at this point to actually frame a decision or vote on a decision. At this point, or whether we wanted to consider the option of having an ad hoc work group, and deferring decision. In order to get more clarity. So I'm going to open it up to the group.
- Mika Sinanan: Mika here, I would argue that we do have enough decision or enough information to make a decision. And in part that's based on prior experience with other complicated discussions of a similar nature, one, two the fact that there are already coverage decisions for these different options or diagnostic options. So it's not as if we are thinking about something which has not had a coverage option or coverage decision already if there had been no coverage decision or previously been denied then the burden of evidence in support of all of those questions safety efficacy and cost effectiveness would be higher, I think. So, my argument would be that we have enough information to make a decision today.
- Janna Friedly: Okay, great, and then Christoph, you have your hand up.
- Christoph Lee: I agree if we can, I think we have enough here. It's just a lot of information, obviously a lot of nuances. But if we look at the current coverage decisions, and the proposed language. I think we could all agree that most of the language we agree with there might be certain points of contention. And we should just focus the discussion on the certain points of contention in the language.
- Janna Friedly: Okay. Does anybody have any other thoughts? Okay. So, Okay, so it sounds like we are in agreement that we should move forward with a vote on coverage. So I think at this point, we, we can take a, we

can take a vote, unless there's any additional discussion that people want to have, or think that we need to have discussion about any particular parts before we we vote on each of these different.

- Mika Sinanan: Mika again, you know, at this stage, what I have found in the past was very helpful, was to go around the room basically when we were in person, and have each person spend a minute or two, just saying what they thought about the presentation, and the strength of the evidence and where they had concerns about our decision making today, which might be slightly different from the questions that we have asked in the surveys, a straw poll, and and might bring up my establish consensus about areas of concern and areas of agreement. Okay, people who have been a little more quiet, have a chance to to voice their thought, yeah,
- Janna Friedly: That's a, that's a great idea. Okay, so let's let's go ahead and do that so Mika, why don't you start then you volunteered.
- Mika Sinanan: Victim right, right. Well, I found this to be an enormously complicated set of issues to focus on because I don't order these tests but I understand that they are out there and that they are being actively used I appreciate the fact that they do represent a significant cost for society and for the state and for the people who we represent, and that they are a moving target, both from a technology standpoint and from a study standpoint. I did not see really significant concerns around safety for any of them. I believe that there are some that were that by the nature of the technique require more radiation and there may be patients who have either a greater radiation sensitivity, or caution or cumulative dose for other reasons, and for whom certain tests might not be appropriate. I think the nuance issues that we talked about are critical we have to preserve enough flexibility so that practitioners with expertise, who are using these to try and deliver the best care have that flexibility. On the other hand, we want to curtail inappropriate diagnosis in patients with minimal risk and minimal symptoms. The recommendations that were provided by the agency's Dr. Chen's presentation, moving the, the bar for higher level more expensive or more involved testing to those patients who had increased risk of having coronary artery disease seems to make sense to me. The efficacy between the different choices, I don't think is a matter. I don't think we saw that enough evidence to suggest that, that one test rose above all others they all had risks and benefits and they were appeared to be different types of information you got from the different studies. Therefore I think that that is within the guidelines and expert determination of practitioners who are actually treating these patients. So those are my thoughts.

- Janna Friedly: Great. Thank you, Mika. That was incredibly helpful. I'm going to just call on people so we can get through the whole committee make sure everybody has a chance. So Laurie, do you want to go next?
- Mika Sinanan: You're on mute Laurie.
- Laurie Mischley: Oh, sorry. I said I certainly echo what you just said that was a concise summary, I appreciate the nuance here and my goal is not to restrict any provider from having tools in their toolbox that they didn't help. This is certainly outside my wheelhouse. This makes brain imaging look easy. Frankly, I'm this, these are not tests I'm terribly familiar with and so the learning curve here is pretty steep and, but I do do comparative effectiveness research, and I do biomarker research, and I was shocked at what poor translation there is to morbidity and mortality. I mean if we could see that if we could just identify these inclusions. We know how to stop these people from having adverse outcomes down the road, we know what to do to dramatically and drastically and consistently. Reduce morbidity and mortality, this would be more compelling, this gets much more difficult for me, when there are so many questions once, once we identify what we go looking for and what happens in clinical the prescribing the correlation with heart attacks down the road, I mean that gets fuzzier and fuzzier the deeper you go. So, I think, Andrea did a phenomenal job with her presentation and what I was struck with most is the lack of compelling evidence that a lot of this stuff translates to reductions in outcomes in real life, patients. If so, so what, and I get that the, what cardiologists are doing in practice this isn't, they're not in the habit of following these algorithms the way we're talking about. But I think that's what exactly we're here to do is maybe draw attention to some of these habits because some of the habits we build in clinic are not reflective of the evidence. So, I certainly support raising the bar a little bit for when some of these tests are used and bringing a little more attention to the clinical practice of habitual testing. Because from my read of how that translates to clinically relevant patient reported outcomes. I'm not convinced a lot of these tests make a really compelling case that they are game changers.
- Janna Friedly: Great. Thank you, that was really helpful and I think just, I will, because I, my thoughts are similar to both of yours I think, for, for me, I also appreciated, thinking about this as, particularly with as sort of a step to approach when it is clinically appropriate. So that, because there aren't in my mind clear differences in terms of outcomes with each of these different tests and I understand there's different reasons why you would choose one versus the other. If there is a test that is less expensive and potentially safer and is indicated for that particular patient and based on their characteristics that choosing that test, and it's available, choosing that test, makes sense. And so, sort of, again, along the lines of

raising raising the bar and providing a little bit of framework to to to try to steer thought to to choosing the appropriate test considering all of those factors to make sense. Let's have Tony go next.

Tony Yen:

So, my feeling about the test I will have spoken about all these years that I think many of these tests are quite equivalent, but I was actually quite interested in seeing is actually how CCTA as a anatomical test performed actually fairly well covered a lot of functional tests on the more commonly orders such as stress ECHO or SPECT scan. I think really choosing between these tests really depends on patient characteristics more than anything else, or availability of that testing done at that particular facility or the expertise without testing that that's really how I see it right now. What I was kind of interested in as an associate looking over the agency medical director recommendations I think a slide 30 about CCTA about how it's covered, I think we'll get to the cover benefits in a while but that seems to be a little bit inconsistent with, I guess, obtaining imaging with low-risk patients. And so that's something I just wanted to just be mindful of as we move forward as a CTA is actually an up-and-coming technology that is becoming increasingly more and more valuable but I'm just just still trying to fit that in within our framework of the additional functional tests that we have with us for quite some time.

Janna Friedly:

Okay, great. and then how about Clint.

Clint Daniels:

Sorry I get my mute to turn off there. Um, I don't have a lot to ask that others haven't already said, other than I talked to both the report, and then the public comments and our experts will really compelling on how nuanced this is. And then I think the AHA and ACC pyramid is also potentially quite helpful in our in our decision going forward. I think Dr. Chen presented that.

Janna Friedly:

Right. And Chris.

Chris Herne:

Um, yeah I mean I think this is a really nuanced topic as other people have pointed out, and I think part of what we're struggling against is that a lot of that nuance is not captured, perhaps, in the data that we have available to us and so it makes this discussion really complex, I think. But it seems that there is a role for some of some of these other modalities, in some cases, and so I would be, you know, I would be hesitant to, you know, for example, to not cover these and so I think I'm moving towards a cover with conditions.

Janna Friedly:

Okay, and Conor.

Conor Kleweno:

Yeah, a lot of, you know, great points have been made already I think the way I looked at this was in two aspects one should there be some sort of criteria that needs to be met to order some sort of events test. And then the second being if that's true then which test to order hearing from the

clinical experts and public comments. You know, I definitely appreciate the nuance so the ladder aspect, it definitely seemed like which test to order should be within the purview of the clinical decision making. And it seems like we've you know been presented with some perhaps some new clinical guidelines that may inform the former issue which is what criteria should be meant to order a test. So I, you know, unfortunately I agree with everyone else and that the data had it quite a bit of noise in it and didn't really inform us and saying, much more than it should be. You know, at the level of the point of care, without additional criteria in terms of choosing which tests in my opinion so

Janna Friedly: Great and Larry.

Larry Birger: I don't have too much more to add I think make a suggestion that we comment. You know, in a way that was not constrained by the direction of the poll questions is helpful and appreciated and more relevant. I think that this discussion and the data presented, pretty much, confirm what you know I've experienced for many years and the clinic. I think that jack, I would just mean very strongly towards not input. Coming to any decisions that would restrict any further the, the nuance and the judgment of the providers that are ordering nice.

Janna Friedly: Great. And then Christophe to do it.

Christoph Lee: I think I've made a lot of comments I think one take home for me is that it's pretty clear from the data that for low risk, low protest likelihood or CAD no imaging should be done. And I think that's probably going to be the most important revision we make to our standing recommendations for coverage. But for me, intermediate risk individuals. I do agree that we need to think about accessibility and think about the nuances of patient characteristics and the goals of the imaging for the certain clinical scenario that we need that needs to leave it more flexible in our language for providers to talk with their patients and make a shared decision-making plan.

Janna Friedly: Great.

Mika Sinanan: Yeah, just one other quick comment. And this is more for Josh than anybody else. It seems to me that this is a kind of question that might be a strategic discussion at a future year where we have multiple tests that we're trying to compare and what is the competitor. How do we choose or standardize the competitor, when we have multiple tests that are the question is raised? So that's one issue. The second issue that might be valuable is figuring out how best to frame the key questions, so that the data is analyzed in a way that it actually asked allows us to answer the questions that were asked to, to answer. And part of the problem was struggling with is, is they followed the available RCT's and data, but they

don't directly address the comparator questions that we're at, we're trying to answer. So we're trying to interpret between different studies and coming up with solutions which is why one reason that we have such a big spread because the data didn't specifically answer the questions that were being asked. Part of that is the availability of the data and part of it is the way that the analysis was done so it seems to me that there may be an opportunity to reframe the way the key questions are framed so that they actually follow the decision-making tool that will be using at the end of the day. Does that make sense?

- Josh Morse: It makes sense. Thank you.
- Janna Friedly: Yeah, great, great point. I think that that's where we struggled quite a bit was, with that, so that that's that's really helpful. Okay well I think that that was, that was helpful and despite, despite a lot of the disparate responses I think we heard very similar comments from every committee members so I think with, with that, why don't we go ahead and go on to the, to the votes for for coverage. And again, doing each, each one of the, the imaging tests separately.
- Josh Morse: So, Janna, do you have, are there criteria you want, are you going to do a straw vote, and then potentially develop coverage criteria? Or..
- Janna Friedly: Yeah, I think we need to we need to have a vote first and then develop. I mean, it sounds like from from what I'm hearing from the group that the most people are, if not everybody has sounded like they were going to cover with conditions. And so I think we'll have to come up with, with language.
- Josh Morse: Okay, thank you
- Janna Friedly: For each of them. But I think the first step is to take the vote right to, to see. Do we have polls for each of the conditions set up?
- Melanie Golob: We do, do you want to start with same order that you did before this?
- Janna Friedly: Yeah.
- Melanie Golob: Okay, great.
- Janna Friedly: Let's do it in the same order for consistency. And so I think we'll go through each of the polls first and then, and then we'll address the, the wording at the end.
- Melanie Golob: Waiting on one more vote, and then we can end this poll.
- Josh Morse: Is there one committee member who has not voted? Eight votes.
- Mika Sinanan: I'm...oh sorry the poll moved my mistake. Oh.
- Josh Morse: There we go.

- Janna Friedly: Okay. Consensus covered under certain conditions. OK, and then let's move on to SPECT. OK, OK, and then PET.
- Melanie Golob: Waiting on one more, hey, there we go.
- Janna Friedly: Okay, again hundred percent covered under conditions, okay and then CCTA. [pause] Okay. And then the last, okay so 100%, good. And then the last one would be CCTA with FFR. [pause] Great, okay, so we have consensus for all of the imaging modalities, cover with conditions. So, now we move on to discussing wording, for those decisions. Do we want to start, it might be helpful to start? I'm sorry you're, you have something up on the screen it's a little too small for me to see, but--
- Josh Morse: Yep, I'm going to zoom in on it. So, as we would normally do I've created a just a blank. It's not a blank, obviously, this is a draft but it cuts some words from the agency medical directors just as a placeholder. So, I can delete all this or I can save the headers if that's helpful.
- Janna Friedly: No, that's great. Okay, well, so why don't we, I think, given that we have these, this wording, I think it would be helpful to, to start with this wording, and and modify, as we need to. So let's, let's start with the stress echo. So--
- Josh Morse: Is this large enough Janna?
- Janna Friedly: Yeah, I have it on my big, my big screen so. So suspected CAD and symptomatic patients or evaluation of known CAD and patients who have new or worsening symptoms and exercise EKG is inappropriate or unavailable.
- Mika Sinanan: Janna, Mika Sinanan, based on the discussion that we had earlier, I would recommend we take out the exercise EKG inappropriate or unavailable.
- Janna Friedly: Um hmm.
- Mika Sinanan: Take out the whole line.
- Larry Birger: And you're saying that to loosen things up, Mika?
- Mika Sinanan: Well because current practice. There's no evidence that we have seen that they are not essentially equivalent studies, and that, in terms of safety, and there is certainly more structural evidence on the basis of the echo that is available from a stress EKG. So that, that's the basis of that. Plus, we don't want to put a put the roadblock of having patients have an unnecessary stress EKG and then have to have, then get set up for a stress echo, or have the justification and roadblock of having to justify or support the language we just deleted.
- Larry Birger: Yeah, I would agree.

- Janna Friedly: So, so I think that sounds reasonable. I think we don't have here, any risk so low, intermediate, or high risk. And we had talked about using that as a, as a framework, would it make sense to include in, intermediate, or high risk or...?
- Chris Hearne: Janna yeah I agree I think maybe instead of saying symptomatic patients, we should say something to the effect of intermediate pretest probability of CAD or intermediate to high pretest probability of CAD, something to that effect rather than symptomatic patients.
- Larry Birger: What are we defining as intermediate the lower threshold of that?
- Janna Friedly: I think that was based on the the clinical guideline that came came out so I think that that's where that came from. So you're right it has to be defined for using, I would assume the same same definition that they use in the clinical clinical guideline would make sense, but if you're trying to define a...
- Christoph Lee: I thought in the prior decisions we had low, intermediate, high risk without defining it?
- Conor Kleweno: Was a good question for Jim to comment on are those guidelines pretty readily universally understood, or you predict them to be?
- Jim Kirkpatrick: There's, there's always wiggle room, I'd have to go back to the actual guideline and see how they defined it and this is all in the context of chest pain or what we used to refer to as angina or equivalent.
- Larry Birger: Since we're shooting for some, you know, allowing for nuance I think that not defining it any further would probably be advisable.
- Janna Friedly: And so, Andrea did point out that the report does not address asymptomatic patients so this coverage decision for all of these really only applies to symptomatic patients.
- Josh Morse: So yeah, here's the scope from the, from the key questions document.
- Janna Friedly: So then is it unnecessary in the wording of the coverage to even say symptomatic, at least for each of the individual ones or is that important to put in there, or some qualification that asymptomatic testing is not included as part of this decision?
- Chris Hearne: I think something we might want to try to what we're trying to do by specifying is to avoid people, and using these technologies to test for people who may have some symptom. But the story is, is very low probability for coronary artery disease, we want to sort of avoid testing those patients. You can't say they're asymptomatic because they have some symptom but everything else in their situation suggests a really low probability of disease and so, saying, eliminating not just asymptomatic patients but also low probability can get to that population.

- Janna Friedly: So symptomatic patients, intermediate or high-risk CAD. With that, praising the appropriate them.
- Chris Hearne: I think that sounds pretty good.
- Josh Morse: Okay so, can you help me or tell me how to craft this intro sentence?
- Mika Sinanan: shallow, what do you think about using almost like the first sentence of the peacocks report? (Inaudible) Josh actually have that screen up before. I thought the language over there was actually fairly good. Josh, I don't know if you're okay with like just flipping back to the screen that.
- Jose Morse: Yeah, no problem.
- Mika Sinanan: If you just read the the patients for need component patients adult patients, you know, parentheses blah blah blah. You guys have read better than I can. But it's that that really kind of describes I think what we're, we're getting to. That's the inclusion criteria.
- Janna Friedly: It is, I think what again it goes back to the intermediate or high, high risk is not really defined in this this description though. Okay, okay. So, that's the, I think that was the. So I don't know that I would, I don't know that I would be as maybe that very first part, adult patients with symptoms of suspected CAD, or at, and again I think if we're if we're whole, it sounded like the whole benefit of the clinical guideline that was it costs the only big difference between them and nuclear. And it's reasonable to promote SPECT, in that case, if they're similar, to me. And it sounded like there was nuance in terms of when you would when you know who would be more. So I think, I think you could you could use the same two bullet points as above inspect and then as a third bullet point. Say, and when SPECT is not technically feasible appropriate or results are inconclusive. I think I would, I think it's not just a technical feasibility but there may be clinical scenarios where it's not appropriate. So I think in my mind putting technically feasible or appropriate make sense, don't
- Josh Morse: Replace this line with the two bullets above to make it very clear.
- Janna Friedly: Yes. Okay. And then put and are right now that I'm reading it then it, then it becomes confusing as to...
- Larry Birger: why you could put or?
- Josh Morse: I see this and would go down here.
- Larry Birger: Could you put 'or' in between those two top bullet points? I mean somehow you're, we're trying to tie those together with the end inclusion.
- Clint Daniels: Yeah, or maybe. Yeah, it's gonna be cleaner to keep it how it was before we're just famous fact, I think I made it worse for you I think I, I, sorry, I

made it worse I think you should say same, the same coverage criteria for respect and.

Janna Friedly: My apologies fresh. There we have worries. We'll figure it out. Patients under the same conditions as expect when I would argue just to say technically feasible or appropriate unless somebody has different wording I feel like technically feasible isn't doesn't quite capture that there may be clinical scenarios where it's just not the right. But you know that they may have better results.

Larry Birger: I agree, but I would put clinically appropriate clinically to distinguish it from technically appropriate. Okay, when it is not technically or clinically appropriate without being not technically feasible or clinically appropriate seemed reasonable I don't know.

Janna Friedly: Yeah, that's, that sounds. That sounds good. Okay, everyone okay with that?

Mika Sinanan: That's good.

Janna Friedly: Okay, then CCTA is uncovered benefit is there, that those two bullet points that the first two bullet points are look exactly the same as the other ones. So, I would, yeah, I would make sure the wording is the same

Christoph Lee: Questions for Jim on this one, are there still people using CT scanners?

Jim Kirkpatrick: 30 slides to DC to as well I don't know that's a great question. Good. Everything's 256 slice now. Yeah, it's, it's pretty amazing, I don't, that's a really good question. I mean, clearly, things before it's kind of out of, out of date now too But yeah, I don't know, good question.

Christoph Lee: I would say that that's really archaic, and I'm probably take it out.

Janna Friedly: That was from the 2009.

Christoph Lee: I think it's pretty clear that everything that we use, nowadays, even in rural settings are more than 64 slice. Yeah, they probably only that one.

Janna Friedly: Yeah, I think that makes sense. I would agree with taking that out.

Larry Birger: Now question here as written. It would seem to me that somebody could say well I don't I'm not going to do a functional test I'm going to do a CCTA because they have the same inclusion criteria. Clinically they're not. They're not equivalent and I do agree with the emphasis of the other experts that we had whose name I'm blanking on as far as the value of, you know, the emphasis on functional testing. So do I don't maybe others don't agree with that number one number two if they do, do we mean, is there something that needs to be a little bit tighter with the CCTA or not.

- Janna Friedly: How would you were saying when when an alternative functional test is not appropriate or? How would you?
- Larry Birger: I don't know that I'm, I'm raising the concern without an answer. How's that, and maybe the Jim, could you weigh in on that?
- Jim Kirkpatrick: Yeah, this is difficult because looking at the evidence, you know, if you look at it the one way of saying well as far as compared to Cath, and to some extent the outcomes there to the different strategies are getting at the same thing. And, and so it'd be reasonable to use the same language for both of them here. But, but you're right they, it really is a bit of an apples and oranges situation. I wonder if perhaps saying something to the effect of when when anatomic assessment is indicated or something like that, to sort of make the distinction from, from the functional..
- Janna Friedly: That are up getting some anatomic assessment with the other ones as well. Maybe not to the same extent but they're very good point. So, it would be an attack coronary artery anatomy, right, because the other ones absolutely are giving you the functional then other anatomic things like ejection fraction and I left the trigger and all that so it wouldn't Yeah, you'd have to specify coronary anatomy, saying.
- Larry Birger: Okay, what are the appropriate use criteria say they still have those we used to have a chart in our clinic where we'd had to meet certain criteria and put them in our dictation. What are they saying now to distinguish them from just ordering a SPECT study.
- Jim Kirkpatrick: I believe that, and that's why I think this new appropriate use criteria may change things a bit. I think the last one I'd have to look this up and I'm, my apologies, but I think that they were still thinking that CCTA was loaded intermediate risk patients in the emergency department, which is what the last coverage decision said, but but obviously there's been a lot of a lot of new data since then. And that's, that's why it seems very reasonable to change it. I don't know that the appropriate use quickly and it could be by just don't know. It could be that it said something to the effect of an atomic versus functional but I don't know.
- Larry Birger: Yeah, because we're, if, if that's what they're saying now something like evaluation in the emergency department we're way broader than that in this wording right now.
- Mika Sinanan: The data that we saw only supports this.
- Larry Birger: No, I'm saying right now. If you were in a, in a clinic, you could say, well, do I want to order a CCTA or do I want to order a SPECT scan they have the same inclusion criteria. And they would just choose one or the other but clinically as Jim pointed out there, there, they have different emphases right now and..

- Mika Sinanan: I understand but but I think one of the concerns we have to be careful about is that these don't represent guidelines for us, or choosing represent what the data supports us being able to say in our data didn't allow us to say anything beyond what those two points are. Unfortunately, in fact, with regard to the anatomic imaging question CCTA had a higher rate of conversion to ICA right to, to a clinical at the base of angiogram than anything else. So, the one that the arguable best anatomic study of the ones that were studied translated to the gold standard of anatomic studies, more often than anything else.
- Larry Birger: So yeah, I wouldn't argue that that's an advantage I would argue that could potentially put the patient at higher harm than that gets back to my comment from years past where there were these pretty significant variations in the possibility of degree of stenosis on the CCTA that then led us to do a Cath because we had to determine that.
- Mika Sinanan: Right. I'm just thinking that the data that we saw doesn't, I think give us a basis to go beyond what those two points.
- Larry Birger: You mean beyond in the sense of more restrictive?
- Mika Sinanan: Correct. And, and, can you help me clarify, I thought also, it was for high, high risk. There was also concerned that in that in the pyramid in the clinical guidelines, wasn't it only for intermediate risk.
- Jim Kirkpatrick: That in the, in the acute setting the high risk generally goes for invasive at but in the outpatient setting. The way the pyramid has it structured is that a high risk, either anatomic or functional testing.
- Larry Birger: Yeah, I'm not comfortable with the breadth of the language for CCTA here, I think that it unless there's some downstream further refinement, that would go into this. To me, this could lead to an inordinate ordering of this test which is as Mika pointed out, it can lead to ICAs it could also lead to things like contrast nephropathy .
- Christoph Lee: So on the flip side though, in an emergent setting has CTA has the highest negative predictive value. So, length of hospitals they decreases dramatically. If you use it in that setting for intermediate risk.
- Larry Birger. Right. What you said is, it would be considered would fall into the rubric of my further refinement statement right but that's with really be have to think about it in the guideline perspective but this is a coverage decision not to say okay for different Okay.
- Janna Friedly: Okay, so with, with that in mind, is this wording then, is everyone okay with this, this wording as as for coverage?
- Larry Birger: Yes, okay. I'm okay with it.

- Janna Friedly: CC CCTA with FF R is a covered benefit for patients under the same conditions as the CTA one further investigation and concerning stenosis identified on initial CCTA is necessary that capture the conditions under which you would need FFR?
- Mika Sinanan: When further investigation is a functional investigation or further investigation of the, of the flow effects of stenosis, it's not just this the stenosis we're not just looking at that comic.
- Janna Friedly: When further functional investigation. Now, for now, I'm not sure how to work wordsmith admin, that might be a good question for Dr. Fitzpatrick.
- Jim Kirkpatrick: I think you bring up a really good point because further investigation could mean something else because you just don't have the technical ability to see this message very well and they really want this would be getting at is that functional significance of the stenosis. That usually the term that we often use this functional significance or....
- Janna Friedly: That's good when so when functional significance of current concerning stenosis is unclear, or...
- Jim Kirkpatrick: I think is necessary as is fine.
- Janna Friedly: And further investigation of functional significance. Concerning when further investigation of functional significance of concerning stenosis is necessary. Good. And then you just have one further investigation of twice.
- Josh Morse: Good work though. Now you have you have when went wrong.
- Janna Friedly: When further investigation that you've got it twice. There you go. And there's two whens. There you go. Yeah.
- Josh Morse: The rest of its right.
- Mika Sinanan: Change the need for functional significance for concerning stenosis. That does that help make it clear. Anyway, I think, I think that
- Christoph Lee: Jim, can you clarify for us, if a patient has a CCTA, did they have to get another CCTA to get FFR?
- Jim Kirkpatrick: You know, that's a good question. I think with the more modern techniques, no, but I don't dislike the question of how fast it has to be, that's a, that's a good question. I'm afraid I don't know the answer to that. Great question.
- Larry Birger: Yeah, because the initial CCTA makes it sound like that is the case.
- Jim Kirkpatrick: There possibly could also be circumstances in which someone gets cast somewhere. And then you want to know the functional significance of it and for some reason they can't do base of FF hard and think to do it and

then you want to order a CTA with so FFR to look at the function significance, I guess that would be rare but the possible.

Larry Birger: Would we be remiss in just exercising that on initial CCTA those three words is that was problematic if we get those out of there?

Mika Sinanan: I think that's a good idea. Yeah. Yeah, I agree, thank sense.

Josh Morse: Sorry, which part?

Janna Friedly: Will CCTA, take out those three words, yeah, there you go. That, that more clear that you can or less prescriptive one you can use it.

Christoph Lee: Maybe reverse the order of identified and stenosis.

Jose Morse: Put identified in front of concerning.

Christoph Lee: Yeah.

Janna Friedly: destination and functional significance up,

Christoph Lee: or just take it out.

Janna Friedly: Or, and can you take out concerning to? I mean, I'm not sure that that's necessary. And if you, if the point is, you saw stenosis and you want to know what the functional significance of been further investigation and functional significance or stenoses is necessary. Let's say that seems reasonable.

Larry Birger: Not to quibble but it seems to me the word of is better than for their now.

Janna Friedly: Yeah, I kind of agree from chromatic.

Clint Daniels: What about moving 'necessary' up to after further investigation, as well? It seems awkward at the end of the sentence. And their investigations is very upsetting significance.

Janna Friedly: When further investigation. Then you'd have to use for me it doesn't work. I, I'm fine with it. It's functionally

Mika Sinanan: Functionally significant for further investing, oh I see, okay, no it's fine, my mistake.

Conor Kleweno: Is clinically indicated.

Janna Friedly: Instead of necessary?

Conor Kleweno: Just giving an alternative, people didn't like 'necessary'.

Josh Morse: What about when function, investigation of function is necessary due to stenosis?

Larry Birger: I like functional significance. Clinically indicated seems like a good substitute for necessary as well.

- Janna Friedly: Yeah, that's my preferred clinically indicated to. Okay, when further investigation of functional significance of students is clinically indicated. Okay, that sounds reasonable to me. Any other comments about these? It, I think we have, we have come up with draft findings for each of these. I know we are quite a bit over our time. Josh, what is next?
- Josh Morse: The part in the story where we pause for a moment and turn our heads away from this. Before we look back and check it and also check in with the agency medical directors to see if they have any concerns about the implementation of this language, so we can consider that two minutes past and look again. It's typically what we do at this point.
- Janna Friedly: Does any do at this point do we want to have them when Dr. Chen?
- Chris Chen: Thanks was that. Sorry, I didn't give it quite two minutes
- Josh Morse: I think but no no that was.
- Chris Chen: Yeah, I'm happy to provide comments if you guys are open to hearing feedback for.
- Janna Friedly: Yep.
- Chris Chen: Yeah, I think this generally aligns with how we were thinking I think the one question was just around the kind of tiered approach in terms of exercise or sorry stress echo prior before SPECT and kind of determining whether an echo was inappropriate, leading SPECT and then it you know I did see that the committee felt comfortable kind of integrating some of the inappropriateness language under the PET. And so, just wondering if having echo is inappropriate prior SPECT was something to consider. But I think otherwise, but I think otherwise, this does seem to gentleman here, how we interpret the evidence report as well.
- Janna Friedly: So, your thoughts, thought your thought is to under SPECT to include patients under the same conditions as stress echo when stress echo is technically is not technically feasible clinically appropriate for. Is that what you're, you're suggesting?
- Chris Chen: Yeah, yeah. For the committee's consideration.
- Janna Friedly: I may hear from other committee members about that? I think, I think we didn't have strong feelings that we could distinguish stress echo versus SPECT in terms of evidence.
- Christoph Lee: I guess my concern with tiering is what do you do with CCTA though. And how do you to do that with other imaging modalities.
- Janna Friedly: From category, right?
- Chris Chen: Yeah, if I might comment on that I think that the interpretation that we had was that the functional versus they have autonomy and atomic

testing was kind of utilized in different scenarios and in different ways, in a way that kind of the functional testing was more kind of considered as a specific category entry point confessed compared to the CCTA.

Janna Friedly: So I guess from my, from my perspective, it seems like using that same language. Patients under the same conditions as stress echo when not tech when when stress echo is not technically feasible or clinically appropriate. That to me is, sort of, again, broadly way to for the physician's to be able to decide which one is appropriate. But yet, does sort of indicate a preference for stress eco first considering it first versus SPECT or PET. So to me that that seems reasonable but I want to hear from everybody else.

Laurie Mischley: Yeah, this is Laurie, it makes sense to me.

Janna Friedly: Mika, do you?

Mika Sinanan: I agree.

Christoph Lee: I'm sorry I guess I don't agree, and I just point to the summary efficacy and safety tables, and I'd like to see where SPECT, if we have enough evidence there to say that SPECT is inferior to stress ECHO for some reason. I'm not sure that we're saying that it's inferior to stress ECHO or more cost effective.

Chris Chen: But I'll just come at I think, generally, the way that we consider various technologies is along the lines of equal effectiveness, and these costs the alternatives. And so where technologies are considered to be equally effective less costly alternative would be more desired I guess and so I think, in the absence of accident compelling evidence that SPECT was more effective than stress echoes and kind of then considering the cost and and potentially a big up.

Judy Zerzan- Thul: I would sorry, go ahead. Go ahead. Oh, so this is Judy, there's a little I wouldn't say that you could say something about the cost because the cost could potentially change in the future. But right now there's there's definitely a cost difference between those two technologies and I, I agree. I'm, I'm not sure there's a clinical difference in terms of how they perform.

Christoph Lee: Is that cost difference enough to say that based on local accessibility and expertise that the efficacy versus cost would always favor respect or always favor echo?

Judy Zerzan-Thul: Chris, what do you think about that?

Chris Chen: Yeah, I think that's part of why we proposed language around inappropriate and so we're in the title unavailability to take into consideration various factors, such as that.

- Larry Birger: Seems to me and doing that we're starting to restrict the nuance factor here. Jim, could you weigh in on that?
- Jim Kirkpatrick: Again I'm, I'm pretty biased in this respect. But yeah, I, it does seem that it restricts it a little bit and I guess, sort of devil's advocate I would question how this would be implemented, because if stress echo say is available but it's not very good and that is only known to the individual at that institution, how would that be sort of handled on a coverage decision standpoint? But on the other hand I totally understand the argument about the the cheaper test if everything is otherwise equal.
- Larry Birger: Yeah, the problem is is it could translate into more staff time and even more physician time to have to try and break through the barriers to getting it covered. Again just speaking to my years in the clinic.
- Judy Zerzan- Thul: That's not really, Judy again, what we'd like you to comment on because we have done as an agency a fair bit of work and continue to do work on Administrative Simplification and automating things, and that sort of thing. So, so some of that wall, it was true it delayed things a lot in the past it doesn't necessarily now. I also think it's important to talk about the cost because I think we often don't think about it. I mean, for sure. When I did more full-time practice, I had no idea how much things cost and I didn't really think about it. And at this point in our healthcare trajectory, it's important to think about that, and to have a good reason to pick a more expensive test is the clinical results is the same or similar.
- Larry Birger: Yeah but, again, arguing back, I haven't been out of the clinics that long so to say things have improved doesn't answer to what I dealt with on a day by day, week by week basis. And, you know,
- Judy Zerzan- Thul: There is about this offline.
- Larry Birger: Yeah, well I'm saying it's relevant to the decision because this decision is going to affect people that were practicing are practicing and context like I was practicing and that's why I bring it up, it does bring other costs, it just pushes them to other areas like, you know, impacting staffing so that you can't see as many patients or you know whatever their their downstream effects.
- Janna Friedly: I think, I think that offer that we had for the PET versus SPECT was in the spirit of being broad enough that it gave discretion to the, to the clinician to determine whether that test was technically or, or, you know, clinically appropriate. And if you don't have availability in your, in your area of high-quality stress echo or an end you know that then that seems like that falls into that category. but I do appreciate that it's that the the interpretation of those words can be a little bit problematic but you know if if it creates barriers where people are judging, what is the physicians description of what's technically feasible or appropriate.

- Mika Sinanan: I agree exactly with what you just said. I think we should use the same language that we use to under PET, and just replace SPECT with with stress eco.
- Janna Friedly: It does seem like that. That gives
- Josh Morse: Me the way the same, you're saying put take this language and put it here?
- Mika Sinanan: Correct for that. And then replace the word SPECT with stress echo.
- Janna Friedly: Yeah.
- Josh Morse: Thank you.
- Janna Friedly: Okay. Okay. So I think we have dropped findings. Now, are there any other comments about the wording?
- Larry Birger: Okay, how does one vote on this. We're going to vote as a composite document Are we going to go section by section? Because I don't agree with that change.
- Janna Friedly: Yeah. Do we are on this little choppy there Janna. Oh sorry, my internet is a little spotty. At this point, do we at this point typically then do a final vote on this, the wording of these coverage decision.
- Josh Morse: Yeah. Yes. So typically your earlier vote would be in it kind of an advisory vote that you're all headed for coverage of conditions which you've done. And now you've developed your conditions, you may not have perfect consensus on these conditions but you could vote to see if everybody what your temperature level is on these conditions, and then you can do a final vote on cover, cover with conditions or not cover.
- Christoph Lee: So make one more comment is that okay. Yeah, it's the current language force that is in congruent with AJ recommendations and guidelines. So, the way I think we should all kind of take time to read it, since we just got it today. But if you look at all the different evaluation algorithms. If a test is inconclusive so stress echoes inconclusive. Usually, the next step is something else, and not another type of stress testing. And maybe Jim can comment on that but I'm just worried that are draft languages and congruent with guidelines.
- Janna Friedly: Is that also true for, for PET versus SPECT as well are you just speaking to the SPECT?
- Christoph Lee: Just SPECT, yeah. From what I can tell from the guidelines is grouped together with all.
- Janna Friedly: Yeah, so. So, one option and I, a nurse nurse fact with think conclusive, I think the idea here is, all things are equal and you have the choice between a stress ECHO and a SPECT that you and choose the stress echo

preferentially because it's lower cost, all things being equal, if they're not equal, SPECT is a better choice because of patient characteristics or availability or expertise, technical feasibility, then, then you would choose fact I think that's that's the spirit of what we were trying to do it.

Larry Birger: You're forcing the clinician and his clinic now to or her clinic to make an argument for why it's not technically feasible that may not fly, as you run it up the the line. But that's also true for PET versus SPECT. That's it. That's a different subject, then stress eco versus SPECT clinically in terms of their clinical utility be considered and

Mika Sinanan: Nowadays we have to provide an indication for all of our tests as you know, in epic it's coded and you can order the test without providing an indication. And I think that the indication language can capture that. Why, why you chose that and not something else pretty easily. I don't see that as a burden. Once..

Larry Birger: I would disagree. I've been in that position quite a few times where I thought I had supplied sufficient justification and then you're dealing with people that are administering this who do not have the level of nuance or sophistication and they have burdensome workloads and then you have to have provider to provider discussions and so forth. I'm talking about the real world. And having been there I was, as you detect I have some pretty strong feelings on this.

Christoph Lee: What do you think about just taking out the sub-bullet point about being inclusive for both SPECT and-?

Janna Friedly: And what I would recommend is that we take out that that bullet and then. And I know, Larry, you, you have different views about the acceptability of this entire bullet point here, but maybe we can we can take a vote on on this, or take a straw. So, not, not with S the PECT sounded like.

Christoph Lee: Oh yeah, both SPECT, with SPECT and PET,

Janna Friedly: Oh with SPECT and PET?

Christoph Lee: And you would pick the most clinically appropriate test and then if a functional imaging test is inappropriate you move on to something else.

Janna Friedly: Okay yeah so I guess that that does make it unnecessary. Okay, that makes sense. And then take out the or, on both of those. Okay. Should we go ahead and take a vote on the wording of these, to do these separately, each one separately?

Melanie Golob: I do have language polls ready if you'd like Dr. Friedly.

Janna Friedly: Okay, let's go ahead and do that and get started with that then.

Melanie Golob: Great.

Josh Morse: Nine of nine for yes.

Janna Friedly: Okay.

Josh Morse: For stress echo.

Janna Friedly: Okay, let's go to the next one.

Josh Morse: Eight yes, one no.

Janna Friedly: Okay. Go to the next one.

Josh Morse: Nine of nine for yes.

Janna Friedly: Okay, and next one. [pause] Okay. And the next one.

Josh Morse: Getting faster.

Janna Friedly: Okay. So it looks like in all but the stress echo warning we had 100% agreement. And, and eight out of nine for the stress echo.

Larry Birger: That's actually mistaken, I hit the wrong button I do not approve of this stress echo language.

Janna Friedly: Why don't we do that one again so we have a clear poll.

Melanie Golob: Is that the stress echo one or the SPECT?

Josh Morse: I thought that SPECT was--

Larry Birger: --I'm sorry, SPECT, it was SPECT I misspoke.

Josh Morse: Stress echo was nine, I think yes, SPECT was--

Larry Birger: Yes.

Josh Morse: SPECT was eight to one.

Larry Birger: I meant SPECT.

Janna Friedly: So that the one that was eight to one.

Larry Birger: Correct.

Janna Friedly: Okay. So SPECT, SPECT. Can we pull that one back up?

Melanie Golob: Yeah.

Josh Morse: It's now seven to two.

Janna Friedly: Okay. Okay, so still 78, 78% to 22%. Okay. So, so with that then we do a final poll for, for coverage.

Josh Morse: Yes.

Chris Hearne: Janna, can I just make a quick comment? I don't want to belabor the point since we're quickly moving towards a decision here, but I just want to, I think it's worth pointing out that this language is clinically appropriate is interesting to me and I feel that in the past, when

making decisions like this, we would have been more specific about what that means, it, maybe in other previous decisions. I'm not, I'm not against using a little bit more loose language in this way I don't think it's necessarily wrong but it just strikes me that it's perhaps a departure from how we've previously done things and maybe worth just keeping in mind.

Janna Friedly: Yeah, I would, I absolutely agree and thinking about an implementation of, of these is important and I think that was, that was brought up before, I think, at least from my perspective, the reason that we sort of landed on on this was really, and in part because the [indistinct] from, from Dr. Chen and the agency, about this, this kind of wording, so I think and the, the reality that if we were to be more clear or prescriptive here then we would we would not be able to come up with language that that would be appropriate. Is that maybe, maybe Dr. Chen can can weigh in on that, or Dr. Zerzan?

Chris Chen: Yeah, I think, along the lines of the discussion around nuance, and that many situations where one test might be selected over another, clinical expertise may vary. I think we, this was an effort to allow that kind of flexibility without being overly prescriptive I guess I should say.

Janna Friedly: I think that, and I think the discomfort from that that's being voiced is, is that when there is some of that sort of discretion, that that can be used in both ways that can give give more leeway to the, to the, to the ordering physician provider, but it can also create some barriers that are imposed with interpretation of the of that on the insurer side so how do we balance those two those two competing issues. And I think that's the crux of what the concerns are about the wording.

Chris Chen: And I think that I mean that could be worth exploring to if it's the committee feels that there are areas to dive into if there are specific parameters to lay out around where it is or isn't appropriate. And, you know, that could either be baked in us examples, or other criteria. But, yeah, that's certainly if there are more defined parameters I think that would be reasonable.

Janna Friedly: I know I'm not confident that we can come up with more defined parameters I think that was the whole, I think that's that's the issue, is that, is that it would. It didn't sound like from the evidence, and then discussion with that in any way without getting an overly restrictive or overly complicated to the point that it that it makes it very challenging. So. So I think, you know, from my perspective, I'm still okay with this this wording and that but I think that is at the sort of the crux of what Chris has brought up and Larry has brought up as well.

Christoph Lee: Can I make one more comment just from the radiology perspective? I understand grouping SPECT, and PET together because they're

interpreted by the nuclear medicine physician and performed in the nuclear medicine department. What's important to point out is that stress echo is read differently, right, because the Echo lab through by cardiologists. It's not in most places, read by the same interpreting physicians. And the same with CCTA right so you have basically different labs, right you have a CCTA me imaging division that will interpret it to the 3d imaging reformats. So the quality and expertise of CCTA SPECT/PET, and stress eco are very different at the same institution. So we talk about access and variability and expertise, I don't see the, the, I guess the, the tiered effect of going from stress eco to PET for SPECT to PET, I see it right it's just more expensive equipment with the same image in group. But, at least from the quality perspective of expertise and availability and access stress echo is separate from SPECT/PET is separate from CCTA. And that's how I conceptualize it and why I have difficulty with tearing SPECT after stress echo.

Larry Birger: I think that was well said and I like to, I just like to piggyback on that I like the you captured the word that I couldn't and that was the word tiered, it didn't make conceptual sense to me. I saw it as being a purely really economically driven decision. And again, no offense by those who haven't had to deal with the years of frustrations that clinicians have that. I'll leave it at that.

Josh Morse: Where does the evidence lead you if the evidence of those two technologies, is that their outcomes are similar? I have to say, then that would be I hope how you're basing your decision. If you know you have evidence of, of how they work how effective they are and how safety are and then you have information about their cost. You know, I think that's what the charge of the committee is to decide when they're there most appropriate and if those decisions are are difficult or don't align with certain things I think that's your charge.

Christoph Lee: Again, I'd like to ask the committee to point out where the differences in terms of effect of efficacy and safety. At least with the cost data that was presented today. There was no convincing argument to me that costs more to do one of the other in terms of the entire clinical episode. So there are so many missing parts to the cost data presented radio nucleotides or that the medications were left out completely right and everything that goes into the cost with that. So, at least from my perspective, there was inconclusive evidence based on the evidence summary provided to us to make a decision about cost effectiveness.

Larry Birger: And I'm saying something similar in my own way is that a significant pieces of the cost equation are being left out. and excluded as evidence. So when you appeal to the evidence, you're, you're not I would I would argue, again piggybacking on that that there's a more comprehensive

sense in which evidence would be taken in this cost analysis, even if we haven't defined it quantitatively, we certainly can define it qualitatively.

Janna Friedly: Okay, so it's, it sounds like, on the positive side we have agreement on four out of the five different imaging tests in terms of the wording, and and decision. The SPECT, it sounds like there's still some, some concern about the the wording and I think there were some good points brought up about, about the, the wording. I think it is given that there was new information provided after, after the poll. We, one option is for us to retake the poll and see if the decision still stands from the majority of the committee or if, if, if not then, then we need to go back and reconsider the wording. But I just we have already voted on the, the wording so I want to make sure that we're, we're doing that appropriately. Does that Josh does that sound reasonable?

Josh Morse: Yes it does.

Janna Friedly: Okay. So, is there any other before we take the new poll, is there any additional information that hasn't been shared that, that would be important for us to consider with respect, coverage wording here? Okay, so, so let's, let's go ahead and take, take a new poll.

Melanie Golob: And this is on coverage for SPECT graduates, it's on the language for SPECT coverage conditions. Okay, give me just a minute.

Janna Friedly: Okay, so it looks like it looks like we, we still have a majority approval vote to approve the language for SPECT as is. Ok, ok so at this point then Josh we, we move to voting for coverage final vote for all five separately.

Josh Morse: No for this language has written. This is that you're voting on the whole, the whole thing, yeah, okay.

Tony Yen: Remember, the word no comment period or net we're just better.

Janna Friedly: You can comment.

Tony Yen: My comment is on all of these different modalities and the wording. If you take a step back and look at the draft language, is it appropriate that we're calling out SPECT compare distress echo and CCTA? Because language for CCTA and stress echo are completely identical, but it's different for SPECT. And do you feel like the evidence presented today will allow for that improve that?

Janna Friedly: Well, I think, and again, this goes back to the functional versus anatomical, and into two separate categories, and so you're right that the wording is the same but the way I think the discussion around this was that the clinical indications for an anatomical test would be different than a functional test, but that it's not part of the policy or the clinical coverage to specifically outline, those conditions for which an anatomic versus functional test would be appropriate here.

Tony Yen: I would agree with that Janna and that's, I think, my point that we can't make that distinction. So, why are we making that distinction between SPECT and Stress enough for the other comparison groups?

Mika Sinanan: Mika Sinanan, my take on that, which I think is a really great question, is that we also got agency information around the actual practical application of this right now. And they showed us that SPECT from a prophylactic is twice the stress echo cost, and we noted that it didn't include the radio pharmaceuticals, the storage, the overhead, etc. that goes into that. So, it would appear from that, those set of data that SPECT is a significantly more expensive option, and the data, the other data that we got from Aggregate Analytics suggested that the two were otherwise relatively similar in their efficacy and safety. So because the cost difference was highlighted but the efficacy and safety didn't appear different as Dr. Zerzan said, we can't take into account cost data in making a recommendation because it's always interim, right though, this is a, this is a re-review and it'll come up again, as the technology changes. It seems reasonable to tier for this, that was my thinking in voting for this.

Larry Birger: Does the language of the ACC/AHA guidelines rec incorporate that same kind of tiering? If it doesn't, I'm not comfortable departing from that, the framework. If it is I'm more willing to, to consider it.

Mika Sinanan: It did come from Dr. Chen.

Larry Birger: I'm sorry I didn't catch all that.

Mika Sinanan: The recommendation for the tiering suggestion came from Dr. Chen.

Larry Birger: I understand, but are those if we were to go to the new ACC/AHA guidelines if they have been updated and if they haven't either way. The latest current ACC/AHA guidelines and how they would, how they would grade. You know indications or whatever, I guess, if there's a conceptual framework that they lay out. That is not tiered, and we're introducing a tiered framework then I'm not comfortable with that.

Janna Friedly: Yeah, and again, I think we talked earlier about the, you know that there will be potentially differences between the clinical guidelines or, you know, in terms of the, how they are arrived at, and they appropriate use condition as well that I don't in my reading of the guidelines, quickly it didn't necessarily the purpose wasn't to go into necessarily compare each of those, this, it was a was a more broad guideline than that. So I don't think that was the it's, to me it's comparing things that are not quite, quite identical. It sounds like the appropriate use criteria, may be more prescriptive and specific to each of these tests but that's not available at this time. Okay, so, I recognize that there's some disagreement about the wording of the SPECT coverage decision, and I think that that's, you

know, that, that happens that we don't all agree on, on wording for, for a coverage decision. At this point, I haven't heard any, any new conversation. I want to make sure we, we voted twice on this. Now, I don't know that there's anything new that has been added that would suggest that we should re vote on, on this, at this point. Should we move then to a final vote of the entire wording, to get a sense of where the committee lands on the, the entire coverage decision?

- Mika Sinanan: Motion to close the discussion.
- Janna Friedly: Thank you.
- Laurie Mischley: This is Laurie, I second that.
- Janna Friedly: Great, okay, all those in favor of closing the discussion and moving to a final vote.
- Man: Aye.
- Man2: Aye.
- Man3: Aye.
- Woman: Aye.
- Man4: Aye.
- Man5: Aye.
- Janna Friedly: Anyone opposed – okay, let's, let's move to a final vote.
- Josh Morse: Okay, the final vote is seven for, two no for the coverage with conditions for noninvasive cardiac imaging.
- Janna Friedly: Okay. And at this point, then, I think the next step Josh is, is to review consistency with, with existing coverage. Decisions--
- Josh Morse: Yes.
- Janna Friedly: --and guidelines.
- Josh Morse: Yes, that's right.
- Janna Friedly: Are you able to pull that up on the screen. That part of the [indistinct].
- Josh Morse: Yes, so this is part of the decision aid that I'm sharing here so the first part is does CMS, have a national coverage determination.
- Janna Friedly: And I'm sorry, what, what page of the report is that on?
- Josh Morse: This, this is on page 92 of the final report.
- Janna Friedly: Okay – okay. So it does not look like, so that is for FFR.
- Josh Morse: Yes.

- Janna Friedly: And that's the only one so that, so that does not seem to be inconsistent with, obviously different wording, but does not seem to be inconsistent with our coverage decision, for FFR, much more prescriptive.
- Mika Sinanan: It is interesting, they're assuming two CCTAs, an initial one and a later one.
- Janna Friedly: Yeah, that's a good point. Okay.
- Josh Morse: Okay and then clinical guidelines. So there is the newer guideline which was not caught in the initial search, which obviously is now available, and in what is in the decision eight here would be guidelines that were caught in the search and reported by Aggregate.
- Janna Friedly: And I think the, it looks like the difference here again as we talked about in terms of the low risk and then on the flip side of the high risk and in certain settings, and our decision was a little bit more broad, it did not specify setting, and it did exclude the low, low risk probability. -- So again I think each of these it looks like to me, really do stray a little bit from the updated guideline, that is stratified with that low, low risk category without imaging, that they don't, they don't distinguish it that way. That seems to be to me the biggest difference.-- And then they're this, and then the one task force that specifically, you know, to the point of our discussion, also talks, sort of groups them all in one, in one grouping, for recommendation for initial test to diagnose CAD, when there is, when there is further testing that needs to be done. So that that is a difference between our, our wording, as we've talked about, then this this guideline from 2019, or task force
- Josh Morse: And Janna, can you offer support for why that might be different?
- Janna Friedly: Well, I think that it speaks to the, the, the difference, our, our discussion that led to quite a bit of discussion about whether or not these each of these tests should be sort of considered, all in the same bucket or should be tiered with one considered first if all things are equal, based on cost and potentially safety. And that's, that's where our committee, the majority of our committee decided that it would be reasonable to have a tiered approach with, with flexibility in the wording to allow physicians to make, make decisions based on clinical and technical feasibility. Clinical appropriateness.
- Josh Morse: Thank you.
- Janna Friedly: And then the NICE guidelines from 2016. And again, I think these, to me, look similar to the other guidelines. [pause] I don't have any other specific comments about that.
- Josh Morse: Okay, any other-- So you've addressed the NCD and the guidelines. Any other considerations were getting guidelines.

- Janna Friedly: I think the only other thing to consider is that it sounds like there will be appropriate use criteria coming out in the future and that's something that we should consider reviewing I'm not, I'm not sure what the process is for doing that, to, to see if there's any discrepancies between our coverage decision and those that would suggest that we need to consider. [pause] That would be the only other thing to make note of. [pause] Okay.
- Josh Morse: Alright.
- Janna Friedly: So I think with that this has been a very interesting discussion. I want to thank everybody for participating and for sharing perspectives I know this was a really challenging topic to cover, and I really appreciated that we, there were lots of different perspectives, provided, I think we have come to a good decision here today, but, appreciate that there are some lots of nuances to this topic that needed to be considered. Josh is there anything else that we need to do before, before we adjourn today?
- Josh Morse: Just, so, couple things. It's two weeks from today that your next meeting will occur, and we need to put a two-week comment period on this draft, which I think will be challenging to happen so the review of this draft and any comments, is not going to happen on the 19th. What we can try to do is consolidate the, this and the next one, and hold a meeting perhaps in January, to address comments on this decision and the one to come on the 19th, and then that also serves as a reminder, next meeting's on the 19th. We'll be publishing those meeting materials on Monday, since we couldn't get them up today during the meeting, but, and that one will be on the Cardiac Magnetic Resonance Angiography. So. Dr. Kirkpatrick will be back for that meeting as well. I think that, those are really the only updates I have.
- Janna Friedly: Okay. Great. Again, thank you everybody, and thank you Dr. Fitzpatrick for joining us today, with your expertise, that was very helpful, and we'll see everybody on the 19th.
- Mika Sinanan: Thank you. Josh, as, as quickly as possible, set the dates or potential dates for the January meeting. We have to change clinics and ORs.
- Josh Morse: Okay. Thank you. Will do Dr. Sinanan, thanks a lot.
- Tony Yen: Thank you Janna.
- Janna Friedly: Thank you everybody.
- Man: Thank you.
- Man2: Goodbye.
- Larry Birger: Thank you, bye.
- Man3: [indistinct]