WPS Government Health Administrators

Draft LCD open Meeting Transcript

Moderator: Dr. Robert Kettler

February 16, 2022

1:00 PM CT / 2:00 PM ET

Dr. Robert Kettler: Uh, Rich, can you hear me now?

Richard Staley: Yes, I can hear you.

Dr. Robert Kettler: Okay, thank you. Not sure what the problem was there, but at any rate, I want to welcome everyone to the WPS GHA Draft Local Coverage Determination or LCD Open Meeting. Today's date is February 16th, and the time is 1:03 PM Central Standard Time.

The purpose of this meeting is to take comments from stakeholders on the draft local coverage determinations that are being considered for adoption. Briefly, LCDs establish coverage criteria for various medical services. Comment on the draft LCDs is the only business for today's meeting.

Before we proceed further, I'm going to ask my colleagues from WPS to introduce themselves, beginning with any contractor medical directors who are on this call.

Dr. Ella Noel: Dr. Kettler, this is Dr. Ella Noel, I'm the J8 CMD.

Dr. Robert Kettler: Do we have any other CMDs?

Okay, then next, would any policy coordinators who are on this call please introduce themselves?

Dr. Denise Nachodsky: I'm sorry – Dr. Denise Nachodsky; I'm one of the CMDs for J5 and J8. Thank you.

Michelle McCary: Hi, I'm Michelle McCary, Policy (inaudible).

Dr. Kettler: Hi, Chri -.

Morgan Covarrubias: Hi Dr. Kettler,

Dr. Robert Kettler: Go ahead Morgan.

Morgan Covarrubias: I was going to say Morgan Covarrubias is on as well, and I believe that was Michelle McCarry that introduced herself.

Dr. Robert Kettler: Yes, I couldn't quite make that out.

Dr. Robert Kettler: Thank you. Any other policy –

Emily Zehner: This is Emily Zehner, I'm one of the RN policy coordinators with WPS.

Dr. Robert Kettler: Okay, and then any other WPS personnel?

Melissa Lietz: Good afternoon. Oh, sorry. Melissa Lietz is on, too.

Angela Mitchell: Angie Mitchell, Vice President of Operations.

Dr. Robert Kettler: Thank you.

Richard Staley: Richard Staley, the Policy Administrative Assistant.

Dr. Robert Kettler: Okay, thank you.

Now I'm just briefly going to go over the procedure for today's meeting, and the reason for this is to ensure an orderly meeting. As I mentioned earlier, the only business that is in order today is taking comments on the draft LCDs. There are two types of comment that we will be taking today: formal presentations of which there are three, and then any public comment that we may have.

In terms of the formal presentations, these have been submitted and registered in advance. When the speakers begin, I would ask that they please give their name, affiliation and a brief summary of any conflict of interest that they have. The presentations are limited to 10 minutes to assure that everyone who wishes to speak has the opportunity to do so. The timer will start with the presentation itself, or, in other words, after the Speaker's introduction and any declaration of conflict of interest. Mister Staley will give the speakers a 2-minute warning and then I will ask the speakers to stop at the 10-minute point. Uh, the speakers will have control of their slides. After the presentation, I will give my colleagues from WPS the opportunity to ask any questions that they have. After any questions I will then move on to the next presenter.

Subsequent speakers do not need to repeat information that has already been presented. If it's necessary that you make a public statement, all that's necessary is that you give your name and say that you agree with the preceding speaker Dr. X. The order of the formal presentations will be: Dr. Campbell Rogers, Dr. Mark Rabbat and Dr. Michael Gallagher.

After the, uh, all formal presentations have been given for a particular LCD, we will then take public comment on that draft LCD. To indicate that you wish to make a comment, please raise your hand using the appropriate Webex icon. Public comment will likewise be limited to 10 minutes for speaker and Mr. Staley will again provide a 2-minute warning. And I will ask the speaker to conclude at 10 minutes. Likewise for public comment, it's not necessary to repeat testimony that has already been given. On completion of a speaker's comment, I will ask my colleagues at WPS again if they have any questions. And we also ask that any written or any spoken comments be submitted - submitted in writing in case there are any audio difficulties and to make sure that we have the comments clear. The comments can be submitted to policycomments@wpsic.com. When there are no more comments on a draft LCD, I will move on to the next draft LCD. Finally, all speakers should be aware that this meeting is being recorded and will be available on our Web site in the near future. Uh, with that, are there any questions on the procedure?

Uh, since there are none, we will proceed then to the 1st presentation, this is related to Draft LCD DL38839, which is entitled Non-Invasive Fractional Flow Reserve, or FFR, for Stable Ischemic Heart Disease. And the CMD who is responsible for this LCD is Dr. Kettler. Uh, Dr, Rogers, you may proceed.

Richard Staley: Dr. Rogers, for whatever reason it is not allowing me to make you a panelist. Um. I'm trying to unmute your line. But Webex is not – watching – allowing my click through, um. Let me try something else here.

Dr. Robert Kettler: I hope everybody's not expecting me to entertain you all while we wait here.

Richard Staley: I apologize Dr Rogers I still cannot get this to. Um, I need -

Dr. Robert Kettler: Rich, are we able to, um, have our panelists or speakers re register or reenter as panelists?

Richard Staley: Yes, that will take me a moment. What I can do – What we can do, I believe we can move on to the next presentation and then we can – I will send Dr. Camp – Dr. Rogers a, um, a panelist invite.

Okay all right. Yeah – letting me make – Dr. Rabbat is now a panelist. For whatever reason it won't let me make Dr. Campbell one. Dr. Campbell, I will send you an invite as a panelist.

Dr. Robert Kettler: Dr. Rabbat are you ready to proceed.

Dr. Mark Rabbat: Yes, this is Dr Mark Rabbat. Can you hear me.

Dr. Robert Kettler: I can hear you. Yes. Um, please proceed

Dr. Mark Rabbat: Beautiful. Let me just share my screen.

Can you see my screen?

Dr. Robert Kettler: Yes, I can.

Dr. Mark Rabbat: Wonderful. Well, thank you very much. My name is Mark Rabbat, I'm a cardiologist at Loyola University, um, and I also am on the SCCT Advocacy Committee, and I'm the chair elect of the SCCT, for the advocacy committee. I'm also a consultant to HeartFlow and on behalf of the Society of Cardiovascular CT, I'd like to thank you for the opportunity to present on this proposed LCD.

Coronary physiology is established gatekeeper for revascularization, and fractional flow reserve is the gold standard use to invasively identify appropriate vessels for stent placement. And using FFR to guide revascularization has been shown to improve our patient's outcomes and reduce healthcare costs.

Now FFR can be derived from a static CT data set and has been proven itself as a reliable non-invasive test and the combination of coronary CTA and FFR CT provides a non-invasive strategy that offers both anatomic and functional data and has been validated through a number of accuracy studies and multiple large scale, clinical trials.

This is a slide on some of the clinical trials published and high impact medical journals and over 6,000 patients was up to 5 years follow up demonstrating the safety of FFR CT in clinical practice. Based on the evidence, the American Heart Association and the American College of Cardiology guideline for the evaluation and diagnosis of chest pain statement recently elevated

coronary CTA as a class 1A non-invasive test and recognized FFR CT as a class 2A with level B evidence, and this was published a few months ago.

I'd also like to point out that the stenosis range is included in these trials and in the recent AHA American Heart Association, American College of Cardiology guideline statement is from 40 to 90% stenosis – Not 40 to 70%.

This is a manuscript we published on the real-world clinical impact of FFR CT and practice. I'd like to highlight a few of our findings. For one, FFR CT was feasible with a conclusive result in greater than 90% of patients, and these weren't cherry picked individuals or patients; they were consecutive patients who had coronary artery disease on their CT central FFR CT analysis.

A diagnostic strategy of coronary CTA plus FFR CT was associated with less invasive, coronary, angiography in patients with coronary disease, compared to CT alone, and among those who deferred their invasive coronary angiography, there were no major adverse cardiac events. So, this was safe at greater than one year of follow up. And a high proportion of those who underwent invasive corner angiography were revascularized, resulting in higher diagnostic ICA yield and more efficient utilization of the cath lab resources.

So, we're sending the appropriate patients who benefit most from revascularization. The SCCT supports the expansion of the stenosis ranges from 40 to 70% to 40 to 90%. This expansion, again, is in line with updated American College of Cardiology and American Heart Association guidelines and will provide more access to appropriate patients.

Not only are we able to use the information from FFR CT as a gatekeeper for invasive coronary angiography, but we're also using the functional FFR CT data to guide appropriate revascularization strategies.

I'd like to share this case:

This is indeed a patient of mine from 2015, and who was having symptoms suggestive of coronary disease. Decided to proceed with a coronary CTA, and he was found to have multi vessel CAD on his coronary CTA.

Based off of the CTA alone, a strategy of coronary artery bypass surgery was recommended for revascularization. After reviewing the data from FFR CT, you can see that the circumflex artery and the right coronary artery had non flow limiting intermediate lesions, so having the data from FFR CT downgraded this patient away from a more invasive and costly coronary artery bypass surgery to a single vessel PCR to the LAD, and I'm very happy and proud to say that I just saw him recently in follow up nearly 7 years later, and he's been doing great without further diagnostic testing.

For the majority – Um, so here's the WPS proposal list of exclusions. The SCCT is requesting removal of exclusion numbers 1 and number 8. For the majority of cases, prosthetic valves and prior permanent pacemakers and defibrillator leads do not alter image quality of the coronary arteries. Thus, the Society of Cardiovascular CT is requesting removal of exclusion numbers 1, and number 8, and we recommend removal based on image quality assessment review by HeartFlow. HeartFlow reviews all of the images, and if CTA image is not adequate to create an FFR CT, the image is returned and there is no charge.

Here are our recommended criteria for the SCCT: In regards to exclusion, again, HeartFlow reviews all of the images and if the CTA is not adequate to analyze for FFR CT, the images are returned and there is no charge.

We also recommend excluding anatomy that would affect hemodynamic accuracy. However, there is contemporary data to suggest that FFR CT in an aortic stenosis patient is okay to include. We would also recommend excluding non-SC-elevation MIs, ST-elevation MIs, and unstable angina less than 30 days. We also recommend excluding new systolic heart failure with no prior invasive catheterization, and as stated earlier, we reco- our recommendation is to remove the exclusions that relate to image quality, such as number 1 and number 8 with prior placement of prosthetic valves and prior pacemaker defibrillator lead placements and the SCCT supports expanding stenosis ranges for coronary stenosis of uncertain functional significance in the range of 40 to 90%.

We also suggest removal of the statement in the paragraph regarding high plaque volumes, I know I don't have it on this slide, but oftentimes high plaque volumes do not necessarily impair CTA image quality.

The adoption of FFR CT to our CTA programs has really transformed the way we diagnose and manage our patients with coronary disease. We are picking up disease that we've been missing with standard of care testing.

And our patients are now feeling better with improved outcomes. At the same time. We're also able to safely avoid many unnecessary, invasive cardiac procedures with the addition of FFR CT. On behalf of the Society of Cardiovascular CT, we would like to thank you for the opportunity to share our suggested revisions and for your support.

Thank you again.

Dr. Robert Kettler: Thank you, Dr Rabbat.

Does anybody have any questions for Dr Rabbat?

Dr. Denise Nachodsky: Yes, I do: Thank you very much, Dr. Rabbat, for your very informative presentation. Can you just expand for us, who might not understand HeartFlow? Is that – see, you made remark regards that HeartFlow reviews all of this data. Is HeartFlow a corporation? A software? I, I'm a little uncertain what HeartFlow in the criteria, if you could expand on that, that'd be greatly appreciated.

Dr. Mark Rabbat: Sure. HeartFlow is the vendor that we send anonymized coronary CTA data sets, in order for them to perform the FFR CT analysis, and they perform their own rigorous image quality assessment in order to determine accurate luminol boundaries, et cetera and, um, appropriateness for FFR CT.

Dr. Denise Nachodsky: Thank you so – and, and his HeartFlow the only vendor that that does the FFR CT?

Dr. Mark Rabbat: They're FDA approved and commercially available.

Dr. Denise Nachodsky: Okay, thank you very much.

Dr. Robert Kettler: Any other questions?

Okay. Um, again, thank you Dr, Rabbat.

Uh, Dr Campbell, are you – or – Excuse me, Dr. Rogers, are you now able to be heard?

Dr. Campbell Rogers: Yes, I am. Are you able to hear me okay?

Dr. Robert Kettler: Yes, very good. Um, then please proceed.

Dr. Campbell Rogers: And are you able to see the slides on the screen?

Dr. Robert Kettler: Uh, yes.

Dr. Campbell Rogers: Great. Thank you very much, and thank you for the opportunity to, uh, provide public comment to start as asked. I have a conflict of interest to declare. My conflict of interest is that I'm a full-time employee of HeartFlow, who is the vendor of FFR CT that was just discussed and I have that conflict. Also, we can confirm that all of our comments here will be submitted in written form during the open comment period, just as you have asked. So, thank you for that, uh, reminder.

(inaudible)

Dr. Robert Kettler: Dr. Rogers, if you're speaking, I can't hear you.

Can anyone hear me?

Angie Mitchell: I can hear you. Dr. Kettler.

Dr. Robert Kettler: Okay. Um, is anybody else able to hear Dr Rogers?

Richard Staley: I cannot hear Dr. Rogers. I do see your screen Dr. Rogers.

And I see that you are not on mute in Webex so check your cell phone and see if you accidentally muted yourself on your cell phone or computer.

Unknown Voice: huh?

Dr. Robert Kettler: Rich?

Richard Staley: Yes?

Dr. Robert Kettler: Um, I'm going to suggest - oh.

(Inaudible Noise)

Dr. Robert Kettler: Was that Dr. Rogers?

I'm going to suggest that –

Richard Staley: I can cancel Dr. Rogers' presentation for now. We can try it again after Dr. Gallagher if you want.

Dr. Robert Kettler: Yeah, that's what I was going to suggest that we move on and try to get back to, uh, Dr. Rogers.

Dr. Gallagher; are you available?

Dr. Michael Gallagher: I am, can you hear me?

Dr. Robert Kettler: I can hear you. Yes. Are you ready to proceed?

Dr. Michael Gallagher: I believe I am, I just wanted – Dr. Rogers, are you – are you still there? Can we hear your voice?

Dr. Campbell Rogers: Yes, are you able to hear me?

Yeah, yeah, you're there Campbells. Maybe might make sense to have. Dr. Rogers go if you're up and live and then I can follow you if that's okay.

Dr. Robert Kettler: That's okay.

Dr. Rogers, we'll try again. And I'm sorry if we're having such difficulty here today.

Dr. Campbell Rogers: I'm sorry as well, I'm not sure where it lies, but I apologize. And now, I'm not able to – oh, now I'm able to share; thank you for that. Give me one second. And now are you able to see my slides?

Dr. Robert Kettler: Yes, it's not a full screen view. Now it is.

Dr. Campbell Rogers: Right, yes so I apologize for the back and forth.

Dr. Robert Kettler: It's okay. We did hear your introduction and conflict of interest, so, uh, you don't need to repeat that.

Richard Staley: Dr. Rogers, you may begin.

Dr. Campbell Rogers: Are you able to hear me?

Dr. Robert Kettler: I can hear you now.

Dr. Campbell Rogers: Okay. I'm not sure why this - Okay, so you can hear me now. I'm going to leave the slides in this view. You're able to hear me, right?

Dr. Robert Kettler: Yes.

Dr. Campbell Rogers: Okay. Good. I'm just gonna do this because when I try to present it, it messes up. I apologize.

Dr. Robert Kettler: Okay, no problem.

Dr. Campbell Rogers: Yeah, so I'm going to talk briefly about the guideline as an intro to some of our comments for suggested revision.

Dr. Robert Kettler: Dr. Rogers, I'm sorry, I can't hear you. Now.

Dr. Campbell Rogers: Are you able to hear me?

Dr. Robert Kettler: Yes, I heard, you know.

Dr. Campbell Rogers: I don't know why it keeps going off. I apologize. It's something in the system.

Dr. Robert Kettler: That's okay. If it works better to proceed with this view, uh, you know, we can try that if you don't mind.

Dr. Campbell Rogers: (inaudible)…guidelines breakdown…(inaudible)

Dr. Robert Kettler: Your voice is very faint. Dr Rogers.

Dr. Campbell Rogers: What I'll do, I'm going to call back in on a telephone. Please proceed with Dr. Gallagher.

Dr. Robert Kettler: Okay, thank you.

Dr. Campbell Rogers: Thank you.

Dr. Robert Kettler: Dr. Gallagher?

Dr. Michael Gallagher: Yes, can you hear me?

Dr. Robert Kettler: Yes.

Dr. Michael Gallagher: Okay. Great. If you just give me just one minute. I'm going to share my screen.

Dr. Robert Kettler: No problem.

Dr. Michael Gallagher: Can you see my screen okay?

Dr. Robert Kettler: I can, yes.

Dr. Michael Gallagher: Okay great. And you can continue to hear me. Okay.

Dr. Robert Kettler: Still hear you yes.

Dr. Michael Gallagher: Perfect. Okay.

Dr. Robert Kettler: Keep our fingers crossed.

Dr. Michael Gallagher: Yes, please. And please interrupt me if you if you don't hear anything.

So, my name is Michael Gallagher. I'm a board-certified cardiologist at Beaumont Hospital in Royal Oak, Michigan and I'm an associate professor at the Oakland University William Beaumont School of Medicine and today I'll be presenting as my own opinion and not formally representing my institution. I'm the medical director for the cardiac CT imaging program, and I'm also the program director for the cardiology fellowship at Beaumont Hospital. As a way of conflict-of-interest disclosure, I have served as a mentor for HeartFlow, which means that I've helped some hospitals and imaging programs across the country as they get started and initiate an FFR CT imaging program in their institution, and I help these physician-lead teams understand how and when to use FFR CT and to share some best practices. So, thank you for the opportunity to provide my perspective on the proposed LCD for Non-Invasive Fractional

Flow Reserve, or FFR, for Stable Ischemic Heart Disease, and to share why I think it's a value for the patients that I and my colleagues treat at several hospitals within our health system.

So, I'd like to provide my thoughts from a few different perspectives, just as a way of introduction. Number 1: as a cardiovascular imager, or a CT and FFR CT reader who's been using cardiac CT for 15 years, and using FFR CT since 2015 in a health system that performs over 5,000 cardiac CTs per year, and number 2: as a practicing physician who regularly evaluates and treats patients in the inpatient and outpatient setting and emergency department setting, and then finally, as a researcher who's published extensively on the role of cardiac CT and on the role of FFR CT, and as a program director of a cardiology fellowship that is really tasked with training our future generation of cardiologists. And so from these vantage points, I'd like to share with you, why I think FFR CT is a value for my patients and reflect on the proposed LCD.

So, the proposed LCD is, as you'll hear from Dr Rogers, is really based on a very strong body of evidence that was nicely published in a recent document in the American College of Cardiology and American Heart Association guidelines document in November of 2021. This publication was, uh, reviewed the clinical practice guideline for the evaluation and diagnosis of chest pain. And I think you'll hear from Dr. Rogers, who, I believe, will give a bit more of a summary of the guidelines, is that we all feel that they truly got it right. And it really – this guideline represents the state of the science, the state of the technology, and really how we, as physicians, and clinicians should approach patients with chest pain. And you'll also hear that these U.S. guidelines elevate the role of cardiac CT to a class 1A level of evidence, and FFR CT to a class 2A level of evidence in patients with acute as well as more chronic symptoms.

So, so that is an introduction in summary. I, and my colleagues really support these guidelines and feel that the proposed LCD update aligns nicely with this multi society, endorsed consensus document. So, the points that I'd like to make today regarding the proposed LCD focus on a few specific areas; number 1: my support of the expansion of the stenosis range, and I'll share with you what I mean by that, to a 40 to 90% window and number 2: I'd like to comment on some of the proposed restrictions. In particular to discuss how FFR CT can inform decision making in patients with prior valve replacement, prior pacemakers, or the presence of coronary artery stents.

And so, to get started, I want to comment on one of the questions that was asked to Dr. Rabbat earlier on really what is FFR CT and how is this used. This figure is really a simplified illustration of how we, as physicians and providers and imagers think about the role of FFR CT. And hopefully this image will help demonstrate our support for this technology and the expansion of the stenosis ranges from the 40 to 90% range; because this expansion to 40 to 90% is really in alignment with the updated guidelines and will importantly provide more access to appropriate patients.

So, so if you can just follow this figure, and if you can see from the illustration, decision making on patients with a less than 40% narrowing on the left side of your screen, is quite simple. And these patients are treated medically and do not require any further testing. But on the right side of this figure, for patients with a greater than 90% blockage or stenosis, these patients typically, as shown below, by the area – area – arrow, undergo invasive coronary angiography or an invasive procedure. It's this group in the middle between 40 to 70, and 70 to 90, so, 40 to 90%, that have been included in the proposed LCD. And we really think this is an important step that

you all have made, and we thank you for making this decision to expand the stenosis range to 40 to 90%. And I think it'd be interesting to share a bit of how I think about this, this strategy. So, again, if you focus on this, this area in the middle: the 40 to 70 and 70 to 90% range, as an imaging cardiologist who reads CTs, we are often stuck looking at a blockage that's in this range, and uncertain whether or not these patients have blockages associated with lesion-specific ischemia and whether or not these patients warrant an invasive heart catheterization and evaluation. And this is precisely where the technology of FFR CT helps improve the overall accuracy of our interpretation and provides clarity for the next step.

So this slide here, you can see that once we've been stuck with not knowing the significance of a blockage, we then send the data off for this FFR CT analysis; very much like Dr. Rabbat outlined before, in response to the question. And this 40 to 90% range, the images are then sent off for an FFR CT analysis. And these FFR CT results that are obtained and come back, allow us, as the interpreting physicians, to make a more accurate interpretation into better informed decision making on the need for invasive capitalization. That's well known that this is an accurate and reproducible technique. And if the data, the results, are abnormal as shown on the right with a red value – of values that are abnormal – those patients get restratified and send for a heart catheterization. But if the FFR CT results are normal, those patients are treated medically without the need for initial – additional – testing. And so I just, number 1, want to agree and think the, the, the committee for, for making these steps.

Finally on this – another point on this side, this slide – is that I do think it's important that I would fully support the minor revision that Dr. Campbell, I believe is going to make some comments on the coverage guidance support paragraph. And he will clarify some terminology and it's important that if we suggest a revision to a comment in the coverage guidance support, that if there's a higher-grade stenosis noted, i.e. greater than 90%, and there are no other stenosis between 40 and 90% identified, that the study is not medically necessary. So we'd like to include, I think we should include that and there are no other stenosis between 40 and 90%. Because it's been clarified in prior MAC discussions regarding the current LCDs that FFR CT is indicated for lesions less than 90%, existing in patients who also have lesions greater than 90% in other arteries, in order to guide management. And this is consistent with the ACC-AHA guidelines.

So, I'd like to maybe share a quick view of why I think the greater than 70% stenosis benefit from FFR CT. This is an example of a patient that I cared for who had a greater than 70% narrowing. We did not perform a heart catheterization because the FFR CT values were normal. The patient then came back to the hospital over a year later with recurrent chest pain, went to the catheterization lab and was found only have mild coronary disease. And so it reaffirmed the accuracy of the original FFR CT. On the bottom; same scenario. This is a patient, on the right, that underwent abdominal aortic aneurysm – surgical repair before surgery. We sent the patient off for a cardiac CT, and the FFR CT results were reassuring and thereby we could avoid any invasive catheterization.

So with that I'd just like to make 2 additional points in the remaining 2 minutes: number 1, I believe I agree with Dr. Rabbat, that I feel that the current version suggest that FFR CT is not considered reasonable in three really important groups of patients that we have found great value in using this technology. Specifically, in patients with prior placement of prostatic valves patients for the -

Dr. Robert Kettler: Doctor, you do have 2 minutes.

Dr. Michael Gallagher: Okay Thank you.

So, we think that this technology has great value in patients with prior placement of prosthetic valves; in patients with previous pacemakers or defibrillators; and finally in those with intra-coronary metallic stent placement. And really, to keep this discussion simple regarding who to include, or who to exclude, I really think this decision should be based upon the quality of the cardiac CT study. If the patient has a high-quality cardiac CT study with arteries that can be analyzed by HeartFlow to assess the FFR CT, there's really no reason why, in my view, we should exclude these patients from the benefit of FFR CT. We often see these patients and we feel that they should be allowed to benefit from this non-invasive FFR CT technology. So, if the CT can be processed, the fact that they've had a prior pacemaker, or valve, is beside the point tonight. We routinely send patients for FFR CT in these subcategories.

And finally, in the last 60 seconds, I do think under the restrictions: patients with a prior interim, metallic, coronary stent, our center is frequently used FFR CT technology in patients with a prior history of coronary artery stent in order to evaluate another non-stented vessel for the assessment of lesion specific ischemia. So, in these situations, our goal is not to obtain an FFR CT value in the vessel with a stent, but rather to evaluate blockages and other non-stented arteries to guide decision making. And so I feel that that is a very useful technique in the sub category of patients. So, with that, I'll bring my remarks to a close and I'd like to thank the committee for allowing me to be part of this important discussion. So, thank you for your time.

Dr. Robert Kettler: Thank you. Dr Gallagher. Are there any questions for Dr Gallagher?

Dr. Denise Nachodsky: Yes, it's Dr. Nachodsky again. Thank you. Dr Gallagher. Very nice slide presentation and really at, at a level that I think all of us can understand. So that was much appreciated. My question is in regards to the intra-cardiac stent: so, your point that you're making is to allow FFR CT, but it would be for the vessel that is not stented, Correct? So, like, if we know they have LAD stent, but you're sending your patient because you suspect that they have circ or RCA disease, it would be those two vessels, really, we do not want exclusion for those vessels because there wouldn't be any scatter effect or any inaccuracy on the unstented vessels. Is that what I heard you were saying?

Dr. Michael Gallagher: Yes, that's perfectly stated. And if you look at this, can you still see my slides?

Dr. Denise Nachodsky: Yes.

Dr. Michael Gallagher: Imagine, for a minute, if this blue – the blue artery on the left – the right coronary artery on the left side of my screen, imagine that artery has a stent, but I am worried about a moderate blockage of 50% of blockage in the artery on the right side of the screen, or otherwise the left coronary system, I can still gather very important information regarding the physiologic significance of the artery that is not – that does not contain the stent. And so this has been well-shown to be accurate in this indication and so that's exactly right. As long as I'm looking at the FFR CT values in the non-stented vessel, we do use and do find great value in still sending these patients off for FFR CT if we are looking at the alternative vessels. So, I think you, you understand that perfectly and it was well stated.

Dr. Denise Nachodsky: Thank you very much. So, in our current LCD, our recommendations, your concern is the terminology that we have should be a little bit more explicit stating, with the exclusions of people who have stented vessels, it would just be having a little bit more clarification in the end. Our proposal is for the unstented vessel to still be able to proceed with that.

Dr. Michael Gallagher: That's exactly right. There, it is a bit more nuanced, and I might even leave that portion to – I think Dr Rogers will be next in line – and he may beautifully articulate that statement. I might leave that to Dr Rogers if that's okay. I'm happy to comment on it more, but I would agree with your statement and there's a bit more of a nuance to it as well to, to add a little bit more clarity.

Dr. Denise Nachodsky: Okay, thank you so much for your time; much appreciated.

Dr. Robert Kettler: Any other questions?

Okay, thank you. Dr Gallagher.

Dr. Michael Gallagher: You're welcome. Now, do I need – okay good: you can change the screen. Perfect. Thank you.

Dr. Robert Kettler: Dr. Rogers.

Dr. Campbell Rogers: Yes, can you hear me?

Dr. Robert Kettler: I can hear you.

Dr. Campbell Rogers: Wonderful, and we have - thank you for your patience.

Dr. Robert Kettler: Oh, so that, you know, in the spirit of the Olympics, uh, I'm awarding extra points because of the level of technical difficulty you faced.

Dr. Campbell Rogers: Fair enough. And Rich – and Mr. Staley is going to share the slides, so I don't stretch my technical skills to that level, which was clearly beyond them. So, okay, thank you.

Dr. Robert Kettler: You're welcome. Looks like we're set so, uh, please proceed and we'll try it again. Hopefully 3rd Time is a charm.

Dr. Campbell Rogers: Great, thank you. I will reiterate, very briefly, my conflict of interest as a full-time employee, and reiterate that we will be submitting, as written comments, all of the comments that we've made – that we'll make – in this brief presentation. If you can go to the next slide, please. Enter the next slide after that, please.

The guidelines were mentioned by Dr Gallagher this, they were published in late October, from the American Heart Association and the American College of Cardiology, relating to the diagnosis and evaluation of chest pain. The reason they're germane here is that there is language in the guidelines, which I think, which is behind some of our suggested revisions to the draft LCD currently released. Go to the next slide, please.

Perhaps most important is this guidelines break down chest pain into 4 quadrants. One division is on the basis of stable versus acute chest pain. This is perhaps the most important comment that we'll make as the draft LCD reflects only – references only acute chest pain, whereas most of the use and focus of the guidelines and of the usage you've heard from Dr's Rabbat and Gallagher, is actually in stable chest pain and we believe it should be listed as both. So, this was the breakdown: the indications were in the guidelines, the classic recommendations were 2A for FFR CT in all four of these quadrants; both stable and acute, both known and suspected coronary disease. Go to the next slide. Please.

In particular, the reference, the guidelines reference, the stenosis range of 40 to 90%. This has been addressed by the prior speakers and I will just stipulate that I agree with their assessment of the literature around this range and appreciate the expansion. Next slide, please.

So, the current indications are listed here, and then the next slide will highlight a couple of the areas, which we would suggest potentially revisiting. If you go to the next slide, please.

So, starting at the top, I've highlighted my highlights in red the verbiage from the draft LCD, the reference to acute chest pain and no known coronary disease, and intermediate risk with acute chest pain and known coronary diagnosis 40 to 90%. In order – and then if you go down below the first horizontal line, our suggestion is to revise this to include stable chest pain, as well as acute, consistent with the guidelines. It is worth noting that in the coverage guidance section of

the proposed LCD, stable patients are referenced so there is this internal inconsistency and this would help resolve that internal inconsistency as well. So, the proposed wording is at the bottom in the box, which would correspond to the guidelines, intermediate risk with stable or acute chest pain with known coronary stenosis from 40 to 90% on CCTA would be our submitted, proposed revision. Go to the next slide please.

The 2nd element we wanted to mention was the caveat in the draft LCD about not using FFR CT in conjunction with stress testing. And it includes the caveat: unless FFR CT was not high quality in an alternative study needed. I believe what was probably intended there was, unless the CTA was not of adequate quality, as the prior two speakers have mentioned the CT quality is a component of the HeartFlow approach for doing an FFR CT analysis. And therefore, the suggested revision would be that this would read, unless CCTA was not an adequate quality for FFR CT and an alternative study needed. Go to the next slide please.

In terms of the coverage guidance support paragraph, I've highlighted again, my highlights in red, the reference to stable coronary syndromes and the reference to the degree of stenosis greater than 90%, not medically necessary. I will simply stipulate here that I agree with Dr. Gallagher's summary of this aspect and reference to stenosis of less than 90%, which may be keeping company with stenosis of over 90%, that those, those would be deemed medically necessary.

The 2nd is, there's reference here – and again, in red – to less than 30%. For internal consistency, our suggestion would be to change that to less than 40%; consistent with the 40 to 90% range.

And then, finally, this note about extensive plaque and high-quality CTA is unlikely. The presence of plaque of course, would only be known by CTA, so the CTA will already have been conducted. And, the suggested revision there is to remove that. And we'll talk about our HeartFlow CT quality assessment process over the next couple of slides. I would point out that high plaque volume does not necessarily connote impaired CTA quality. Go to the next slide please.

In terms of the restrictions, the prior speakers have spoken about the ones which are in red: prior placement of prostatic, heartfelt inter-coronary metallic stents; prior pacemakers. And, the final piece of a stenosis of less than 50%, again, would suggest revision to less than 40%, again, for internal consistency within the draft LCD. You go to the next slide please.

In terms of the plaque volume comment, there is significant published literature looking at the use of FFR CT in patients with extensive coronary disease, including 3 vessel coronary disease and high syntax scores, which is a scoring of disease, severity and volume – to some extent disease volume. So, I would draw the, draw WPS's attention to this literature, and again, we'll do so and provide the references in the submitted comments. You go to the next slide please.

And finally, in terms of CT quality, I wanted to share – and I will not go through these in detail, we will provide detail in our written comments – but, as other speakers have mentioned, what HeartFlow does when CTAs are sent to us for FFR CT analysis, is, the first step is to conduct an incoming CTA data quality inspection. And, there are extremely specific criteria for CTA, which our trained analysts review for each scan. And if in fact, there are image quality shortcomings, then the scan is not processed. So, for example, if somebody has a pacemaker lead, and it happens to be in a position where the artifact impairs seeing the coronaries on the CT, that will

be rejected, returned by HeartFlow. However, in another patient where the pacemaker lead is in a different position and the coronaries are able to be resolved, then that patient does pass through, and the HeartFlow analysis is completed. The last couple of bullet points here are important. We do not complete FFR CT analysis nor charge for cases that failed to meet the incoming image quality specifications. And then we also go the extra step when this does happen, to provide an explanation for each failed case and training to the site so that they can, perhaps, the next time this comes around, have improved image quality. You go to the next slide, please.

These are simply examples for the, uh, for consideration of what good sort of satisfactory, but calcified and poor image quality looks like. These are important discriminations and there's, there's a process underway to sort cases. As was mentioned, I believe, by Dr, Rabbat, over 90% of cases currently sent in are accepted, but some are not and they are returned as described. You go to the next slide,

Dr. Robert Kettler: Dr. Rogers, you have 2 minutes.

Dr. Campbell Rogers: Yes, yep. And this is my last slide. Go to the next slide.

I want to speak briefly about inter-coronary stents. This was discussed in the Q & A for Dr Gallagher as well. Our instructions for use provide very specific language around which stents – which patients with stents – are possible to be processed for FFR CT by HeartFlow, and which are not. The discussion on the last – at the end of the last presentation – was spot on in terms of the clinical role this plays and assessing non-stented arteries. And again, our IFU spell out in great detail exactly what configuration – so this is known by the person who's doing the CTA at the time they are choosing whether to order the FFR CT, they will know these from the CTA and then can discriminate this patient will be processable and this patient will not. So, these, this language is here and again, we'll provide this in our in our written comments and it may be of help as you consider this aspect of the draft LCD. So, with that, I'll conclude and thank you again for the patience and the opportunity.

Dr. Robert Kettler: Thank you, Dr. Rogers. Are there any questions?

Dr. Denise Nachodsky: Yes, it's Dr. Nachodsky. Thank you again, Dr. Rogers, beautiful presentation; slides are very informative. I would be greatly appreciative, that the literature in regards to – with the syntax guard – you spoke in regards to the volume of the plaque is not always a deterrent, and I'm in search agreement with that. Just, if you could send that literature for support to us, that it's not a large volume of plaque does not mean that FFR CT could not be performed. In fact, it may be very much indicated; it's more that the type of the plaque, though. If you could just, please send that literature with, with any other information, be greatly appreciated.

Dr. Campbell Rogers: Of course, we will. You bet.

Dr. Robert Kettler: Any other questions?

Okay, well, thank you. Dr Rogers. And again, I'm sorry we had these technical issues, but I'm glad that we were finally able to get through things.

Um, at this point, then, I will move on to public comment. Just as a reminder, those who wish to make a comment on the LCD may do so by using the unmute icon on their Webex screen. And so, do we have any comments rich?

Richard Staley: Attendees if you would like to use the raised hand icon, or just put your name in the Q & A box if you have a comment, I will gather those up and unmute you individually as they are received, thank you.

I'm seeing no hand raises and nothing in the Q & A. I'll continue to monitor.

Dr. Robert Kettler: Well, thank you, Rick, just as a reminder. The comment period for this LCD closes on March 12th of 2022. So, we would be accepting comments up to that date.

The next draft LCD then is DL35490, Category III codes, and basically this is because of a reconsideration request to add coverage of Parkinson's disease to CPT code 0398T. 0398T indicates focused ultrasound for the non-invasive creation of an intracranial stereotactic ablation lesion for the purpose of treating movement disorders. And as I say, the request was that we had Parkinson's disease as a cover diagnosis for this. There are no formal presentations on this draft. LCD, so we can now take any public comment that there might be. Please use the raised hand icon or as Rich mentioned, enter your question in the Q & A.

Richard Staley: There are no raised hands and nothing in the Q & A at this time.

Dr. Robert Kettler: Okay, thank you. Rich. Likewise, the comment period for this LCD closes on March 12th of 2022. I did neglect to mention that the CMD responsible for this LCD is Dr Kettler.

I'll ask one last time Rich. Do we have any comments?

Richard Staley: There are no raised hand icons and nothing in the Q & A at this time.

Dr. Robert Kettler: Okay, thank you. There'll be no further business. We are adjourned at 2:00 PM, Central Standard Time. Thank you, everybody.