WPS GHA Open Meeting

Moderator: Dr. Barry Whites
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1:00 pm CT (2:00 pm ET)

OPERATOR: This is Conference # 4175517.

Operator: Ladies and gentlemen, thank you for standing by and welcome to the October Draft LCD Open Meeting. At this time, all participants are in a listen only mode. Later, we will conduct a question and answer session and instructions will follow at that time.

If anyone should require assistance during the conference, please press star then zero on your touchtone telephone. As a reminder, this conference is being recorded.

I would now like to turn the conference over to host Dr. Barry Whites, please go ahead.

Barry Whites: Thank you very much. Welcome everyone to this Draft Local Coverage Determination Open Meeting.

The topics today are five different policies, one is considered redetermination but they go through the same process and did not used to but they do now. We have the Colon Capsule Endoscopy, the Non-Invasive Fractional Flow Reserve for Stable Ischemic Heart Disease, Endoscopic Treatment of Gastroesophageal Reflux Disease, a MolDX policy for Minimal Residual Disease Testing for Cancer, and the Facet Joint Intervention for Pain Management.

I will give a brief synopsis of each of these policies. We have three presenters in FFR the Fractional Flow Reserve and so that I'll not be quite as detailed in that. Our presenters will be presenting significant amount of detail, extra detail for those policies.

For the first policy that we'll be discussing, it seemed like something out of Star Wars or maybe Epcot at Disney World is the colon capsule endoscopy. It's a non-invasive procedure that does not require (inflation) or sedation, and allows for a minimally invasive and painless colonic evaluation.

It's a tiny wireless capsule about the size of a vitamin capsule that takes pictures of the G.I. tract once swallowed. The camera is housed inside a vitamin type pill, as mentioned, and it's swallowed with water. It travels through the G.I. tract taking pictures that are transmitted to a recorder, worn by the patient like a Holter monitor. The images are then transmitted to a computer and special software where the images are strung together to create a video.

The provider then reviews the video to look for any abnormalities within the G.I. tract. It really sounds high tech. And it is – it can only identify with accuracy certain items, it cannot get lesions less than six millimeters with the actual reliability. I think what needs to be mentioned is it does not have universal coverage for every incident. The U.S. Multi Society Taskforce was fortunate enough to give us three very good definitions for cancer screening, diagnosis, and surveillance.

The cancer screening refers to those people who are asymptomatic and no previous history. And, rarely is cancer screening covered by Medicare, except for special statute. Cancer diagnosis, is those patients who have symptoms are suspicious of malignancy or have had a positive screening test. Surveillance refers to those interventional utilizations and diagnostic strategies and people with previously detected cancerous or precancerous lesions.

This policy covers diagnostic and surveillance but not screening strategies. It is medically necessary and we have covered indications listed there too as a primary procedure or secondary procedures. Also listed are limitations, which is not medically necessary and I'll refer you to those policies.

The next item is the Functional Flow Reserves. And, that LCD is a multijurisdictional policy done with the workgroup from all of the Medicare Administrative Contractors. The FFR-CT is performed in a patient who has stable coronary symptoms. It should not be performed until after the base study, the coronary C.T. has been completed and interpreted.

The discussion today, well, you will find is the – our presenters will be primarily on not the indications but the percentage of lumen stenosis that we consider for coverage and non-coverage. That way, they will be going into detail on that. So, this is a study that is an addition, add on. It is sent to the

company. The classification of moderate stenosis is defined in different ways, by this policy in one case. It is defined as being 30 to 50 percent or intermediate stenosis. In another case, it found it's being 40 to 70 percent. And all of that will be discussed in our – with our presenters today.

The third item that we will be discussing will be Endoscopic Treatment of Gastroesophageal Reflux Disease. This is a non-coverage policy for reconsideration for gastroesophageal reflux using the Stretta procedure, the Bard EndoCinch suturing system, and the Pilacator are similar treatments for procedures not considered, were not being considered reasonably necessary for the diagnosis and treatment of an injury or disease and therefore non-covered.

The substantial peer reviewed literature evidence to fully support these symptoms remains to be published and clinical data from the studies are emerging. But, at this time, open label studies and patient registries with short term follow ups, are the dominant source of data. The overwhelming predominance of reviewing remains equivocal in their support, and it's called for randomized control trials with long term follow up.

And, the absence of evidence of such studies and the absence of wide acceptance endoscopic treatment of reflux disease is not proven and therefore not reimbursable, even though they may have associated CPT and outpatient provider service codes.

The third item, again, is a – to me, an amazing technology that now seems to have some merit and this is another MolDX test and we are a member the MolDX consortium. And, this has to do with minimal disease testing for cancer. Minimal residual disease testing for cancer, is rapidly becoming a sensitive and specific method for monitoring the relative amounts of tumor derived genetic material circulating in the blood of a cancer patient.

The test leverages new genomic technologies that allow detection of extremely dilute tumor material, leading an extremely sensitive method for determining the continued presence of tumor or by simply testing the individual tracking the disease but tracking the relative increase or decrease of tumor material being deposited in the blood and therefore, showing an efficacy of treatment. Although it is relatively new, it has practically

demonstrated its ability to impact patients in several ways in cancer diagnosis and in treatment.

This is being utilized in both solid tumors, including colorectal tumor, as well as hematopoietic malignancies. Again, this is another MolDX policy that has been approved through our consortium and is referenced primarily first beginning in the National Coverage Determination 90.2 with genomic sequencing testing. I think again, it's something that we're going to be seeing more and more of and it does not have uniform coverage, but there are limitations and you're referred to any indications that are so listed in our proposed LCD.

The last policy to be discussed is for Facet Joint Interventions for Pain Management, which to me is one of the more complicated policies to read through and to go over. The coverage indications are defined for both at the facet joint, which includes medial branch nerve and facet joint injections as well as well as the radiofrequency ablation.

There are several indications but all with caveats having to meet all of some, some of the other criteria that are listed here. There are limitations on coverage that are so mentioned and those are the 10 listed. And, we'll refer it again to the policy but that would take all of our time if we went through this policy I can assure you.

In addition there are 29 definitions that must be applied to this policy and go to the facet thing, it's the facet level and intra-articular injections medial branch neuropathic pain, what noninvasive conservative management means, what radiculopathy means, regions as defined, and there are only two regions even they're joining together cervical and thoracic is one and lumbar and lumbar sacral is the other.

It's a complicated policy. But the problem is due to the lack of reliable history, physical exam or imaging to predict response, providers must rely on these inner diagnostic injections to give for diagnostic purposes to determine if a facet joint is the source of the pain. This continued controversy on the optimal selection or diagnostic injection with measures successful response and type and number of diagnostic injections.

Most of these recommendations are taken from the pain management to evidence based medicine and there is a consensus guideline that is used

primarily for these determinations and you have to go through the definitions and the limitations to be sure that you get all of the specific consensus guidelines appropriate.

At this point in time, I would like to open up the presentations. First will be Dr. Rancati. She's the PhD Medical Director of Medical Affairs for Medtronic to discuss the PillCam. I would also request that, in addition, that these presenters give us, to start off with, their conflict of interest and any disclosures that they need to make before proceeding with their presentation.

Also, to remind each of these presenters that what you tell us here, obviously will be taken into consideration, but to get it full benefit of being considered, we must have the presentation. We must have any documentation that you present in your presentations presented to us in full content.

We do not need just abstracts. Abstracts will not be considered. We need the full content and also, be sure that you have permission to send that. If you do not have a copyright all of these, please so note and we will try to print it ourselves, but if at all possible, we do need the full articles that you're referencing, whether they'd be guidelines, whether they'd be scientific articles, no matter what type your referencing, we need a copy of those in addition.

And now we'll turn it over to Dr. Rancati, talking about the PillCam COLON 2 System.

Operator: At this time, Dr. Rancati, please press star one. Again, Dr. Rancati, please press star one on your telephone keypad. Your line is now open.

Francesca Rancati: Thank you. Thank you. Can you hear me?

Barry Whites: Oh, yes, we can. Please go ahead.

Francesca Rancati: Thank you. Thank you very much. So again, my name is Dr. Francesca Rancati. I've been working with Medtronic as a Medical Affairs Director since 2015 in the G.I. business unit and I'm a PhD in biotechnology as education.

So on behalf of Medtronic, I would like to highlight that we appreciate the efforts, you know, that were made to develop the proposed LCD for colon

capsule endoscopy and we appreciate in particular the WPS recognition that PillCam COLON 2 qualifies for Medicare coverage as a diagnostic test.

And, it's a test that is safe, effective, and as well reasonable necessary for a defined patient population, so the defined patient population is represented by a patient that had an incomplete colonoscopy and inadequate prep. And so, colon capsule is used to identify colon polyps in these patients and to make a complete evaluation of colon that was not technically possible and in addition, this device is intended for the detection of colon polyps in patients that have a higher or major risk for colonoscopy for moderate sedation, like for example, patients that have lower G.I. bleeding.

Second, we recognize that this policy has a limitation about the fact that it's not for colorectal cancer screening, known even in patients that are carrying risk factors for the development of colorectal cancer. So Medtronic, again, recognize and support these limitations. And, respectfully request the WPS move forward with the coverage of colon capsule endoscopy based on the approved indications by the FDA, which I listed earlier.

And guys have any comments or questions?

Barry Whites: Thank you very much for your presentation. Again, any items that you feel that were not included in the proposed LCD, if you would like to be considered or any changes that you would like to make, if you would certainly send those to us. And, I'll be going over this after each of the presentations.

We have an e-mail address, its policycomments, all one word, at wpsic.com. We would need you to include or attach any articles that you might have. And, if you would like to also include your presentation, as well as any other written comments for us to consider, we will be happy to do so. Thank you so much.

Next, we will move on to the Noninvasive Fractional Flow Reserve. Dr. Rogers. If you're ready, could you please proceed?

Operator: At this time, Dr. Rogers, please press star one. Your line is now open.

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

Barry Whites: Yes, sir. Please go ahead. This is a second time you had an excellent presentation yesterday. So continue, yes, I listened to that too. So, that's great.

Campbell Rogers: Well, this will sound extremely familiar to you then Dr. Whites. And, let me begin with my conflict of interest, which is that I'm an employee of HeartFlow, which is one of the manufacturers of FFR-CT, which is the topic of this draft LCD.

I would like to express gratitude to WPS for putting together the draft LCD and for allowing us this opportunity to comment. Of course, we will be also submitting just as you instructed written comments with the full references appended for each of the points which we'll make today.

I'd like to begin with just a brief outline of the pathway for testing which Dr. Whites alluded to in his introductory comments. In that test, we – it relates to patients who have stable coronary artery disease and are presenting for evaluation for noninvasive evaluation. The noninvasive evaluation in this pathway begins with a coronary C.T. angiogram.

And, in about three quarters of patients that is the only test that's needed to define the coronary disease or absence thereof, which they may have. In about 25 percent of patients, the coronary stenosis are found on the angiogram, narrowing of the coronaries to the heart, but the functional significance of those cannot be determined from the C.T. scan alone and therefore a second test is required and that's where the FFR-CT analysis comes into play.

In terms of the LCD, draft LCD areas which we would like to touch on, just as Dr. Whites alluded to, they really dwell on both the areas of the list of draft exclusions, as well as inclusions, and I'd like to take those in turn in these comments. In terms of the exclusions, there are six, numbers one, two, three, five, six, and nine in the draft LCD, which we'll be commenting on and I'll call out what they are as we go through.

The first set of three, are exclusions number one, two, and nine. And they are severe obesity placement, prior placement of prosthetic heart valves, prior placement of pacemaker or defibrillator leads. Each of those three, for us, we believe should not be considered exclusions. The way that our process works is that when C.T. images are sent to HeartFlow. The first step that is

undertaken is to assess the C.T. quality and the ability to define the coronary anatomy based on the C.T. images.

The reason these three, obesity, valves and lead placement, are included in as exclusions is related to their potential to cause artifacts in the images which inhibits the ability to look at and define the coronaries. When those artifacts are present, which they are in some, but not all of these patients, when those artifacts are present, HeartFlows process reviews them, and then if the image quality is degraded because of these implants or obesity, then the studies are not processed further by HeartFlow. We do not charge for the cases if they fail to meet our image quality standards for these reasons.

We provide an explanation for the failed case and then, as appropriate, we provide training to help improve the image quality of future studies. So, when these patients with these exclusions may have images which are suitable for analysis and when that is the case, then we are able to provide the FFR-CT analysis and add that to the information available to a physician to help care for the patient.

These, so …

Barry Whites: Dr. Rogers?

Campbell Rogers: Yes?

Barry Whites: Can I interrupt you for one sec?

Campbell Rogers: Yes?

Barry Whites: Could you when you go to your next slide, would you say the slide, seven slide? We were trying to follow you along.

Campbell Rogers: Oh, sure. Oh, I apologize.

Barry Whites: So that would be very helpful to us. Thank you so much.

Campbell Rogers: Of course.

Barry Whites: I'm sorry to interrupt.

Campbell Rogers: Yes, yes, of course. No, no. And I didn't know you were looking at them in real time, so I apologize. Yes.

So if you look at – if you now go to slide nine, our suggested revisions to these draft exclusions are that they should not be exclusions, and it should be that if image quality is unacceptable, just understand that HeartFlow will provide feedback, there will be no processing and there will be no charge. And I'm now going to the next slide, which is slide 10, which addresses the exclusions of number three, known severe aortic stenosis and number five, suspicion of acute coronary syndromes.

For known severe aortic stenosis, it is our suggestion that this should be removed when patients have homeostasis between coronary flow and myocardium. Even in the setting of, for example, the left ventricular hypertrophy, which may accompany aortic stenosis, that that homeostasis allows the FFR-CT calculations and the models and algorithms upon which it depends to be accurate.

So, there is no impact on the physiology being assessed through FFR-CT by virtue of left ventricular mass as this is taken into account in the FFR-CT analysis.

Number five is suspicion of acute coronary syndrome. It is our suggestion that as Palmetto released last week in their final version LCD, this be revised. So it is not all patients with suspicion of acute coronary syndrome who are excluded, but that it is those patients who have suspicion for acute coronary syndrome, where acute myocardial infarction or unstable angina have not been ruled out.

And this is the verbiage they have used. And it's certainly consistent with the clinical data which we have gathered for validating and understanding the clinical utility of FFR-CT and has been published in the peer reviewed literature.

I'm going to the next slide now, which is slide number 11. And, this is regarding exclusion number six for intracoronary metallic stent. It is true that when patients have intermetallic – intracoronary metallic stents that HeartFlow is not able to assess the vessel, the specific coronary artery which has a stent.

However, there are many patients with intracoronary metallic stents who have coronary disease in other vessels. And, in most of those cases, we are able

to process and provide important FFR-CT information for the vessels which do not have stents within them. There are very specific labeling which is on our instructions for use in which is on this slide, which is the coronary stents in the following cases not to be processed and we don't process and they should be excluded.

Those are metallic stent in the left main coronary artery, or left main stenosis more than 30 percent, and stents in the left system, or two or more systems in the coronaries, which have metallic stents. Those should be excluded. The broad patient level exclusion, we believe should be revised.

The next slide is slide number 12. And this relates to a passage in the draft LCD not listed as a formal exclusion. But, I think it's very important to discuss. And that is the passage which reads Medicare will not pay for both CT derived FFR data and FFR data obtained by pressure wire and catheterization in the context of the same clinical evaluation.

It is our view that this restriction should be eliminated. There, and I've spent many years practicing as a cardiologist and an interventional cardiologist, it is clear that there is clinical utility to knowing the invasive FFR or IFR measurements in some patients, even after they have an FFR-CT measured noninvasively before their trip for invasive assessment. So, it's our view that this prohibition on invasive pressure wire use at catheterization should be removed from the draft LCD.

Finally, for the last couple of minutes, let me turn to the proposed list of inclusions and Dr. Whites referenced this earlier. I will not read through all of the inclusions, I believe some of the other presenters may go into more detail. I would just like to focus and now I'm going to the next slide, which is slide 14, on what we know and have published in the peer reviewed literature about the discordance between the physiologic impact of a stenosis, and the degree or severity of the narrowing as measured anatomically of that stenosis.

In the draft LCD, generally speaking, aside from the left main coronary, there is reference to a range of 40 to 70 percent stenosis, which would be covered for FFR-CT. It is our belief that the range of 70 to 90 percent, which is currently not included, should be. And the reason is that in vessels in our published studies with stenosis of that range 70 to 90 percent, 25 percent of

such vessels will actually be FFR negative, that means that the flow is not reduced to a level that should, all else being equal, require invasive evaluation.

So, 25 percent of patients with narrowings in this range, could potentially avoid an invasive procedure, if the FFR-CT were provided for this range. For that reason in our studies, and I'm going to the next slide, slide 15, we have looked specifically at the impact on care of the utility of this range of stenosis of knowing FFR-CT. And it found that 62 percent of patients with a stenosis in this range, had a different management plan after their physicians were told the FFR-CT information, then would have been the case based on the CTA images alone.

Because of the magnitude of this impact, it is our belief that the range should be expanded to include 70 to 90 percent stenosis in vessels which are not the left main coronary artery. If we go to slide 16, which is my last slide, this includes at the bottom, the proposed revised verbiage for the list of inclusions in vessels other than the left main coronary artery disease with stenosis of uncertain functional significance, lumen reduction 40 to 90 percent.

With that, I'll close. Thank you very much again for the opportunity. And we look forward to submitting these comments with references during the written comment period.

Barry Whites: Thank you, sir. Question, were these, any of the limitations that are so noted in our policy, and you say that are need to be revised, were they initially present in the FDA clearance or there's a change?

Campbell Rogers: Yes. So, some were present in the FDA clearance. And, we have subsequently introduced, they're now found in our IFU, as revised, based on additional data that we've been able to gather. And, we certainly will be submitting that with our written comments.

Barry Whites: Good. That's great. I just want to be sure it was going to be there. Thank you so much.

Campbell Rogers: You're welcome.

Barry Whites: Next we will have – I surely appreciate it. Next we'll have Dr. Samuels who's at Cedars-Sinai Smidt Heart Institute. Have an interesting presentation.

Operator: Doctor, please press star one.

Barry Whites: I'm sorry. Dr. Samuels could not make it and Dr. Kenneth Rosenfield is going to be presenting in his behalf.

Operator: Doctor, your line is now open.

Kenneth Rosenfield: Hello, this is Dr. Kenneth Rosenfield. Can you hear me now?

Barry Whites: It's Dr. Whites, very well. Thank you. Yes, we can. Thank you very much.

Kenneth Rosenfield: OK. Thank you.

This was a surprise. Dr. Samuels, unfortunately, at the very last minute, was unable to attend. I think he's probably doing an invasive procedure that he got tied up in maybe even using invasive IFR. I don't know. And I'm much less of an expert, but I am an interventional cardiologist who practices at Massachusetts General Hospital. And I'm a prior president of the SCAI, which is the Invasive Cardiology Society representing about 5,000 invasive interventional cardiologists around the country.

So, I'm going to be very brief. First, I – it's an honor always to follow my friend Campbell Rogers practicing in Boston with me many years ago and his comments are much more detailed. I'm going to make general comments. First, I would say that CT-FFR, I think is a huge advance. It's a great thing for patients, a great thing for the cardiology community and the community at large, especially the E.D. which is faced with a lot of these patients with chest pain.

So, we are very supportive as an interventional cardiologist of keeping patients out of the lab who do not belong in the cath lab, minimizing therefore risks and so on. And, in fact, CT-FFR is a great advance on top of cardiac C.T. in identifying patients who really do not need to be in the cath lab.

Our position as Dr. Rogers stated that representing the interventional community that CT-FFR does not replace invasive physiologic monitoring and for patients who actually get into the cath lab, invasive physiologic monitoring really needs to be preserved as an option and as a reimbursed option for patients, for the sake of patients.

And, in fact, anything which the data are very clear that invasive physiologic monitoring, IFR and FFR, are the tools which are critical to performing procedures and actually in preventing us in the lab from doing unnecessary stenting, unnecessary intervention.

They are more effective at reducing intervention and reducing costs in the lab than they are actually the opposite way around. So, we believe that it's critical to maintain this ability and not discourage or dissuade interventional cardiologists from using invasive, physiologic monitoring.

In fact the SCAI and all of the sort of gurus in interventional cardiology are trying, really, trying to disseminate this technology more rather than less because we believe it actually, more accurately, in the lab assesses whether patients really need invasive therapy or not.

So that's really and the reason for that is because angiographic imaging has been shown clearly to be insufficient and deficient in many respects when you have calcium, when you have tortuosity, and other challenging anatomy, which is difficult to assess.

So I'm going to stop my comments at that point and say that SCAI, the society that I was president of is submitting written comments. I think they will come from Dr. Joaquin Cigarroa who's the chief of Cardiology at OHSU. And in addition, Dr. Samuels submitted some comments and I believe that some of the multiple industry companies, industry producers of these devices, which obtain invasive physiologic measuring will also be a submitting written comments.

But, it’s critically important to preserve and in fact, if anything, encourage the use of invasive physiologic monitoring or measurement. So with that, thank you very much for the opportunity to comment.

Barry Whites: Thank you very much and again, submission of your comments as well as the data that utilized value for the recommendation, need to be presented in their total. Thank you. Next, we will go to Dr. Mark Rabbat from Loyola University Medical Center.

Operator: Doctor, please press star one. Your line’s is now open. Your line’s now open, Doctor.

Mark Rabbat: Can you hear me?

Barry Whites: Yes, we can. Please go ahead.

Mark Rabbat: Great. Thank you very much. My name is Dr. Mark Rabbat. I'm Associate Professor of Medicine and Radiology on the Division of Cardiology at Loyola University.

And on behalf of the Society of Cardiovascular C.T., I'd like to thank you for the opportunity to speak at today's open meeting and the Society of Cardiovascular C.T. plans to submit final written comments as you had alluded to. I'd also like to disclose that I do indeed serve on Advocacy Committee of the Society of Cardiovascular C.T., and a consultant at HeartFlow.

So, fractional flow reserve is the gold standard test to identify appropriate vessels for stent placement. And now FFR can be derived from a static C.T. data set with high diagnostic performance. And if you're following along with the slides, that was slide number two.

Now if you go to slide number three, you'll see that over 6,000 patients with follow up of one to five years have been performed to date in multiple high impact clinical trials, demonstrating the improvement in long term outcomes for our patients undergoing this diagnostic pathway, and the safe deferral of unnecessary invasive coronary angiography and those with coronary artery disease.

I'd also like to add that in these clinical trials, patients were included with diameter stenosis of 30 to 90 percent reduction and up to 25 percent of those patients with 70 to 90 percent stenosis are indeed FFR negative, and can safely defer invasive coronary angiography. Now in addition to that, and those with multi-vessel severe stenosis, we're seeing a change in management after the utilization of FFR-CT and bridging that with anatomy.

And oftentimes, we'll see a downgrade in their management strategy away from more invasive and costly and at risk procedures such as coronary artery bypass graft surgery to single vessel PCI or two vessel PCI or even optimal or medical management alone in some patients with severe multi-vessel disease.

On the next slide, you'll see some data from our own experience that was published earlier this year of over 400 patients who underwent C.T. and FFR-CT diagnostic pathway in their coronary artery disease assessment and FFR-CT was feasible and greater than 90 percent of the patients. After incorporating the FFR-CT to the C.T. data set, there was less, significantly less invasive coronary angiography, and there were no major adverse cardiac events in those patients who were deferred from invasive coronary angiography.

And, a high proportion of those who underwent invasive coronary angiography were re-vascularized. So, that translated into a higher diagnostic ICA yield and more efficient utilization of the cath lab. Now the Society of Cardiovascular C.T. recommends that for those performing C.T. and FFR-CT to adhere to the CCTA guidelines for the performance and acquisition of coronary CTA.

As of April 2020, a positive FFR-CT finding can indeed be used in lieu of invasive either IFR or FFR in NCR Cath PCI Registry and the appropriate use criteria for revascularization and stable ischemic heart disease and this was published this year, endorsed by the American Heart Association, as well as the American College of Cardiology.

Now the Society of Cardiovascular C.T. has reviewed WPS's proposed list of exclusion, as well as inclusion criteria and based on our experience and the clinical literature, our recommended criteria is as follows. For the exclusions, I believe Dr. Rogers had spent some time talking about image quality and we would recommend acceptable image quality as defined by HeartFlow's rigorous criteria that's employed.

In addition, we recommend only excluding anatomy that would affect hemodynamic accuracy, so the aortic stenosis would be OK to be included. We also recommend what Palmetto published last week, which states suspicion for acute coronary syndrome, where acute myocardial infarction or unstable angina have not been ruled out.

And again, we'd like to emphasize the importance of including coronary artery disease with coronary stenosis of uncertain functional significance, including 40 to 90 percent diameter reduction. And, we believe that not including those individuals with stenosis of 70 to 90 percent diameter reduction would be a

disservice to our patients, in addition to left main disease with intermediate coronary stenosis of 30 to 50 percent diameter reduction.

Recently, the American College of Cardiology underwent a CTA roundtable summit and the call to arms and that summary around widespread CMS coverage and payment for both FFR-CT and CTA is clear. And, the summit supported and endorsed a coronary CTA first and FFR-CT, when indicated, evaluation and diagnostic pathway in patients with stable coronary artery disease.

I have a few references that I submitted with our slides and we would like to thank you for your support.

Barry Whites: Thank you, sir. Again, if you – the references are noted, what we would need to receive from you full articles if you don't mind.

We need to find out whether we were having some difficulty seeing if Dr. Smuck from Stanford was on the line. Dr. Smuck are you there?

Operator: Again, Doctor, please press star one.

Barry Whites: It appears that Dr. Smuck is not with us. We do not see his name on our list of attendees. We will now entertain any comments from the audience.

Operator: At this time, if you would like to make a comment, please press star one. We have Dr. Robert Safian, your line is open.

Robert Safian: Yes. This is Dr. Safian. Can you hear me?

Barry Whites: Yes, we can. Please go ahead. Thank you.

Robert Safian: Thank you, Dr. Whites. I appreciate you giving me time to speak for a few minutes. I'm a cardiologist at William Beaumont Hospital, which is one of the largest medical centers in the Midwest. We have a very, very high volume program in the cath lab. We do a little bit under 3,000 PCIs per year.

We have I think, one of the highest volume programs in cardiac C.T. angiography and FFR-CT. We do about 5,000 cardiac C.T.s a year and about 1,500 FFR-CTs. I'm one of the physician leaders and champions in the cath lab and also in C.T., because I'm board certified in both specialties within cardiology. So, I have a lot of experience in all of these areas.

I wanted to make a couple of comments regarding the clinical scenarios that Dr. Rogers mentioned with regard to obesity, prosthetic heart valves, the presence of pacemaker or defibrillator leads and things like that. We do C.T. and FFR-CT quite routinely in those kinds of patients, the limitations are more related to the quality of the C.T., rather than issues that are specifically related to FFR-CT.

So personally, in our own experience, you know, we don't have any problems, ordering, getting back results, et cetera on FFR-CT in those kinds of patients. So, personally, I don't feel that those should be excluded outright. As Dr. Rogers mentioned, if there are issues with the quality of the C.T. and FFR-CT cannot be performed at HeartFlow then the study is returned to the center and there's no charge to the patient.

One of the other clinical areas I just wanted to mention was the elevated troponin issue. We use C.T. angiography as well as FFR-CT quite commonly in a patient population that's characterized by atypical symptoms and elevated troponin. As you may or may not be aware, troponin assays are extremely sensitive and sometimes elevator troponin levels return but don't really fit the clinical picture of acute myocardial infarction or an acute coronary syndrome.

In those patients, the preferred assessment of those patients is with a C.T., FFR-CT pathway in our institution. We find that much more reliable than doing any other functional studies such as a stress perfusion study and certainly preferable to an invasive angiogram and those kinds of situations. And, more often than not, by using the C.T. and FFR-CT, we're able to avoid doing invasive angiography on a large subset of those kinds of patients.

The second thing that I wanted to discuss was related to the assessment of the stenosis severity and whether FFR-CT would be appropriate or not for certain grades of stenosis. Before I get into that in more detail, I just wanted to mention that when we assess the severity of stenosis, whether it's by a C.T. or whether it's in the cath lab, it's done by a visual assessment. So, in other words, it's an eyeball. These measurements typically do not involve detailed quantitative measurements, it's usually just a an operator like myself looking at it and saying, well, I think it's, you know, 50 percent or 70 percent or what have you.

So, we know from a lot of data that's been published previously that visual estimates of stenosis severity are not precise. With regard to C.T., there's recognition that visual assessment of a C.T. stenosis severity is also somewhat limited and according to the SCCT guidelines for interpretation reporting of C.T., there are grades of stenosis or ranges of stenosis that are used.

So for example, if there was a heart that was normal, that would be reported as normal. There could be a stenosis that's less than 25 percent or 25 to 50 percent or 50 to 70 percent or greater than 70 percent. So we don't normally record something like a 60 percent stenosis that would routinely be reported as 50 to 70 percent, recognizing the limitations of, you know, an eyeball estimate based on a C.T. angiogram.

The reason why that's important is that in patients who have 25 to 50 percent stenosis, we found in our own experience here, and this is consistent with what's been reported elsewhere, that about 10 percent of those patients actually have positive FFR-CT, even though the stenosis severity was not really considered to be, you know, sort of, quote significant. So we do pick up a number of abnormal FFR-CTs, even in these, you know, moderate lesions.

On the flip side, for patients who have greater than 70 percent stenosis by C.T., we find that about 20 percent of those patients have negative FFR-CT. So I think, in my opinion, I think it's reasonable to include a stenosis severity that ranges from 25 percent to 90 percent would be appropriate for FFR-CT to pick up some of these positive cases on the low end and some of the negative cases on the on the high end of stenosis severity.

The third comment that I wanted to make was regarding the reimbursement decisions relative to obtaining FFR-CT and invasive FFR. You know, these are certainly complimentary procedures and I can tell you that, you know, based on our own practice that there are circumstances where patients have an FFR-CT, and they go – patients go to the cath lab and then the operator decides to do an invasive FFR, even though there was a previous FFR-CT.

So, you know, I don't think it would be reasonable to handcuff operators in the cath lab from doing what they think is clinically appropriate, which is to use invasive measurements with FFR or IFR as they feel are applicable to the patients they're taking care of.

In our center, we found that FFR-CT and invasive FFR are concordant in about 80 to 85 percent of cases, which means that about 15 to 20 percent, the measurements are discordant. So, if we're in a situation where, you know, operators in the cath lab and even though there may be a positive FFR or even a negative FFR, if the operator feels that doing an invasive procedure is appropriate, you know, there shouldn't be any constraints on their ability to do that.

As an aside, I will also mention that there have been a lot of studies that looked at the concordance and discordance between various invasive measurements of blood flow using FFR and IFR and in about 15 to 20 percent of those cases they are discordant as well. So, we have to recognize that there may be some biological variabilities, you know, patient to patient variabilities.

But, you know, legitimate reasons why measurements of these types may be discordant. And the operators and the patients shouldn't be restricted in terms of using things that they feel are clinically appropriate.

So I'll end my comments there and thank you very much for giving me the time to speak today. I appreciate it.

Barry Whites: You're quite welcome. If you would like your – please send these in. Again, you mentioned several items that we would need to have that your documentation of your references, if you wouldn't mind providing those to be considered and we thank you very much.

Robert Safian: Thank you.

Barry Whites: Thank you, sir. Dr. Kettler, you had a question for our panel?

Robert Kettler: I did, yes and I just want to make sure that I got this right. This last speaker said that he doesn't believe that there's a problem with doing FFR-CT in the presence of devices like pacemaker leads, is that correct?

Robert Safian: Yes, sir. I said that.

Robert Kettler: Now and you don't have a problem with accepting the results but, has anyone actually compared FFR-CT obtained in that situation with some type of gold standard, like maybe FFR obtained by catheterization?

Robert Safian: So, Dr. Rogers may have more information about this than I do. We've done a lot of comparative studies between FFR-CT and invasive FFR and I don't have data specifically that relate to the subset of patients with permanent pacemakers or ICDs.

Robert Kettler: OK and you're not aware of any then?

Robert Safian: No, sir. I'm not.

Robert Kettler: OK. Thank you.

Barry Whites: Dr. Rogers and Dr. Samuels, any comments on that same question? Did (inaudible) be known? I guess not, OK. We will then proceed with further questions. If you would, go ahead, operator.

Operator: Thank you. We have Mr. Josh Young. Your line is now open.

Barry Whites: And if you would go ahead and give us any disclosures or conflict of interest that you may have please, sir.

Josh Young: Hey, this is Josh Young from HeartFlow. I actually hit the star one previous to Dr. Safian's comment. I just wanted to make sure that he was in to comment. So, that's all it was. Thank you.

Barry Whites: Thank you, sir.

Operator: We now have Joaquin Cigarroa, your line is now open.

Joaquin Cigarroa: Good afternoon. This is Joaquin Cigarroa. I am the Chief of Cardiology at OHSU, an interventional cardiologist and Professor of Medicine and today I will be speaking on behalf of the Society for Coronary Angiography and Interventions. I have no financial conflicts of interest. I do, however, serve as the co-chair for the SCAI Government Relations Committee.

So, this afternoon, I'm representing SCAI. And, I would like to thank you for the opportunity to provide our comments. SCAI is a nonprofit professional association with over 4,500 members representing interventional cardiologists. We promote excellence in interventional cardiovascular medicine through education, representation, and the advancement of quality standards to enhance patient care.

SCAI believes there is strong scientific evidence for the diagnostic performance of FFR-CT as a noninvasive screening tool. The focus of my comments will, however, be solely on the proposed restriction on coverage of both FFR-CT and invasive FFR procedures. Right before the summary of evidence section in this proposed LCD, it states and I quote, “Medicare will not pay for both CT derive fractional flow reserve data and fractional flow reserve data obtained by pressure wire at catheterization in the context of the same clinical evaluation or onset of a new symptom complex.

Both concurrent studies may be covered with submitted documentation of discordant clinical data or the onset of a new symptom complex” unquote. We at SCAI fail to see the reason to require the submission of documentation for both of these procedures in 100 percent of the instances when both are performed. Does the MAC have any evidence that a significant number of inappropriate invasive FFR procedures are being performed after FFR procedures or vice versa?

Generally speaking, interventionists who are performing invasive FFRs are seeking data that may clarify the need for interventional procedures, especially at the borderline thresholds of noninvasive FFR-CT values, where we know the percentage of discordant results markedly increases and, therefore, correlation decreases substantially. There is no real financial incentive to perform unnecessary invasive FFR procedures.

Operationally, we're also concerned that there's no time limit on this restriction. A provider planning to perform an invasive FFR procedure may not have access to the FFR-CT results done weeks or even months earlier.

Additionally, over time, symptoms do change and one test may have been done weeks or months before the next. The biology of coronary plaques and their impact on coronary blood flow can change necessitating reevaluation by invasive FFR time at the time of revascularization.

Invasive FFR used to guide the decision to proceed or withhold the performance of PCI has been demonstrated in multiple randomized clinical trials to allow one to determine prognosis. By doing so, we're able to defer, in a substantial number of patients, the performance of PCI.

Another operational complexity to this covered study is identifying which procedure will be non-covered and how that determination is made. These

procedures are commonly done by different providers and they may in fact, not even be part of the same medical group.

Will all the burden be placed on the provider who gets his claim in last? Even if the clinical and pathophysiologic scenario actually indicates that the invasive FFR is a more relevant test at that moment for optimal patient treatment, and therefore outcome?

In summary, we support the proposal to codify coverage of FFR-CT, but find the restriction on the coverage of invasive FFR to be unnecessary and potentially deleterious to patient care. As CGS identifies individuals who are routinely billing for both procedures, it should investigate, but a blanket requirement that both provide documentation to support procedures an unnecessary and may well be unworkable.

FFR-CT is complimentary to invasive physiology, and is effective as a screening tool, but not a substitute for invasive FFR to guide how one proceed with PCI. Thank you so much for your time and consideration. I'd be happy to respond to any questions or comments you may have and we will submit formal documentation.

Barry Whites: Thank you, sir. Are there any questions at this point?

Robert Kettler: Barry, this is Bob. I do have a question if I may.

Barry Whites: Certainly.

Robert Kettler: You know, I was wondering if the last speaker is, I forgot his name, I'm sorry. Could you provide the indications for doing invasive FFR subsequent to FFR-CT, you know, indications that you feel would then warrant coverage?

Joaquin Cigarroa: Thank you for that question. This is Joaquin Cigarroa, again, on behalf of SCAI and so, you know, the performance of C.T. and the addition of CT-FFR as a screening tool is incredibly effective to determine in which patients deferral of invasive angiography and continued treatment of the stable ischemic heart disease with risk modifying therapies such as statins, antiplatelet therapies, and antianginals is effective.

The tool has not been prospectively studied to determine in the invasive laboratory, which lesions specifically should we proceed with PCI and those in which we defer. In the invasive laboratory, the use of invasive FFR to defer

or proceed and to determine lengths in a single vessel in which the stenosis are to be covered or not covered by PTC or stent has consistently been demonstrated.

So, we advocate very strongly that the incorporation of noninvasive CT-FFR is very effective in allowing one to more effectively screen who should not come to the laboratory, however, it is not prospectively studied and does not have the data set that we have in the invasive FFR relative to predicting future outcomes by either deferring stenting at the time of invasive angiography or proceeding with stenting.

Robert Kettler: You know, thank you. Did you envision a time when the invasive FFR should just be bundled into the catheterization procedure?

Joaquin Cigarroa: So, the question is whether or not there'd be added reimbursement as part of a diagnostic angiogram in which one would be able to perform PCI?

You know, from my perspective, the position that our national societies including SCAI have taken, and myself as an interventional cardiologist, is we certainly are advocating that the use of invasive coronary physiologic testing is an important adjunctive tool, especially in moderate stenosis, between 30 to 70 percent, that I'm talking about in the lab, should be encouraged and facilitated.

And, that is, there are lesions that we think may be causing functional ischemia, that with invasive assessment by FFR are not. And, conversely, there are other moderate lesions in which we might not think that they are physiologically significant, due to the combination of length and plaque burden, are actually causing ischemia and that patients would benefit from intervention.

And, so, we certainly believe that it should be used in a substantially greater number of patients to guide the decision to PCI or not and to guide how much of the vessel or conversely, how little of the vessel should be stented.

Barry Whites: Thanks for the question. Another question, I guess.

Robert Kettler: I'm done Barry. I was just thanking him.

Barry Whites: OK. Thank you, sir. Appreciate it. Any other questions?

Joaquin Cigarroa: I very much appreciate the opportunity.

Barry Whites: Yes, sir. Thank you so much for your presentation. And, as always, I'll say one more time, we have the comments to all those who have presented and who characters need to come to policycomments, all one word, at wpsic.com. And that should include your comments as well as any documentation references. I noticed you mentioned multiple randomized clinical trials, those would certainly be helpful that the higher level that we look for and making our decisions.

Our goal is to not deny claims, but to make sure appropriate claims are paid that will benefit our, and I think they are patients, beneficiaries is what Medicare likes to call them, but as far as I'm concerned, they are patients and they're your patients andwe want to pay for what they need. We don't want to pay for what they don't need and we certainly appreciate everybody taking their time to help us clarify some items.

I'm trained in pulmonary and clinical care and certainly not trained in cardiology and the real world of cardiology is an ever changing one, faster than most and I do appreciate all of your comments. Do we have any other comments, operator?

Operator: Yes, we have Dr. Rabbat. Your line is now open.

Barry Whites: OK.

Dr. Rabbat: Hi. Can you hear me?

Barry Whites: Yes, we can. If you would just give us any disclosure, a conflict of interest that you may have, again please, that would be great.

Dr. Rabbat: Great. So, this is Dr. Rabbat, Society of Cardiovascular C.T. Advocacy Committee and consultant to HeartFlow. I would like to add that I've had over five years clinical experience with the technology.

And oftentimes, and this is well documented in the literature, that C.T. tends to overestimate stenosis severity compared to invasive coronary angiography assessment. So, indeed, a 90 percent lesion on C.T. may, in fact, be around 70 percent in the cath lab, so I think that's important to consider as well, in the determination.

Now, I know that there was also some mention in regards to pacemakers and in our clinical experience again, over the last five years, indeed, we do not see much artifact of the coronary arteries in those patients and the majority of those cases are indeed valuable.

And, in fact, even if there was some artifact associated with the pacemaker typically involves the right coronary artery and if the, the area of interest, the region of interest is the lesion in the LCD and circumflex coronary artery, those indeed are evaluable. So, I think that's also an important comment to consider in this dialogue. Thank you very much.

Barry Whites: Thank you, sir. I do appreciate it and as you and others have mentioned, multiple clinical trials, multiple studies, please include those in your comments to the e-mail address that has been provided.

Are there any other comments, questions, criticisms we might entertain before we go forward with our dismissal?

Operator: There are no further questions or comments at this time. Dr. Whites, please continue.

Barry Whites: Thank you so much. I want to again, thank everybody for their contributions. It's been an educational experience and I hope that each of you will take to heart, the necessity of providing your comments to us in the comment policy and providing those articles you want to be considered.

We want to include everything that's necessary to make the correct decision. These comments, because this is a group or a collaborative policy, will go to all of us, we'll be sharing them as we've shared our decision here on the proposed LCD.

We will be also sharing these comments and getting a wide variety of opinions and be sharing comments that others have gotten on these policies. So, we want to thank you. You will have far reaching implications to these policies that we have proposed and we couldn't do it without you.

So without further ado, we'll call this meeting to end and thank everybody again for their patience and their contributions. Thank you.

Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect.