Novitas Solutions and First Coast Service Options

JH/JL/JN Contractor Advisory Committee (CAC) Meeting

Tuesday, February 18, 6 p.m.

Topic for Evidentiary Review: Non-invasive Ultrasound (US) -Extracranial and Upper and Lower Extremities

Corporate Participants

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CAC Panelists

Darpan Bansal, MD, FACC - JL CAC Member, General and Interventional Cardiology

John Evans, DPM, FACFAS, DABFAS - Chief of Podiatry, Department of Orthopedics, Corewell-Beaumont Hospital (MI)

Jonathan Levison, MD - JL CAC Member, Vascular Surgery

Clifford Sales, MD, MBA - JL CAC Member, Vascular Surgery

Jayesh Shah, MD - JH CAC Member, Hyperbaric Oxygen Therapy and Wound Care

Presentation

Monica McKenzie

Welcome. My name is Monica McKenzie, and I'll be your Webex host for today's Novitas Solutions and First Coast Service Options, JH, JL, JN, Contractor Advisory Committee meeting on non-invasive ultrasound, extracranial and upper and lower extremities. Before we get started, I want to take a moment to remind everyone that this meeting is being recorded. CMS requires all MACs to record each CAC meeting and maintain it on their respective website. By remaining logged in and connected via webinar, you acknowledge that you have been made aware that this CAC meeting is being recorded and you are consenting to that recording. If you do not consent to being recorded, please disconnect from this virtual CAC meeting. Otherwise, your continued connection to this meeting constitutes your consent to this recording. This meeting is open to the public to observe. CAC panelists participating in today's meeting have signed conflict of interest and disclosure to publish forms on file. At this time, I'm going to turn things over to First Coast Executive Contractor Medical Director, Dr. Anitra Graves.

Dr. Anitra Graves

Good evening and welcome, everyone. We are so pleased that you are here participating in our first evidentiary meeting or CAC meeting for 2025. My name is Dr. Anitra Graves, and I will be facilitating this CAC discussion. We have an excellent panel of CAC members who have graciously volunteered their time to discuss the certainty of evidence supporting the use of non-invasive arterial ultrasound testing. We also have our Contractor Medical Directors participating and listening in: Dr. Patrick Mann, who's the Executive CMD for Novitas JL, myself, Dr. David Sommers, who is the Executive CMD for Novitas, Dr. Benita Jackson, as well as Dr. Vishnu Potini. Our distinguished panel includes Dr. Darpan Bansal, Dr. Jonathan Levison, Dr. Clifford Sales, Dr. John Evans, and Dr. Jayesh Shah.

The purpose of today's meeting is to discuss a well-accepted imaging modality, which is non-invasive arterial ultrasound, and its application for the evaluation of extracranial upper and lower extremity arteries. Specifically, we're going to be talking about the specific patient populations for arterial duplex ultrasound of the extremities considering recently published guidelines. We'll also discuss the necessity of surveillance ultrasound imaging and the clinical utility thereof, as well as that for for-cause arterial ultrasound imaging. We're also going to examine the associated clinical uses and improved health outcomes that have been documented by the literature in the Medicare population. The CAC panelists are helping us to determine whether or not there is an insufficient, low, moderate, or high certainty of evidence to support the use of arterial ultrasounds for the specific conditions and patient populations that are associated with the questions we will be covering during this meeting.

The evidence our panelists will be referencing has been published on our website. And this includes 83 searched and submitted articles. 20 key clinical questions for the panel discussion will comprise most of our remaining evidentiary meetings. These were provided to our panelists back on January 9th, and they are also posted on both the Novitas and First Coast websites.

Our goal is to facilitate a lively and thorough discussion. So as we move through the questions, panelists, please raise your hand and then accept the invitation to unmute your phone line if it is muted to make a comment. We really want to encourage open dialogue and urge you to share your thoughts with us fully on each question. Please consider the following questions from a Medicare Part B perspective, as we are not discussing patient care for those who are ill enough to be admitted to the hospital.

So we're going to actually skip question 1 so I can make sure that we have time for all of our questions, particularly the priority ones. So we will come back to that as long as we have time at the end. So our first question to warm us up is going to be question 2. And this question is, should specific patient populations - and we'll discuss one at a time for ease of our conversation - receive arterial duplex ultrasound of the extremities? And this is, of course, as it relates to the literature that you have been provided to answer this question. So the first patient population I'd like to open the discussion with is, should diabetics receive arterial ultrasound of the extremities, and for what purpose? Panelists? Yes, Dr. Sales.

Dr. Clifford Sales

I have a question for you before I answer. Are we discussing arterial ultrasound, or are we discussing plethysmography also as a type of test?

Dr. Anitra Graves

Well, you're welcome to discuss plethysmography, but this CAC is focused on the arterial ultrasound modality.

Dr. Clifford Sales

So I mean, your question is, should patients with diabetes undergo non-invasive arterial ultrasound of the lower extremities? Is that the specific question?

Dr. Anitra Graves

Correct. Yes.

Dr. Clifford Sales

I mean, I think that the answer is going to be yes. I mean, there are certain instances which they should. Sure.

Dr. Anitra Graves

And what would that be?

Dr. Clifford Sales

Anybody who's suspected of having arterial insufficiency of the lower extremity. I think most people who manage this disease would start with an ankle-brachial index, and then proceed to a full-fledged pulse volume recording or a plethysmograph, reserving the ultrasound for later on. I think ultrasound is more valuable in planning since it's, for the most part, an anatomical test as opposed to a physiologic test, which is the plethysmography. So I think that simply going right to an ultrasound as a first test is probably not a cost-effective way to manage patients with diabetes.

Dr. Anitra Graves

That's really helpful. So are you suggesting - because I don't want to put words in your mouth - that in a patient that would be presenting to you with diabetes, the modality to investigate whether or not they have peripheral artery disease you would start with are more physiologic tests as opposed to an arterial ultrasound study?

Dr. Clifford Sales

Yes. The direct answer is yes. I believe that first of all, before you subject anyone to the tests-- we're not talking about asymptomatic patients now. So we're not talking about screening tests. Is that correct?

Dr. Anitra Graves

That's exactly the purpose of this discussion. So would you not recommend, in a diabetic patient population for those who do not have symptoms, that they undergo this type of testing, or would you prefer to have testing-- or excuse me, would you prefer to have testing in patients that have symptoms?

Dr. Clifford Sales

I mean, this is big, big, big questions, I mean, in my opinion. One is a screening test, and we can talk about the value of a screening test. I mean, the value of a screening test for lower extremity peripheral arterial disease is probably more important for identifying occult cardiac disease than it is for identifying occult peripheral vascular disease. So I would definitely say that starting out with an ultrasound is not the appropriate way in an asymptomatic patient and maybe in a symptomatic patient. That's probably a little more tenuous in my feelings about that. I think Dr. Levison is on. I'd be curious to hear his thoughts also.

Dr. Jonathan Levison

Yeah, I would agree. Arterial duplex is really best suited for an operator that is planning an intervention on a patient that is known to have peripheral arterial disease. Part of the problem with diabetics, if you back up and you say, "Okay, let's start with a plethysmography as a first line of testing," in someone who obviously was examined with a good physical exam and noted to have a diminished pulse on exam. And so you go into the next step of doing non-invasive testing or plethysmography. A lot of diabetics who have calcinosis of their vessels are going to have non-compressibility on the non-invasive arterial exam or the PVR or-- I'm using those interchangeably. And there's not much value in that study. And so then it brings on the next level of testing, which would be arterial duplex to really kind of hone in on where exactly in the arterial tree the disease is located. But that information is really most valuable for planning an intervention if the patient truly has an indication for intervention.

Dr. Darpan Bansal

Yeah, I think I agree with-- this is Dr. Bansal. I agree with what has been said. And that kind of brings to the point that typically an intervention is needed when patients have symptoms. In other words, this might be a good test when somebody presents with symptoms, possibly attributable to peripheral arterial disease, but for an asymptomatic patient, to do this as a first test may not be appropriate.

Dr. Anitra Graves

Would it change your position if the diabetic has acute or acute on chronic edema? In other words, it sounds like from this discussion that leg pain would be a symptom that you perhaps would consider reasonable to instigate investigation using arterial ultrasound. However, what about those diabetic patients or patients that have chronic edema? Should those patient populations receive arterial duplex testing?

Dr. Clifford Sales

Edema, as a stand-alone physical finding, is not indicative of arterial disease. There are many etiologies for edema, of which venous would be probably more likely to be considered. Certainly, there are others, such as lymphedema and all other causes, but that's not benefited from arterial interrogation.

Dr. Darpan Bansal

As a cardiologist, I do see a lot of patients with edema. And just like it was just mentioned, that it's typically less likely to be related to an arterial cause, peripheral arterial disease-related, most likely either venous cause, or oftentimes, we do an echo to rule out cardiac cause, which is a very common etiology as well. So yeah. It's not one of the-- now if somebody has edema and also has leg pain associated with that, then that's different. But just pure acute edema or chronic edema, the etiology being arterial would be less likely.

Dr. Clifford Sales

I would add to what Dr. Bansal was saying. I would be a little more emphatic. Edema is not an indication for an arterial duplex, period. Doesn't mean edema can't be with something else, as Dr. Bansal said, if there's leg pain. But edema as an indication for an arterial duplex is not acceptable, in my opinion.

Dr. Jonathan Levison

Agreed.

Dr. Darpan Bansal

Agree.

Dr. Anitra Graves

Thank you so much for the-- thank you so much for the responses. We'll go on to question 3. And it's a similar question. However, this is more of a physiologic test. So for the patient populations that we were discussing, should those specific patient populations receive ankle-brachial index - and this is to bring us into that plethysmography discussion that someone suggested earlier - or other non-invasive physiologic testing?

Dr. Clifford Sales

This is Cliff. I think, absolutely. I mean, that is the test of choice. I'd even extend it to saying that it's reasonable to do that as a screening test in the asymptomatic patient who may be at risk for generalized atherosclerotic disease, specifically cardiac disease.

Dr. Jonathan Levison

Yeah. I mean, unfortunately, diabetics are tricky often. Because, again, back to this, the information from an ABI can often be misleading, especially in an advanced diabetic. In patients with edema, again, if you're looking for specific patient populations that would benefit from a plethysmography as a first go around, you're really looking at those patients that present with our typical risk factors, as said before, for atherosclerosis, smokers, hypertensive patients, patients that are presenting with abnormal pulse examination and certain factors on their history or a chief complaint that align with early stages of peripheral arterial disease, such as claudicators.

Dr. Anitra Graves

This is very helpful. So again, it sounds, based on your review and your own clinical experience, that there is clearly a difference in patient populations where there is for-cause so that there are some signs and symptoms of hemodynamically significant arterial disease versus that of surveillance. Any other comments on question number 2 that we may not have-- excuse me, 3, that we may not have discussed?

Dr. John Evans

This is John Evans speaking for podiatry and basically primary care. The physiologic testing is crucial to our patient population. Really, as the doctors have said before, the arterial Dopplers are very good when you're determining what segment may need to be intervened. But prior to that, most of the work should be done around the ankle-brachial index and also considering the toe-brachial index, the ABI post-exercise, those and the plethysmography, different aspects. These, we can monitor patients, pick up those that have some issues instead of waiting until-- what we basically do now is wait until someone becomes symptomatic, which means they've reached an ischemic level that there are symptoms of either claudication, or delayed healing of wounds has occurred. So, yeah, I think it's very important that in this early stage, we determine whether someone has reached a level of atherosclerotic disease in the extremities, that they need to be watched closer. We have excellent guideline medication therapies in place to be used.

But really, with the number of PAD patients increasing-- I mean, we talk about there being 8 to 12 million in the US, but those numbers are based on calculations from 1995. And we certainly know diabetes has blown up as has obesity. And we've got an older population than we had then. And all of these are risk factor accelerators for these atherosclerotic diseases. And as the doctor pointed out, one of the probably most important things about screening for PAD is you're going to pick up a cardiac disease because PAD is just a subset of atherosclerotic disease. And really, if somebody's got PAD, there's probably a 50 to 90 percent chance they have coronary disease in addition. So we need to find some way to identify these patients in a relatively cost-effective means, and that's where these other testing fall into place, in my opinion.

Dr. Darpan Bansal

I agree with Dr. Evans, that as a screening modality-- I mean, this is a great resource, especially once you diagnose PAD with this, you can be aggressive in terms of risk factor modification, making sure their LDL is well controlled and whatnot, and which also reduces cardiovascular mortality in turn. So these are very effective tools to affect the health of the population in general as a screening modality.

Dr. Anitra Graves

This is quite helpful. Thank you for those comments. And let me go a little bit further regarding the issue regarding coronary artery disease patients. And I, again, do not want to put words in your mouth, but it sounds like in patients that have known coronary artery disease, however, may not have known anatomy of their lower extremities. You are suggesting that that would be a reasonable patient population for the non-invasive physiologic testing. However, if there was symptoms such as leg pain in the lower extremities, you would recommend both or to begin with non-invasive physiologic testing in both cases. Can you expand on that?

Dr. Clifford Sales

Yeah. I mean, I think you always need to start with physiologic testing. I think that the arterial duplex, the anatomic testing, again, as most of the people have said, it really needs to be reserved for the most part, not always, but for the most part, as a prelude to an intervention. I think that all too often, we see patients getting arterial ultrasounds with meaningless reports. I mean, meaningless numbers associated with them. And it doesn't take into account the clinical situation. So I think a physiologic test will put you into the ballpark of if someone may need to be treated or not. I mean, obviously, it's the clinical story that really tells it all. But I do think that-- I don't think that going to an arterial duplex as an initial test is the right thing to do because I don't think it gives you meaningful information for the most part.

Dr. Anitra Graves

So we are going to even push this issue even further on the next question, because with these same patient populations, the question is, should they receive arterial ultrasound imaging of the extremities more than once annually? And before we get to your responses, I neglected to provide a little bit of background. The reason that we are asking our jurisdictional SMEs about this modality is that, based on the guidelines that we've seen published, specifically even the newer guidelines published last year, despite that, those guidelines do not align with what we are seeing in terms of utilization. And so we're wanting our SMEs and those that take care of these types of patients to weigh in so that we are understanding, from your perspective, how those guidelines apply to your patient population. So in addition to what we've already discussed, can you also talk about repeat or imaging more than once in a 12-month period, and whether or not that should be done in these patient populations?

Dr. Jonathan Levison

I can kind of take that from the start. That answer is really most applicable to a patient that has undergone an intervention in the form of either an endovascular intervention, or an open revascularization. In those cases, arterial duplex performed within the first year several times is of very high value. For example, the patient with a vein bypass in the leg. The recommendations for those patients is to have arterial duplex of the bypass every 3 months for the first year to make sure, because the data clearly shows that when you pick up some sort of abnormality somewhere along the vein bypass, intervention is usually minimalized when you treat it before it actually closes, which leads to a lot of morbidity. For patients that have an endovascular intervention such as an angioplasty or a stent, we use duplex as well multiple times at first to be sure that there is not either intimal hyperplasia within the stent within the first 6 months or something that is leading to failure. So for us, in the vascular surgery population of patients, we use it mainly for those that have had something done. I don't see a value-- at least I don't see it for repeating it multiple times - and we're talking about arterial duplex here - unless I'm looking for something in particular.

Dr. Clifford Sales

Yeah. I mean, one indication for excluding the patients who have been intervened upon. But if there's a change in symptomatology or a change in the non-invasive study, in other words, there's change in the plethysmography study, then again, that goes back to the question number 2, which is the first question we discussed at the top of the hour, was what are the indications for an arterial duplex? So it goes back to that question. Certainly, to perform it multiple times within a-- just repeating it because it's been done before is not appropriate.

Dr. Darpan Bansal

Yeah. I agree with what Dr. Sales just mentioned, is I think if there's a change in symptomatology or a more objective evidence of change in the findings of the ABIs or the PVR or something within a year, then it's not unreasonable to perform this. But in absence of that, it might be hard to do it unless, of course, if the patient has been revascularized, got a stent or a bypass, then that's different.

Dr. Anitra Graves

Well, we will cover that patient population as well. So thank you for that. It may allow us to pass those questions even more efficiently. So thank you. Any other comments on this question? Okay, seeing none, we'll go to question 5. Should patients receive arterial ultrasound imaging and/or ankle-brachial index to diagnose peripheral artery disease? We somewhat touched on this, but if you could expand on the discussion about using the physiologic tests first and when and in what circumstances you would, if ever, use both physiologic as well as arterial ultrasound imaging, that would be helpful.

Dr. John Evans

I think the first line of testing after your physical exam and someone you suspect has peripheral arterial disease would be to do an ankle-brachial index. I think that is a great starting point to identify a patient that has arterial occlusive disease in those patients. And I think it also should be mentioned-- we haven't really talked about it, but I think the stress PVR for patients that are suspected of being claudicants is probably underused. I think it's probably underused in our practice just from a logistics standpoint. But these are patients that potentially could have pulses that are palpable in their feet that when you stress them for a period of time, they do demonstrate a drop in their ankle-brachial index. It's really those patients now that are identified as patients that do have peripheral arterial disease that potentially would benefit from arterial ultrasound imaging. And again, when I say potentially, I typically don't go ahead and do that right away unless I really am suspecting that this patient is going to need some sort of intervention.

[silence]

Dr. Clifford Sales

I think the answer to the question that's posed is yes. And it should be in a stepwise, thoughtful fashion, as Dr. Levison said, beginning with a plethysmographic or a physiologic test, and then followed by an arterial duplex if there's a consideration for proceeding with an intervention. The only caveat in all of these things is aneurysmal disease of the lower extremities. I mean, if on a physical exam someone feels a popliteal aneurysm or if there's a concern of a femoral pseudoaneurysm after an intervention, that's a different situation. Well, I mean, that's not PAD, but I don't want to get that lost in this discussion.

Dr. Anitra Graves

Yeah. That's very helpful. I'm sorry. Go ahead. I interrupted.

Dr. Jonathan Levison

If the question is to diagnose PAD, then certainly the physiologic testing makes the most sense to start. We know there's problems with the ABI that have to do with-- it depends on the vessels being able to be compressed. And we also know there's a lot of arterial hardening and stiffness that occurs, especially in patients with diabetes or renal disease, that these vessels are not compressible, that give you abnormally high values. But it's the least expensive and simplest way of determining if something is going on. Ankle-brachial index is also great because it's not affected by the arterial stiffness as much. So it's very useful in patients with diabetes or a renal disease. And as was pointed out, the exercise, the ABI or TBI post-exercise, really does a good job of pointing out people that are falling within the normal range, but you still think something's wrong because they've got some degree of ischemic symptoms.

The next step, possibly, is the plethysmography with looking at waveforms, because we can get a lot of information just by looking at the waveform and determining its shape.

And really, those are the early ways that, how I look at it, that we would diagnose this disease. And at that point, if we believe there is something going on, us in the primary care arena, we're going to refer it to a specialist in vascular disease. Now, one of these specialists that can treat this with either guideline-directed medical therapy, or if it's to the point that they require an intervention to determine which is best for that. And that's where ultrasound is really good. But for the simpler, from the initial diagnosis or monitoring stage, whether the patient is asymptomatic and has a number of risk factors or accelerators that we can talk about later, or they have some degree of symptoms, claudication or slow healing, we would start with the physiologic testing and then refer to the specialists for the arterial duplex testing.

Dr. Clifford Sales

I think it's probably important to stop at this point and just differentiate between three different things. One is the ABI, the other is a single-level plethysmography test, and the other one is a full PVR, because they're different and they have different values. The ABI, which I do not believe is a reimbursable test from Medicare, simply measures the pressures. And that is what we've been referring to as problematic in patients with calcified vessels. The single-level PVR, or plethysmograph, does the same as the ABI, measures it, but it does get a waveform at the ankle, which does add something. The plethysmography test, which is what the doctor was just referring to, is what gives the true information and can differentiate a patient with a non-palpable pulse due to calcinosis, versus a patient with a non-palpable pulse due to disease. I think any of my colleagues disagree with that or want to amplify on it. So I think that's important to understand as we kind of formulate a system here.

Dr. Jonathan Levison

I agree.

Dr. Anitra Graves

Okay. This is very helpful. And I'm hearing, and just trying to summarize a little bit, that the physiologic testing is quite informative and perhaps has a more functional role in managing these patients where there is concern for arterial disease, particularly involving the lower extremities. I hear you loud and clear. Let's go to the next question.

Dr. Clifford Sales

I just want to-- one more thing. I think that arterial duplex - I've seen it - leads to inappropriate testing and intervention because, as we all know, there are three vessels below the knee. I've seen it on more than one occasion, but someone gets an arterial duplex that shows one of the three vessels is occluded, and next thing you know, the patient's getting an angiogram and an atherectomy or something for that. So I think that there is a significant danger in allowing these duplexes to be done in the wrong hands.

Dr. Jonathan Levison

So in other words, an intervention that's done to treat supposed claudication makes no sense if it's to treat a tibial artery that's occluded, because claudication is only going to really be caused by occlusion of the femoral vessel, or popliteal vessels, or iliac vessels.

Dr. Anitra Graves

Understood. Now, I'm actually going to take a little liberty here and get a little bit more detail from you as someone else brought up this idea of the guideline or goal-directed medical therapy. And would it make a difference for you if a particular patient that has risk factors is already receiving guideline-directed medical therapy versus someone that is not? Would your decision for imaging be different between those patient populations?

Dr. Jonathan Levison

I don't think so. I think, again, it's largely based on what your intent to treat is from an intervention standpoint, not just from medication. For the patients that get treated with medication for claudication, they get followed up in a several-month time period, and usually will get another ABI at that point in time, a single-level ABI, to see whether or not there's stability or any deterioration and so forth.

Dr. Darpan Bansal

Just to get to the point of the guideline-directed medical therapy, again, we know that the target LDL that one would shoot for when somebody has a confirmed PAD diagnosis would be much lower than, say, asymptomatic guy who doesn't have any confirmed PAD diagnosis. But again, I mean, the point being that the initial test to screen for PAD would still be the ABIs and the physiological testing rather than going directly with the duplex ultrasound.

Dr. Clifford Sales

Agreed.

Dr. Anitra Graves

Okay. Thank you for indulging with that one. It wasn't previously on there, but I was interested since we were talking about it. So we will go on to the next question. This does have a specific focus on those with endovascular surgical intervention. So the question is, should beneficiaries who have had endovascular or surgical intervention undergo arterial ultrasound imaging? If so, when, how frequently, and for how long?

Dr. Clifford Sales

I think someone addressed that before. But certainly, in the first year-- excuse me, pardon me, probably every 3 months is reasonable. And then the second year, I think the guidelines from the Society for Vascular Surgery, every 6 months. And then after that, it's probably annually. Obviously, if there's a change in symptoms, that's a whole different story. But in terms of someone who has had no change in symptoms, I think Q3 months, Q6 months, and then Q year. That would be arterial ultrasound, is really what that should be.

Dr. Anitra Graves

Any other comments?

Dr. Jonathan Levison

Yeah, I think that we start to get into a lot of individual case scenarios. And we're talking about a vein bypass versus a prosthetic bypass versus a stent. The highest acuity is going to obviously be for the vein bypass because if that occludes, the patient is faced with a high morbidity. If it's a prosthetic bypass and it occludes and you kind of missed an opportunity to intervene, it's usually not the end of the world because we can lyse those patients open and then treat them if it's found in a reasonable timeframe. So I think there probably is, on a subtle level, some differences between those as far as how closely they should be followed. But the point is, yes, different intervals for different patients, but the punchline is, yes, multiple intervals during that first year.

Dr. John Evans

And if I could add, it really depends on the procedure that's being performed. More recently, there are some procedures that the risk of the artery or graft is going to shut down. And so during that first 3 months, they're checking it more frequently, and it's appropriate because if it shuts down, the procedure is going to fail.

Dr. Anitra Graves

And so we can go to the next question. It's very, very similar, but this specifies the patient population. So for here, we're asking, should beneficiaries who have had endovascular surgical intervention undergo surveillance arterial ultrasound? And I think a lot of you have already answered that question. Do you have any recommendations or are they different in this specific patient population if we're talking about surveillance versus for-cause? So would you expect they have serial arterial ultrasound imaging as you suggested, so particularly, in the beginning, but would it be more frequently in someone that has an issue that developed, specifically as it relates to arterial ultrasound imaging? Would that change your position on whether or not the beneficiary should undergo if it's a surveillance scenario?

Dr. Jonathan Levison

Well, so if you look at the algorithm-- and again, our practice has been taken from what the SVS, the Society for Vascular Surgery recommendations have been. And they've basically culled all the data and kind of have come up with an algorithmic approach to the use of the vascular lab with managing patients that have undergone infrainguinal revascularizations. And so let's look at a lower extremity vein bypass. The recommendations were that a duplex be done - and this is a surveillance duplex - at 3, 6, 12 months and annually if no significant stenosis. If the patient shows any significant stenosis in the vein bypass, then an intervention is either done or not done, kind of it kicks back. The intervals can be shortened at that point in time based on the findings. That's with the vein bypass. If it's a prosthetic lower extremity bypass, we don't tend to follow those as often. But the recommendations were for 6 months and annually with surveillance testing, assuming there's no problems with the patient and they're not complaining of anything.

Dr. Anitra Graves

Any other comments?

Dr. Clifford Sales

No, I think the answer to your question up on the screen is yes. I think that the intervals that Dr. Levison said are, I think, pretty well tried and true.

Dr. Anitra Graves

We've been talking mainly about lower extremity arteries. Are your responses the same if we are considering those with extracranial interventions or status post endovascular surgical interventions in the extracranial vessels, would your responses be the same?

Dr. Clifford Sales

No. Those are totally different.

Dr. Jonathan Levison

Those are a little-- those are different.

Dr. Clifford Sales

I mean, we can talk about that now as separate, but that's very different. That's a completely different animal.

Dr. Anitra Graves

And how so?

Dr. Jonathan Levison

Well, if you just look at the arterial tree you're looking at with the extracranial circulation, first of all, it's not as lengthy in the sense that you're basically looking from the common carotid artery as far as you can see into the internal, which is just up to the level of the jaw. So for those patients, you're really just mainly looking at the area of the carotid bifurcation because that's where the disease usually occurs with atherosclerosis. So for those patients, we have a different set of intervals that we use for either screening purposes in patients with known disease or for those that have had an intervention.

[silence]

Dr. Anitra Graves

So that's helpful. So to make sure I summarize properly, your response is that those patients that are being evaluated, and in this case we're talking about endovascular surgical intervention, they have had that, that extracranial ultrasound imaging is appropriate, and in some cases, in serial fashion based on guideline or algorithmic determinations, right?

Dr. Jonathan Levison

Yes.

Dr. Anitra Graves

Thank you. Any other comments on this one?

Dr. Clifford Sales

Are you asking, if patients have had endovascular surgical intervention on their legs, is that an indication to look at the carotid arteries? Is that the question?

Dr. Anitra Graves

No. No, sir. No, sir. For that patient population, it was those that have had endovascular surgical interventions in the carotids.

Dr. Clifford Sales

Oh, oh, oh. Okay. Okay.

Dr. Anitra Graves

All right. So we'll go on to question number 8. And this is also involving those beneficiaries who have had endovascular or surgical intervention. And this question really is for ultrasound-determined ABI testing, is there a role for that patient population? And again, this is specific for surveillance? And if so, when, how frequently, and for how long? ABI testing.

Dr. Jonathan Levison

That would typically be an annual event in a stable patient with known disease.

Dr. Anitra Graves

Any others?

Dr. Clifford Sales

I agree.

Dr. John Evans

I agree.

Dr. Anitra Graves

Okay. Dr. Shah, are you with us now?

[silence]

We will go on to the next question while Dr. Shah tests their sound. So to question 10, should concomitant arterial duplex ultrasound and non-invasive physiologic testing of the extremities be performed in beneficiaries with known peripheral artery disease but without symptoms? If so, how frequently and for how long? Sales?

Dr. Jonathan Levison

Again, I don't use arterial ultrasound just to follow a patient that has never had an intervention on any type of regular basis. It's usually for a patient that I have some sort of plan to do something for. And the physiologic testing has indicated that it's abnormal. I'm not sure what the value is of looking at velocities in your femoral artery and just to look at the velocities.

Dr. John Evans

I think if we're limiting this question to whether you should have arterial duplex ultrasounds done just to see what's going on, I don't think that's appropriate. But I do think it's extremely important to have these non-invasive physiologic testing done on a regular basis. I mean, it's very similar to how often you do an EKG if you want to see if something's wrong with the heart. These physiologic studies are the simplest way we have of determining the vascular arterial health of the legs. So certainly, in patients who are at greater risk of having problems, every decade in life after age 50, the risk goes up. So age is important.

If they have certain diagnostic accelerators, such as any of the other atherosclerotic diseases, whether coronary artery disease or cerebral artery disease-- I mean, hypertension falls in that category too, along with smoking, renal disease, and certainly those with diabetes. Because really, other than smoking, that's the highest risk factor we're going to run into. And the longer these patients live, the worse their arteries are going to get. Peripheral arterial disease doesn't really get better. It starts in your youth and continues until you die. So the physiologic testing is one way we can monitor these patients, hopefully before they get to the point that they have an ischemic symptom. And at that point, we're talking about more powerful treatments or interventions. So I think it would be important that they are done on a regular basis. Certainly, there are different algorithms as how often they should be done, and we can certainly talk about that. But I do believe it would be important.

Dr. Clifford Sales

So I have a question for you, Dr. Evans. Are you suggesting that an asymptomatic patient have a PVR done - we'll pick a number - annually?

Dr. John Evans

I think if the patient is asymptomatic, maybe not. But if they're 65 years old, have diabetes, hypertension, and dyslipidemia, I'm a little bit more concerned. And I'm not necessarily talking about plethysmography, doing full-body type things. I think it's extremely beneficial to be able to look at waveforms if I've got a Doppler and I can just look at a pulse at any of the arteries in the extremity just to check things. But certainly, ABI or TBI, I think, are reasonable.

Dr. Clifford Sales

Yeah. I'm not sure I agree with that on a clinical level. Certainly, as a screening study, I think that's important. If you've got someone-- I'm just wondering how it would change anything. If you have someone on day zero at the age of 65, has a normal PVR, and then they come back next year, they're doing okay. And let's just say their ankle-brachial index now is 0.6 instead of 1.1, which it was a year ago, but they're asymptomatic, and with all the risk factors you identified, what's that going to change? I mean, the high-risk patient, you're still going to give the appropriate podiatric care. You can still warn them about what to look for. And I'm not sure I understand how a test in an asymptomatic patient is going to change the overall management of the patient.

Dr. Darpan Bansal

I mean, I think there are pluses and minuses to both aspects. And oftentimes, at least in cardiology world, one can argue that, "Okay, you could become a little bit more aggressive with risk factor modification. You can shoot for a lower blood pressure target. You can shoot for a lower LDL target." But again, I mean, to your point, in terms of it will not change the management acutely whether you'll intervene or whether you'll offer any definitive percutaneous or any of those kind of therapies, it doesn't change any of that based upon the knowledge, based upon the information we'll get from this kind of testing.

Dr. Jonathan Levison

So, Dr. Graves, to bring back to the question of 10, I can say no.

Dr. Anitra Graves

Thank you for that. And I just want to make sure that for all the panelists, this particular question-- which, by the way, that was very helpful. But for this one, I am very interested to understand if these beneficiaries that we're talking about, the patient populations that we're speaking on, should have both arterial ultrasound testing and non-invasive physiologic testing on the same date for the same diagnoses, if they do not have signs and symptoms of disease. And it sounds like the answer to that is no, but I want to make sure I'm-- I don't know that all are in agreement with that.

Dr. Darpan Bansal

No. I agree. I mean, it shouldn't-- the concomitant probably, I agree with what was just said. I don't think there's much indication for doing concomitant arterial duplex and non-invasive physiological testing in this scenario. So I agree with what was just said.

Dr. Anitra Graves

Okay. Great. And we're going to go on to the next-- okay.

Dr. Jonathan Levison

And I agree that they would not be done together. But I totally disagree that we would not have physiologic testing done in patients that we're more concerned could develop these symptoms, because the majority of patients who are on medications for cardiovascular disease, they're not necessarily following all the guidelines. They're not fully guideline-implemented. People are tough about medications. And again, if I have a patient that I see, as the doctor mentioned, somebody whose ABI drops 0.5 within a year or so, well, those are people I'm going to make sure they're on full guideline therapy. I'm going to be talking about exercise therapy with them because I don't want to wait until they have ischemic symptoms to say, "Oh, maybe we should have done something last year." So I believe that surveillance for patients that are at higher risk for PAD but may be asymptomatic should be instituted, but not necessarily combined with ultrasound. Really, that should be held up for people who seriously-- we've got symptoms to the point we're considering that they may need some sort of intervention.

Dr. Anitra Graves

Understood. Let me just interrupt. I think Dr. Shah has now been able to join us. Dr. Shah, can you raise your hand so that we can find you in our participant view? And while Dr. Shah is doing that, we will press on to the next question, number 12. Next slide, please. And this one, I know this is going to seem like a very straightforward question, and it is, and it's intended to be. Should arterial duplex ultrasound testing be used in patients with isolated lymphedema?

Dr. John Evans

No.

Dr. Clifford Sales

No.

Definitely not.

Dr. Anitra Graves

All right. We will go to the next question. It sounds like that is a resounding no. This next question is, should arterial duplex ultrasound testing be used in patients with stable intermittent claudication? Now, this example is a patient that has leg pain. It's typical with, for example, going upstairs, but they rest, it goes away, and it's not accelerating. So for that patient, should arterial ultrasound duplex, ultrasound testing be used in them?

Dr. John Evans

No.

Dr. Clifford Sales

I mean, only if there's a plan to intervene. I mean, we generally try to avoid intervening on claudication. So no stands out on that. But if there's a plan to intervene.

Dr. Jonathan Levison

But that would imply unstable.

Dr Clifford Sales

I guess that's probably true. Yeah. Okay. Fair enough.

Dr. Darpan Bansal

Yeah. I mean, there could be one situation in which it may still be stable, but the patient may have decided that he would want to proceed with the intervention to get rid of it, in which case one could argue-- I mean, in most cases, you wouldn't do that, but there may be isolated scenarios in which you may do this if there is a plan to intervene just like it was pointed out based on patient wishes or specific clinical scenario.

Dr. Jonathan Levison

Right. So then we would add stable, disabling intermittent claudication.

Dr. Anitra Graves

Yeah, that's fair. So sufficient enough to impair functional status and/or limit their activities, I assume. Is that what you're referring to?

Dr. Jonathan Levison

Yeah.

Dr. Anitra Graves

Okay. Any other comments on this one?

Dr. John Evans

Yeah. Just to interject, claudication is kind of a weird bug. Patients who have diabetic neuropathy, per se, often won't have classic claudication symptoms. And a couple of studies have shown that less than 20% of patients who have PAD have typical claudication symptoms. So it's easy to miss them. So really, just to wait until somebody is a claudicant before you evaluate doesn't make any sense. But certainly, you shouldn't start out with arterial duplex unless you're pretty sure something's clogged up along the pipeline.

Dr. Anitra Graves

Well, let's follow that a little bit because one of the indications that we've seen-- or diagnoses, I should say, not indications. The diagnoses that we've seen is leg pain. So as it relates to a diabetic, according to you, they don't get the typical claudication. Would leg pain be a reason to perform arterial duplex ultrasound testing in patients, just leg pain?

Dr. Clifford Sales

No. No, I don't think so at all. I mean, if you take a history, and you do a physical exam, and you have a reason to suspect peripheral arterial disease, yes. But I mean, most patients with leg pain have arthritis. I mean, that's the most common cause, given the entire population. So I don't think you want to be doing PVRs on just the leg pain as a garbage can diagnosis.

Dr. Jonathan Levison

It's interesting. What's happened over the last several years is that the private payers have been pushing the interventionalists to get a certain level of intervention approved for a patient that has symptomatic peripheral arterial disease. They want to know, "What segment of the arterial tree are you treating?" Not just, "I'm going to go in and look for something and treat something." "Are you going for the femoral segment, the popliteal segment, the tibial, whatever?" They want to know, and so for us, this is where the arterial duplex has become very valuable. It's almost like a cost-effective, safe arteriogram to really do all your planning in advance, and that's what we're using it for.

Dr. Anitra Graves

So what you're suggesting is-- it sounds like you've already made the decision or your intention is to perform an intervention in that scenario, correct?

Dr. Clifford Sales

Correct.

Dr. Jonathan Levison

Yeah.

Dr. Anitra Graves

Okay. One more time. Dr. Shah, can you just let me know if you're available? Okay. I'm not hearing Dr. Shah, so we will press on with this conversation. I really appreciate this discussion. So we'll go to slide 14. And this is very similar to before, but again, should concomitant arterial duplex ultrasound of the extremities and CT angiography of the extremities be performed in beneficiaries with known peripheral artery disease? If so, how frequently and for how long?

Dr. Jonathan Levison

Yeah. The question is, do I own the CT scan machine?

Dr. Clifford Sales

Yeah, exactly. [laughter] Yeah. I think that's what you're getting into here. Yeah. I think the answer is-- the question of frequently shouldn't even be discussed. The answer is no. There's no frequency with which CT angiography should ever be performed on the extremities. Are there instances where an arterial duplex is performed, and then you need to do CT angiography or vice versa? The answer, of course, there is. For example, CT angiography is a much better test for the iliacs than duplex ultrasound. Up until recently, I would have said that duplex is a better test for below the inguinal ligaments. Probably the CT has gotten better, and I certainly think that from the inguinal ligament to the popliteal, CT angiography is a good study. But there's definitely not a-- again, these two tests, in my opinion, should be used as planning stages for an intervention. I don't think someone should be subjected to a CT angio if there's not a real plan or a willingness to intervene.

Dr. Jonathan Levison

Yeah, I think from an algorithmic standpoint, specifically, those patients that, on physical examination, are found to have absent femoral pulses, that are planning on undergoing an intervention, this is a very good test CT scan, CT angiography in conjunction with duplex to look in the leg. The problem here is that we see often in our practice patients present to us for a consultation that have already had a CT angiogram ordered by another specialist at an outside facility. And part of the problem with the CT angiograms is that sometimes it's difficult to ascertain what's going on in the infrainguinal vessels when there is the presence of concomitant calcium. It makes it difficult to actually appreciate a patent flow lumen. Even when you subtract out bone windows to look at the imaging studies, it can be somewhat confusing. But I said before, I think it's most valuable for aortoiliac disease in patients that don't have femoral pulses. It really helps you understand what you're getting into and helps from a planning purpose.

Dr. Anitra Graves

Okay. Any other comments on that one? With that we'll press on to-- oh, go ahead.

Dr. Darpan Bansal

Oh, no. I would just say I agree. I mean, it's very helpful for planning. If you're planning to intervene, then I think CT angiography has a role. But otherwise, yeah, I agree with what was just said.

Dr. Anitra Graves

Excellent. Next question. This is question 15. Should specific patient populations receive surveillance arterial duplex ultrasound of the carotid extracranial arteries. And we somewhat touched on that earlier, but I want to make sure that we talk about each of these patient populations, specifically diabetics versus those with known peripheral artery disease or coronary artery disease. Should they receive surveillance arterial duplex ultrasound of the carotid/extracranial arteries?

Dr. Jonathan Levison

So you're talking about a screening carotid duplex examination?

Dr. Anitra Graves

Correct.

Dr. Jonathan Levison

Well, currently, that's not approved by Medicare.

Dr. Anitra Graves

But I'm asking based on the literature, should that testing be done? So based on the literature that we've provided you, in someone with known diabetes or peripheral artery disease or known coronary artery disease, should they receive imaging of their carotids?

Dr. Jonathan Levison

I think, at least a one-time screening study, similar to what was approved with the aneurysm screenings in patients that were smokers greater than 60. I believe that that is warranted.

Dr. Clifford Sales

I would agree with that also.

Dr. Anitra Graves

Okay. Anyone else?

Dr. John Evans

I would agree also. I mean, there's a significant relationship between the different atherosclerotic arterial beds, whether the heart or the brain or the legs. And if one is involved, there is a chance another one might be also. It's called polyvascular disease. And with each of those, the significant risk of major adverse cardiovascular and limb events go up. So at least it should be watched if even infrequently.

Dr. Anitra Graves

So you're very astute, and you picked up the focus of this particular question. And that is whether or not the literature would suggest that this type of disease would be present in coronary artery disease in these patient populations, therefore, in that scenario, it would not be considered screening and rather surveillance. In other words, the expectation of disease would be there, which would then potentially inspire a physician to look at those carotids because of the patient's concurrent or comorbidities. So just so we are complete on this discussion for this particular issue, as is stated, in someone that you are treating or known to have peripheral artery disease, coronary artery disease, diabetes, would you recommend, based on the literature that we've provided, surveillance testing of the carotid or extracranial arteries?

[silence]

Dr. Clifford Sales

Yes. I think that's reasonable. I do.

Dr. Jonathan Levison

Agreed.

Dr. Anitra Graves

All right. So we will press on to the next question, number 16. And I think we've discussed this, but just in case there are any other opinions that would like to be shared, should Medicare patients who have had endovascular surgical intervention have duplex ultrasound of the carotid arteries?

Dr. Clifford Sales

I think that's the same answer as the last question. Someone who's got peripheral artery disease has had—

Dr. Anitra Graves

This is a little different because this is a patient that [crosstalk]-- yeah.

Dr. Jonathan Levison

No. The patient's had an intervention here. So the guidelines that we use, again, the SVS vetted guidelines, are that for a patient that's had either a carotid endarterectomy or a carotid stent, we perform arterial duplex baseline every 6 months and every 6 months for 2 years, and then annually thereafter until it stabilizes. And then when I say stabilizes, that means no restenosis observed in two consecutive annual scans.

Dr. Clifford Sales

I misread the question. I thought it was if the patients had a peripheral endovascular surgical intervention. If you're talking about a carotid intervention, yeah, definitely, the patient needs to have follow-up scans.

Dr. Anitra Graves

Okay. Any other comments?

Dr. Darpan Bansal

I agree.

Dr. Anitra Graves

Thank you. Let's press on to question number 17. Should non-invasive physiologic testing of the extremities be performed in Medicare patients with known peripheral artery disease? I think we have discussed this, but are there any other comments to summarize this question?

Dr. Clifford Sales

I think the answer is yes.

Dr. Anitra Graves

Excellent. Okay. Let's go on to question 18. Should arterial duplex ultrasound testing of the extremities be performed in Medicare patients with known peripheral artery disease? If so, how frequently? And again, this is more of the surveillance. The patient has known peripheral artery disease. And we did discuss this earlier, but any other comments on this?

Dr. Jonathan Levison

Yeah. You know what? My only comment that I have is that we often are sent arterial duplex study—

Dr. Jayesh Shah

Phone, and I can see the screen.

Monica McKenzie

Okay. Let's see. And I'm trying to see if I can see you listed. Okay. Okay. I can see you.

Dr. Anitra Graves

Dr. Shah, is that you?

Dr. Jayesh Shah

Yes, it's me. Can you hear me?

Dr. Anitra Graves

Yes, we can. Thank you. Sorry to interrupt whoever was speaking. Can you continue?

Dr. Jonathan Levison

Yeah. I mean, we often see a patient in consultation that's already had an arterial duplex at an outside lab. And we see the patient and agree that the patient needs an intervention. My concern with this is with regards to the frequency of study, is that if I'm the one doing the intervention, I would want to be there with my lab while I'm there in the office, having the study done and looking at the study. And my concern is, is that if we set some sort of fixed number of scans, that it wouldn't either be compensated for and so forth. And I don't know from your standpoint how that could be handled, but if the operating surgeon should have the opportunity in his own lab to do his own arterial duplex, if he's going to intervene.

Dr. Anitra Graves

Others? I think that's an interesting perspective. Anyone else?

Dr. Clifford Sales

Yeah. I think that the arterial duplex, as we've said a bunch of times, is a valuable tool for intervention planning. The only way that can be helpful is if the operator who's going to be doing the intervention has actual hands on that. You can't read on a piece of paper or look at a diagram or even look at images and determine what needs to be done in the operating room or in the cath lab. It doesn't work like that. Somehow or another, we have to sort of weasel in here that a repeat study is not okay unless it's being done by the operating interventionalist for planning purposes.

Dr. Jonathan Levison

I totally agree. Especially since the duplex ultrasound is so user-dependent on how they're holding the transducer. So I mean, if an operator isn't working with an interventionist directly, I mean, how can they trust that they're actually seeing the anatomic alignment that's going on in the vessel? You don't want to find out when you get in there that it was a bad ultrasound before.

Dr. Clifford Sales

No, no, you don't.

Dr. Anitra Graves

So if I'm hearing you correctly, and particularly those of you that are interventionalists, do you feel strongly that the planning arterial ultrasound testing should be done by the person that intends to do the intervention rather than perhaps the provider that initially found the disease, and is sending that patient to you? Are you suggesting that it really is the interventionalist tool and not that of the medical manager?

Dr. Jonathan Levison

Yes, and speaking now for the vascular surgical discipline, all the trainees now, they graduate these programs with additional certification in vascular ultrasound and interpretation. And so that's an integral part of what we do. And I said before, this type of study is too user-dependent just to rely on what's written on a piece of paper.

[silence]

Dr. Anitra Graves

Thank you. Any other comments? Any other comments regarding, if it's done in repeated or serial, how long would you expect that to be necessary?

Dr. John Evans

Again, in a patient who has not had an intervention, I would not be repeating arterial duplex simply for surveillance purposes.

Dr. Clifford Sales

I do want to bring up just one point here that I think we have to be cognizant. We live in New Jersey and you can roll a nickel and find an ultrasound machine six times. But there are places in the country where getting the physiologic test, the PVRs, and maybe in this jurisdiction somewhere, are not so easy. PVRs, they're not nearly as common as ultrasounds. So if you're in a place where there's nothing, I mean, a duplex at least will raise the question or the concern that there is peripheral arterial disease. I'll leave it to the policymakers [inaudible] to figure out how to deal with that issue. But I think that that's-- I mean, you guys probably have the data showing where PVRs are being done. And I would be surprised if you had a lot of them done in some of the more rural areas.

Dr. Anitra Graves

Dr. Shah, if you'd like to comment, we will unmute your line.

Dr. Jayesh Shah

Yeah. I think the real question is-- because I think you are saying, are we going to need-- if there is no change in the symptoms, right, before intervention, if you've already done the arterial duplex ultrasound, you already know the patient has a disease. If you're not going to change the management, will you need another one if the patient has not had any new symptoms? That's my question.

Dr. Clifford Sales

I think, Dr. Shah, we kind of landed earlier on the lack of utility of a duplex ultrasound in diagnosing disease. I think we kind of all agreed that it was helpful in the planning of the intervention-- more in the planning of the intervention phase than in the diagnostic phase, which we all thought that physiologic testing, PVRs, and what you have is probably more valuable than an anatomic test such as duplex.

Dr. Jayesh Shah

Okay. All right. So I'm sorry I missed some of this discussion, but thank you.

Dr. Anitra Graves

Yes. Thank you for joining us. Apologies for the technical difficulties. We will go on to question number 19. Should non-invasive physiologic studies be used to predict ischemic events?

Dr. Clifford Sales

I wish they could. That'd be great.

Dr. Jonathan Levison

That's a trick question.

Dr. Clifford Sales

Yeah, really. I think this was what Dr. Keane was talking about-- Dr. Evans, rather, was talking about before. Maybe he wants to chime in on this.

Dr. John Evans

Most of the research that's been done tries to look at outcomes of ischemic events. So certainly, amputation is a big one. And so a lot of the physiologic studies we have look at amputation as being one of the subjects of their study. So it is being used. And it's appropriate because, bottom line, you want to know if someone's got a higher risk of losing a leg or dying, if they should have a certain physiologic test that could help initiate some degree of treatment prior to that MALE or MACE event?

Dr. Clifford Sales

Yeah. Maybe I'm going to twist the question, and maybe it's not the right question that I'm answering. But I think we do utilize physiologic testing to help us decide on the likelihood of a wound healing. You'll do a PVR. And you'll look at it. And you'll say, "I don't think this has a shot to heal. We're going to go do an intervention. Or maybe we'll try it. We'll see." So if that's the question-- if the question is from someone who's asymptomatic doing a study, probably the answer is a little more quasi. But I do think we use-- no, I know that we've used physiologic testing to help predict the chance of healing of a wound in the leg, the lower extremity.

Dr. Jonathan Levison

Yeah. And I mean, again, if you just rephrase the question to, could non-invasive studies be used? Yes, absolutely. And we look at the ABI. And we can tell the patient confidently that, "Don't worry. You're claudicating. There's very, very low to no chance of you losing your leg at this current state."

Dr. Jayesh Shah

This is Dr. Shah, again. Can you hear me?

Dr. Clifford Sales

Yep.

Dr. Anitra Graves

Yes, we can.

Dr. Jayesh Shah

Yeah. And for wound healing, we usually use physiologic studies to decide whether patient will need amputation or not. And typically, we will use transcutaneous oxygen studies. I know we are talking about non-invasive arterial ultrasound here. But yeah. I think when you have a wound problem, we want to know. So we use it to predict ischemic events. And typically, we will use transcutaneous oxygen studies to decide that because ABIs have not come out as good as TcPO2s in most of the studies because of calcified vessels, especially in diabetics.

Dr. Darpan Bansal

Now, when you say to predict ischemic events, does it also mean, like previously pointed out, MACE events, major adverse cardiovascular events? In other words, do ABIs predict cardiac events or future cardiac events, which they do. And that's why we use them for screening. But I think this question is slightly different in terms of to predict wound healing. Is that the crux of this question, or is it just any future cardiac or ischemic limb events?

Dr. Jayesh Shah

That's a good question.

Dr. Anitra Graves

The latter.

Dr. Jayesh Shah

Yeah. That's for Dr. Graves. Are we asking for wound healing, or are we asking for any ischemic event?

Dr. Anitra Graves

Any.

Dr. Clifford Sales

Yeah. I think that's a great point. I think we made the point early on that PVRs are a good predictor of occult coronary artery disease.

Dr. Darpan Bansal

Correct.

Dr. Anitra Graves

Thank you. Any other comments on that one? Okay, let's press on to question 20. Should ultrasound measurement of the intima media thickness be used to assess carotid artery disease in Medicare patients with TIA or transient ischemic attack symptoms?

Dr. Jonathan Levison

It's not used commonly anymore because we've been able to predict just simply with extrapolating velocities of the artery and correlating that with percentage of stenosis. And that is kind of how we've been most successful in managing this disease.

Dr. Clifford Sales

I think IMT has been utilized more for research purposes than it has been for clinical purposes.

Dr. Anitra Graves

Any other comments here?

Dr. Clifford Sales

Well, I mean, there are some cardiologists on the call. My experience has been that the cardiologists often use it to gauge the effectiveness of the statin therapy. I may be misspeaking because that's so far beyond my pay grade, but.

Dr. Darpan Bansal

No, I agree. I mean, that's what the studies have been done, is basically to see the effectiveness of the lipid-lowering therapy. So yeah, for this particular indication, I'm not sure if it is used in a clinical sense. And yeah, so I agree with what was said previously, but it definitely has been used to see the effectiveness of statin therapy.

Dr. Anitra Graves

Okay. And we will press on to the next question, which is the one that we saved for the last. And that is, should there be required qualifications for an individual performing arterial ultrasounds?

Dr. Clifford Sales

This is a 30-year-old question. Come on, this has been around since I started practicing before then. Are you referring to the tech or are you referring to the individual interpreting them? Or are you referring to both or either?

Dr. Jonathan Levison

Or the institution that's performing the study and their accreditation?

Dr. Anitra Graves

Comment on all the above.

Dr. Clifford Sales

Well, I would say that the answer is yes, because I think somebody pointed out just before, that ultrasound is extremely technician-dependent. I mean, I can't tell you how many 23-year-olds we've cured of carotid disease just by repeating a carotid duplex in our office. So it's all about the angle of insulation and understanding the physics of it and all that. So without a doubt, the problem that Medicare has had has been in implementing this and the pushback that's been gotten from a lot of other places. So the answer is yes to the question. The concern is you have these rolling ultrasound machines that pull into the doctor's offices on Thursday night and line up and do 12 carotid studies and 6 echos for the internist who's there because he still, quote, "rents out his space to the lab." And you wind up with a bunch of studies. Now, in fairness to the patient population, what this tends to do is overcall disease, right? So they find disease. So those patients get identified and they get hopefully sent to a right person who will tell them, "No, you're actually okay." As opposed to if they didn't have that, they might not even know that they had the patients who were found to have disease. So there is some value to allowing some of this chicanery to go on. But in terms of the qualifications, there's no doubt at all that a qualified vascular technologist, whatever their training is-- I don't really care. I don't care if it's radiology or vascular what, cardiology, but a qualified technologist who's in an accredited laboratory is going to give you a more valuable and a more useful study than not.

Dr. Jonathan Levison

Agreed.

Dr. Darpan Bansal

Agreed.

Dr. John Evans

If I could comment from a different direction, basically from my profession, podiatry, the biggest problem that we have is that, unless you have gone on for advanced training outside of what a normal residency or fellowship would be, we're not really performing arterial ultrasounds. You have to have a high degree of training, and it's quite specific and a lot rides on it. My issue is that in many of the LCDs across the country over the last 35 years, they have linked physiologic studies with ultrasound studies, meaning that the person who performs it needs to be-- or a some type of certification in vascular medicine or surgery or one of the physicians that would do an intervention. Whereas for the physiologic testing, I think with the technology we have now, we're quite able to be able to perform ABIs and TBIs and even waveforms to be able to determine whether these patients have some degree of PAD, and then we can refer them to the most appropriate specialist. But right now, the LCDs have often been linked so that podiatrists cannot perform these because they don't have these certifications in vascular technology. So I need to be able to separate the physiologic testing from specific ultrasound arterial testing. And that really should be pointed out in the LCD.

Dr. Jayesh Shah

And this is Dr. Shah. And I agree, because for wound care docs, we do transcutaneous oxygen studies, and we find that some of the ultrasound technicians are not trained, while hyperbaric technicians are trained to do TcPO2s much better. And that is also technically very dependent. And we find wide variation when we say, "Only the person we certified to do arterial ultrasound can do transcutaneous oxygen studies," and we don't get the same, technically, good results. And the study is very technician-dependent. So I think separating it out and saying, some physiologic studies, which are like transcutaneous oxygen studies, requires different kind of training and certification than arterial ultrasound. But they're all lumped together, right now, in LCD.

Dr. Anitra Graves

That's very helpful. Very helpful. Any other comments on this? So I want to make sure I summarize properly. You are suggesting that the qualifications actually not be just for the individual, but also for the institution in performing these arterial ultrasounds based on the necessity to obtain good images or acquire images that are potentially actionable. And that you suggest that this be specific for arterial ultrasound versus the other non-invasive physiologic modalities that were discussed. Do I have that right?

Dr. Jonathan Levison

Yes.

Dr. Anitra Graves

Excellent. Any other comments on this one? Fantastic. I have learned so much, and I'm sure all of us that are listening have as well. This has been a very eye-opening discussion, and I can't express enough gratitude for spending your evening with us and providing us this information. Can you go to the next slide, please? And this is the-- both the CAC panelists and our CAC members will all receive a set of polling questions by email to complete, documenting the takeaways from this evidentiary meeting. We are interested in hearing from all of you. Using the information gathered today, Novitas, First Coast will determine if LCD revision development is warranted. And at that point, we just ask that you watch our website for additional information. And if that is ultimately decided, that proposed policy would be published for public comments, integrating much of what we learned today during this evidentiary review. Thank you again. Please, please be looking out for an email from us so that we can get your takeaway comments regarding the questions in this meeting. And also any other feedback would be very welcomed as we continue to improve our evidentiary meeting process. Thank you all for attending this meeting, and we look forward to the next session. Thank you so much.

Dr. Jonathan Levison

Thank you.

[Inaudible]

Thank you.

[silence]