National Government Services, Inc.
Moderator: Craig Haug, M.D.
June 24, 2020
12:00 p.m. CT

Coordinator: Welcome and thank you for standing by. At this time, all participants will be on listen-only until the question-and-answer sessions of today's conference. At that time, you may press Star, 1 to ask a question. Today's conference is being recorded. If you have any objections, please disconnect at this time.

I'd now like to turn the meeting over to your host. Dr. Haug you may begin.

Dr. Haug: Thank you, Amber and welcome everybody to today's NGS J6/JK open meeting. Next slide please.

Just as a note, this call is being recorded and transcribed and will be posted within a few weeks after the meeting. The next slide please.

In the next slide, you have a list of the NGS CMD Doctors Awodele, Boren, Cunningham, myself and McKinney. Next slide please.

These are the five policies up for comment today. Monitors will be the first discussed and that's a new policy. The second will be percutaneous arteriovenous fistula for hemodialysis. That's also a brand new policy.

The percutaneous vertebral augmentation frosty product, which is vertebral compression fracture, is an existing policy that has some revisions to it that we'll

have comments on. And then water vapor thermal therapy for lots BPH is also an existing policy that has the revision.

Then finally, computed tomography cerebral perfusion analysis (CTP) is another brand new policy. Next slide.

So, as I said, the first policy up for discussion will be the implantable continuous glucose monitor and Dr. Burrows will be leading this discussion. Dr. Burrows?

Dr. Burrows: Thank you Dr. Haug. Good afternoon, I'm going to give an overview of the implantable continuous glucose monitors. The Eversense continuous glucose monitoring system is the only FDA approved, implantable continuous glucose monitor. The device was initially approved by the FDA in 2018 with expanded non-adjunctive indications in June of 2019.

The implantable continuous glucose monitor is a prescription device that provides real-time glucose monitoring every five minutes for up to 90 days and it is designed to replace finger stick blood glucose testing for diabetes treatment decisions as indicated in the FDA 2019 approval. Next slide please.

With respect to covered indications, therapeutic implantable glucose monitors are considered reasonable and necessary when all of the following coverage criteria are met. The beneficiary has diabetes mellitus. The beneficiary has been using a blood glucose monitor and performing frequent defined as four or more times a day testing.

The beneficiary is insulin treated with multiple meaning three or more daily injections of insulin or Medicare-covered continuous subcutaneous insulin infusion pumps. And the beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of a blood glucose monitor or continuous glucose monitor testing result.

And within six months prior to ordering the implantable continuous monitor, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determine that criteria one through four above are met.

Every six months following the initial prescription of the implantable monitor, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their monitor regimen and diabetic treatment plans. Next slide.

With regards to limitation of coverage, the implantable monitor devices will not be considered reasonable and necessary for individuals who do not require insulin therapy and short-term diagnostic use to find 72 hours to a week is also not necessary. Next slide please.

Regarding analysis of evidence, these implantable continuous glucose monitors are shown to produce similar results to the current FDA approved. Non-implantable therapeutic monitors and implantable continuous glucose monitors will similarly improve health outcomes for these Medicare beneficiaries with diabetes on insulin.

Objective criteria of this implantable device are similar to the external sensor therapeutic continuous glucose monitors. So, coverage of this device will be in line with current continuous glucose monitoring criteria. We have two registered presenters. Amber, can you please open the line for Dr. Kaufman?

Dr. Kaufman, I know your slides state this, but for the sake of the audio recording, can you please state your name, affiliation and any conflicts of interest?

Francine Kaufman: Certainly, can you hear me?

Dr. Burrows: Yes, I can.

Francine Kaufman: Oh, great. Thank you. My name is Dr. Francine Kaufman. I'm the Chief Medical Officer at Senseonics Inc. and I'm also a practicing pediatric endocrinologist. And my

conflict of interest is that I'm an employee and a member of the board of directors of Senseonics.

Thank you very much for the opportunity to present on the Eversense Continuous Glucose Monitoring System. The first long-term implanted CGM. I do want to state that the goal for the presentation is to describe the Eversense CGM System, its components and then to show a case example of a patient requiring insulin in the Medicare age range.

I do want to add that a number of Senseonics colleagues are on this call, including our president, Dr. Tim Goodnow. (Unintelligible) days that continuous glucose monitoring, CGM is considered the standard of care for type one and intensively-managed type two diabetes.

The American Diabetes Association that amends their standards every year has recommended CGM as a tool to improve glucose control and to mitigate hyperglycemia. The American Association of Clinical Endocrinologist or AACE had their standards developed in 2016.

And again saw the benefits of using CGM to improve glycemic control and to reduce both the cost and the medical consequences of severe hypoglycemia. And the endocrine society stated essentially the same in their 2016 standards that CGM can be used to improve diabetes outcomes. Next slide.

This slide describes the FDA indications for Eversense as a therapeutic CGM. It's indicated for adults for up to 90 days. The system provides real time glucose readings every five minutes, glucose trend information, alerts to detect or predict episodes of high or low blood glucose. The data can be shared with up to five care partners in real time.

And the data is retrievable by both patients and healthcare providers to adjust their diabetes regimen. The device is used as a non-adjunctive system to replace the

information from standard blood glucose monitoring and it does require calibration. Next slide.

This slide shows the components of the Eversense CGM system. There's the center, which is fully implanted. The smart transmitter, which is worn over the center on the skin in place with a mild silicone-based adhesive. The information is being on the mobile app of a smartphone and as well the cloud-based data management system is available. The sensor again lasts up to three months.

If for implanted, the transmitter has the unique feature of allowing for on-body vibratory alerts if the smartphone is not within the carrying of the individual and the transmitter can be easily taken on and off. Next slide.

This slide describes how the Eversense system works. The on-body transmitter wirelessly powered the implanted sensor. The antenna on the center receives the energy and receives its power thereby. The indicator polymer on the center of fluorescence when glucose is present in a reversible reaction.

The sensor then sends back the raw data to the transmitter that actually calculates the glucose values. The values can then be seen on the mobile device, where it displayed as well as trends and alerts can be shown. And again this can be shared with up to five care partners in real time. The next slide.

This slide shows the Eversense insertion and removal procedures. All done in a sterile field in the health care providers' office. To insert a sensor, a small five-millimeter incision is made after numbering with glaucoma anesthesia. A sterile tool is inserted to create a pocket.

The center then placed in that pocket and the skin is clothed with Steri-Strips and a small bandage is placed on top. So the removal procedure again done under sterile conditions involving anaesthetizing the area of this small five to six millimeter incision, inserting the clamp, resting the sensor and removing it.

And then the incision is closed with Steri-Strips and a small bandage is placed on top. Next slide.

I wanted to share with you this example of how the system is used by a patient with intensively managed diabetes taking insulin. This is a report from the BMS system for a 71-year-old patient with longstanding diabetes.

It shows that she wears the transmitter almost all the time, therefore is able to obtain the glucose information almost all the time and that the glucose level she achieves are remarkable. And the glucose values in the CMS system are shown in multiple ways for survey.

Average glucose values, there's an estimation of the hemoglobin A1c from these glucometrics. And I do want to suggest that this has been of incredible value during the time of COVID, when patients were either unable or unwilling to get a laboratory measurement of their A1C. You can see this patient's A1C is quite excellent, it's 6.3.

And then you can see that the glucose information is then shown. The low values are shown. The in-target range is shown and the high values are shown in addition. And there are targeted numbers for each of these values so that the healthcare provider and the patient can see how the patient is doing again established standards of care.

The coefficient of variation and the variation show measures that are seen like variability. If all you can see the ambulatory glucose profile shows the median glucose value by time as well as in a quartile range. Next slide.

And the next one after this, if I could just comment briefly on the coverage criteria, which we agree with. However, I do want to point out that many beneficiaries are performing blood glucose monitoring as suggested four or more times a day. However, not all of them are able to do this. Some of them are already using a different CGM device and are no longer using blood glucose measurements with any frequency or even at all.

Therefore, criteria too of the blood glucose testing of four or more times a day might not be met, so we're hoping that this criteria could be revised. And I want to thank you for your attention. I'd be more than happy to answer any questions you may have. And again, thank you on behalf of Eversense the first long-term implantable CGM system.

Dr. Burrows Thank you Dr. Kaufman for that presentation. Our next registrar presenter is Mr. Bushman. (Amber), can you please open Dr. Bushman's on? Sorry, Mr. Bushman, I know that your slide status but for the sake of the recording, can you please state your name, your affiliation?

Jesse Bushman: So, can you hear me?

Dr. Burrows Yes, I can.

Jesse Bushman: Okay. So, first of all a correction, I dropped out during my PhD program, I am not a doctor.

Dr. Burrows Sorry.

Jesse Bushman: So, my name is Jesse Bushman. I am the Senior Director of Health Policy with JDRF International. It's the leading charitable organization funding Type 1 diabetes research.

And its mission is basically to accelerate life-changing breakthroughs and look for a treatment and take care of people while they're looking for cure. I have no financial relationship to the organization that manufactures the device that is subject to this proposed LCD.

JDRF strongly supports the conclusion of the proposed LCD that coverage of this device will be in line with currencies and criteria. There are more than 300,000 Medicare beneficiaries with Type 1. The mainstay of Type 1 disease management

insulin has been around for about 100 years now. It's not a cure. There are significant unmet needs and the disease management burden still exists today.

People with Type 1 and their caregivers are responsible for 24 hours a day and often minute-to-minute disease management needed to survive. And the exogenous insulin replacement that they use does not work the same as that created by their own bodies. And that leads to some significant challenges with glucose control and the increased risk for complications.

Data published earlier this year from the T1D Exchange clinical registry tells us that less than a third of adults and only a fifth of children in the US meet recommended glycemic targets as measured by HbA1c. The average patient spends seven hours a day hypoglycemic and over 90 minutes hypoglycemic.

In addition, real world studies have estimated that most individuals with Type 1 diabetes experience approximately two episodes of hyperglycemia each week and one severe event per patient per year. Because of the state of diabetes care, there is a need for technology that can improve outcomes and meet the unmet needs of the Type 1 population.

Continuous glucose monitors have been proven repeatedly to improve outcomes and people with diabetes specifically lowering their A1cs. Study of older adults using CGM funded by JDRF was just published in JAMA on the 16th of this month. And it demonstrates that use of CGM in this population reduces incidence of hypoglycemia increases time and range and lowers A1c.

Consequently, anything that we can do to encourage the use of CGM will help improve outcomes and decrease the costly consequences of diabetes, including things like hyperglycemia and the more unpleasant long-term complications that Medicare largely pays for.

JDRF knows from unpublished internal surveys that people with diabetes are very sensitive to variation and features of CGMs. Some will not use the devices because

their specific features are problematic for them. Making another CGM option available to Medicare beneficiaries, like, this proposed LCD will do will increase the number of people who use CGM and this will have beneficial results.

JDRF strongly supports the conclusion of the proposed LCD that implantable CGM should be covered by Medicare and we support the designation of the device as a physician service and as payment under the Physician Fee Schedule. We would request three changes in the eligibility criteria.

First, the proposal requires that beneficiaries be conducting at least four finger sticks per day in order to qualify for CGM coverage. And we believe that that should be eliminated or reduced to no more than three fingers sticks per day. People who are diabetic and using insulin three or more times per day will necessarily be testing their blood glucose levels each day.

It's unnecessary to impose the testing as a requirement as they will already be doing that simply as a matter of taking care of themselves. Further, Medicare standard covers for test strips only provides for three test strips per day.

And some major suppliers for example, CVS, refuse to provide more than three test strips per day because of the challenges associated with obtaining documentation to demonstrate the need for larger numbers of testers and the associated auto test.

Finally, subgroup analysis and two important studies concluded that there was no difference in the outcomes of CGM usage among those patients who had previously use four or more finger sticks and those were tested with fewer than four.

An article reporting on this subgroup analysis concluded that "There is no evidence that frequent SMBG or finger stick testing or Type 1 diabetes has predictive a successful outcome with CGM use." The proposed LCD requires that the patient be treated with (unintelligible), so this is the second request that we're making.

And that is that the proposed LCD requires that the patient be treated with injections of insulin in order to receive coverage for CGM. There is at least one form of inhaled insulin on the market. There are some suppliers who are leery about providing a CGM if the person is using inhaled insulin because of that specific word injection.

So, to accommodate that reality, we suggested the wording within the LCD be modified to require administrations on insulin. The third thing that we would request is that the proposal to do requires a visit with the prescribing professional at least every six months.

The only implantable CGM on the market, the subject of this proposed LCD must be replaced every 90 days. Therefore, patients will by default be seen their professional managers of service at least frequently. The manufacturer of the device is working to get approval for a 180 day versus the device, which would still necessitate a visit with a prescribing professional every six months.

In the case of this CGM, it would seem that a requirement that the patient visit with the prescriber at least every six months would be unnecessary since the nature of the device already requires that. Consequently, the inclusion of this and eligibility requirement simply creates a paperwork burden for patients, providers and suppliers that could be eliminated.

If CMS chooses to retain that requirement for periodic visits and documentation and then we believe that that requirement should be modified to require that documentation once per year and only more frequently if the provider and the patient determine that it's necessary.

With that I'd like to thank you for your time and the opportunity to talk today and present the views of JDRF.

Dr. Burrows: Thank you, Mr. Bushman.

We're now going to open the line for any additional comments on this draft policy. If you're on the line and you'd like to make a comment when your line has been opened, please start off by stating your name, your affiliation and any conflicts of interest.

(Amber), can you please open up the lines for comments?

Coordinator: Thank you. If you would like to ask a question or you have a comment, please press Star, 1. You will be prompted to record your name. Please be sure to unmute your phone. Once again, if you'd like to ask a question or you have a comment, please press Star, 1.

We'll pause for just a moment to allow those to start coming through. We have no questions or comments coming through at this time.

Dr. Burrows If there are no questions or comments, I think we can move on.

Dr. Haug: Thank you Dr. Burrows. So, we will close the open meeting comments on implantable continuous glucose monitors.

The next policy to be discussed is percutaneous arteriovenous fistula for hemodialysis. And as I mentioned earlier, this is a new policy.

In (unintelligible) digital forum, ABS has been the gold standard for hemodialysis access. So the Fitzgerald's first campaign was launched by CMS in 2003. Unfortunately, up to 50% never become usable especially in the elderly. A major cause of this is just an anastomotic stenosis through the new intimal hyperplasia thought to be due at least in part to surgical trauma to the vessel and surrounding tissues.

So, a percutaneous approach to an ABS potentially minimizes this trauma. And this policy looks at two endogenous methods of creating a proximal forum ABS. Next slide please.

Key outcome metrics after two years show relative parity between surgical and endogenous approaches to proximal radiologically ABS using the Ellipsys system.

And so, we believe that it should enjoy comparable indication as a second access option after a so called wrist fistula. The proposed LCD does not cover the wavelength system due to ongoing safety issues and limited longer-term data. Next slide.

I believe these coverage criteria for KVF are pretty self-explanatory and relatively non-controversial. The main point of contention probably will be the non-coverage of the wavelength device itself. Next slide.

We have four registered speakers for this policy. The first is Dr. Wasse. Dr. Wasse, and operator if you could open his line. Dr. Wasse, are you able to…

Dr. Monnie Wasse: Yes, I'm here and I'm a female, as you'll recognize from my voice.

Dr. Haug: Okay.

Dr. Monnie Wasse: That's right. My name is Monnie Wasse, I'm an interventional nephrologist here at Rush University Medical Center in Chicago. I was the current past president of the National Society, which is known as the American Society of Diagnostic and Interventional Nephrology. And my conflicts today, I'm a consultant for Avenu Medical and Xactimate and then a speaker for W.L. Gore and Medtronic.

We can go ahead with the next slide. Thank you. So, I wanted to give the audience today, first of all, thank you for allowing me to speak. I'm really doing this on behalf of our patients or dialysis patients. And I wanted to give the audience today a clear idea of what the potential benefits are for percutaneous fistula.

So, just by way of background for those of you who aren't quite as familiar with dialysis access. These first two slides will get you there. So, as what many of you

know, the surgical AV fistula is really the preferred form of vascular access, largely due to its lower frequency of stenosis, thrombosis and infection.

But the real sticking point for surgical AV fistulas are that the outcomes tend to be variable and can be quite poor and up to 60% of surgical AV fistulas in fact failed to mature for use. As has been determined, one to two of the large studies that have been conducted by the NIH. Moreover, surgical expertise is widely variable and regional.

And in many cases, fistula need to require several one to two, maybe three interventions in an effort to try and promote maturation and prepare them to be able to be usable for dialysis. All the while that that is occurring patients who initiate dialysis do so via a catheter. And protracted use of a catheter clearly places them at increased risk of infection and central stenosis.

Next slide please. So, I think it's important to emphasize what this protracted use and the length of time that it can actually pick to get a fistula what it can actually be. Studies done, I'll be presenting two of these just very briefly.

One done in Birmingham showed that amongst those individuals who started dialysis with a catheter timing was marked from the time at which the patient actually got their first surgical appointment to the time at which they actually started to use their fistula.

And as you can see on the right, that time is substantial. The time to first access surgery was nearly five months from the referral point and time to first use amongst this patient group was up to one year. So, all of the efforts that these patients go through to try and get a fistula can take a tremendous amount of time to occur largely because of the surgical.

Many of the steps that the patients have to go through and an effort to get this done as well as the fact that surgeons are often very busy and have other types of surgeries that they conduct. Next slide, please.

When the same evaluation was done in a patient and group of patients that actually hadn't yet started dialysis, those patients with chronic kidney disease stages four and five, similar results were found.

In fact, the time from nephrology evaluation to the surgical referral was nearly a month and then the time to evaluation was another 52 days and then the time to surgery was 30 days. That was nearly 3.5 months for a patient to go from evaluation by their nephrologist to obtaining a surgery for a vascular access.

And this doesn't account for the time that it takes for the fistula itself to achieve maturation. So, a substantial amount of time can pass before our patients are actually able to get a surgical fistula. Next slide please.

So, you can imagine that nephrologists were all very excited about the fact that finally a new technology had come about knowing what the problems were and knowing what the amount of time it was that could fistula could take to even get placed.

And that new technology is a percutaneous fistula creation, which will be discussed by both myself and then the next couple of speakers. Really, these devices allow patients greater access to fistula creation by placing at a fistula creation into the hands of interventionalists.

And the idea here is that there can be that reduction in the delays that many patients face, the repeated scheduling of office visits and then the pre-surgical procedures that are oftentimes required by our surgical colleagues in advance of this procedure to be performed. Next slide, please.

So again, you'll be hearing more about this but there are two current FDA approved devices. One is the wavelength, which is a dual catheter device using an RF electrode and it's utilized under fluoroscopy in order to create a fistula.

Then the second device is the Ellipsys, which is an ultrasound guided single catheter electric artery device that's placed under ultrasound. Next slide please.

So in general, these two technologies really focus on the use of vascular anatomy and the proximal forearm.

And as a nephrologist, we like to use the distal arm as much as we possibly can in patients in an effort to try and afford them as many options over time because oftentimes fistulas and graphs can run out or they no longer become usable. So, we like to give patients as much what we call vascular real estate as we possibly can and we start, like, to start as distal as possible.

I think it's also important to note though that the use of the proximal forearm fistulas vessels versus fistula creation is not new. Kenneth Kratz first described the use of the proximal radial artery to perforate a vein fistula in 1977. And the growth fistula is a surgical fistula that's been in use for many years. Next slide please.

So, when we look to see what the two devices currently look like in comparison to a surgical fistula, there's some, a few things that are worth noting.

The access type obviously is differentiated by the type of device that is that has been constructed single puncture versus open surgical incision versus a dual puncture and then the AV axis creation method. One is a fused anastomosis that's using the Ellipsys device. Obviously, a surgical fistula is created using suture and then the wavelength is used with a slit fistula with RF energy creation.

Image guidance as I've touched upon includes ultrasound for the Ellipsys device and then ultrasound fluoroscopy and then use of contrast for the wavelength device. Procedure time based on the two pivotal trials can vary from anywhere from 24 minutes to over an hour.

And maturation time, you'll note for the percutaneous devices to date appears to be significantly better than that of surgical fistula. The time to use for dialysis has been reported and the Ellipsys device is being shorter than that of a surgical fistula.

And then the cumulative patency for the two percutaneous devices are improved at 12 months beyond that of a surgical fistula. And the cumulative patency of an Ellipsys device is around 91% compared to the surgical fistula of 64%. Adverse events vary anywhere from 0% up to 3% as you can see there. And then you can see where the data originated for the pivotal trials for these two devices compared to that of surgical fistula historical studies. Next slide please.

So just briefly, it's worth covering the fact that not every patient is a suitable candidate for percutaneous fistula.

Eligibility in general for these devices includes anticipated life expectancy greater than a year, which I would say is probably similar to that for a surgical fistula. The individual should not be a candidate for surgical wrist fistula because again as I mentioned that's a territory that we'd like to start with.

So, if a patient can have the anatomy to support that, that's the ideal starting point for a patient. This is an opportunity for a patient to get a fistula who wants to avoid open surgery. Those individuals who have no evidence of infection are potentially candidates and then obviously one centimeter vascular parameters for the respective devices.

And importantly, an adequate infrastructure needs to be in place to support thoughtful cannulation whether the patient wants to do home hemodialysis and self-cannulate versus doing in-centered dialysis. Next slide please.

Woman: We're down to a minute in presentations please.

Dr. Monnie Wasse: Thank you. Several ways by which the percutaneous fistula differs from a surgical fistula as you can read there the one that I'll point out too is that currently,

it's less invasive, it appears to have improved maturation and shorter cannulation time. Next slide please.

As you can see here, distilled fistulas ideally are surgical and as you move to the proximal forearm that's when we employ the use of a percutaneous fistula. Next slide please.

So, finally potential advantages include reduced delays for fistula creation, the opportunity for more anatomic options for percutaneous fistula and improvement in patient choice for procedures for those who wish to avoid open surgery. Thank you.

Dr. Haug Dr. Wasse, thank you. There's a couple questions for you. Do you do both procedures?

Dr. Monnie Wasse: I don't do both procedures. There are two or three interventional nephrologists in the US that do both procedures. But in general, those of us who work at a hospital setting oftentimes either our interventional colleagues do one or the interventional nephrologists do the other.

There are obviously issues around you know, the ability for the hospital to be willing to pay for both devices to have on formulary. So, those are some things that are critical issues.

Dr. Haug Do you have a preference?

Dr. Monnie Wasse: Well, I mean, the data so far is supportive, I think of both. I think that the - what I would say is that I like long-term data and I think the data that is best supported with long-term data suggesting fewer outcomes or fewer complications and good cannulation. That data is supported by the Ellipsys device.

But I do know that many of my colleagues have used the wavelength device and are having very good success with that and in places around the country, including St. Louis and Dallas, Texas.

Dr. Haug Do you think some patients would not be a candidate for Ellipsys but might be a candidate for wavelength?

Dr. Monnie Wasse: Yes, I think based on the opportunities for both the four and the six fronts devices for the wavelength, there's an opportunity to approach the arm if we can go back to one of my previous slides. It gives the opportunity for more distal creation with a wavelength device.

You can see there that in Zone 2, the wavelength would be ideal for a patient and then the Ellipsys would use the proximal radial artery and the perforator. So, it's slightly more proximal than the wavelength.

So, you know, if you're looking at it purely from an anatomic standpoint and choosing where the patient has their optimal vasculature and meets the criteria, the wavelength actually is appropriate for certain patients and the Ellipsys is appropriate for others. This image came from Dr. Scheffer Dion, who's a vascular surgeon in Germany.

And he actually uses both devices. And oftentimes on his social media does in fact report that he has used the wavelength in a patient and then subsequently gone on to use the Ellipsys device. So, there is a role for both, from what the data supports and for those practitioners that actually are presenting their data from time to time in our meetings.

Dr. Haug Thank you Dr. Wasse.

Dr. Monnie Wasse: You're welcome.

Dr. Haug: Okay, our next registered speaker is Dr. Jennings. Operator if you could open up Dr. Jennings's line.

Dr. William Jennings: Hello, this William Jennings. I'm a Professor of Surgery with the University of Oklahoma here in Tulsa. Next slide.

I, disclosure policy, I do have a stock in the Avenu Medical with the Ellipsys device. Next slide.

So, these slides are a little tedious, but they're reviewing literature. So initially, these talks about some articles about surgical proximal radial artery fistulas which has been a topic I've been interested in for several decades.

I use this a lot when working with Larry Spergel. We did all the fistula first meetings for those many years working on increasing the number of fistulas in the United States. The first article is a meta-analysis looking at proximal radial artery fistulas. It emphasized the very low risk of steal syndrome, arm edema and other complications associated with proximal radial artery fistulas versus brachial artery fistulas.

The next paper is number two was a publication from Boston by our next speaker and his colleague Dr. Ozaki, prospectively looking at brachial versus proximal radial artery access noting the much fewer risk of complications, adequate flow and good functional success in both groups.

And lastly, just a reference to an article of mine of a 10-year experience of about 1400 proximal radial artery fistulas with primary patency at 24 months and cumulative patency of prime at 24 months of 91%. Certainly, these patients needed intervention to keep this going. However, the cumulative effect was excellent. Next slide.

So, here's the Ellipsys device which we have used in our practice. It's a single venous access catheter placed through a superficial vein into the deep communicating vein. The jaws are opened and you can see in the lower right hand image a model of an actual anastomosis where you have fused pressure and heat to create a secure and anastomosis.

An image on the left lower from the pivotal study showing an actual fistulogram done of the proximal radial artery fistula created by the Ellipsys system. Next slide.

So, here's a schematic image showing the needle has been introduced with ultrasound imaging only. Through the superficial system into the deep communicating system, the needles advanced to the back wall of the deep communicating vein, where it is adjacent to the radial artery. The needle goes into the radial artery followed by a guide wire. Next slide.

The devices in advanced to over the guide wire of the jaws are closed. A few seconds of the delivery of the energy from the device creates the anastomosis. In the original pivotal study, these patients were returned after a week for follow-up and generally most often had angioplasty of this anastomosis to complete the maturation.

This is long ago been replaced by an immediate balloon maturation at the time that the procedure that's just an integral part of the procedure now, so that secondary balloon is not necessary unless some stenosis develops. Next slide.

So, the initial studies, Dr. Hall and others, it was five centers. As I recall, it was four interventional nephrologists and one interventional radiologists about 100 patients. And you can see from the results that cumulative patency at the termination of the study was close to 90% and functional patency was very good.

Dr. Mallios, trained here with us and then now is in Paris and his initial study of these Ellipsys devices showed great technical success and long-term patency. Flow rates are about 900 milliliters per minute. Overall, he encountered no complications such as Steal or arm oedema and patency rates were great.

He noted and continues to notice fewer needs for superficialization or lipectomy in these individuals because of the territory saved by avoiding a surgical incision. Next slide.

Longer follow-up is important. And this first references by Dr. Berthoud and myself and Terry Litchfield looking at maturation of the original pivotal study group, they were all able to be followed.

You can see from the - I don't need to read all that back to you but the duration of the fistula with cumulative patency of almost 93% at two years was outstanding. Litchfield did a post-procedure evaluation emphasizing a really as expected high-level patient satisfaction with these outcomes.

Dr. Mallios has now approached 300 patients and his review recently of 234 individuals, once again technical success was 99% with much longer follow up flow, slow values were about 900 milliliters per minute on average. No significant, zero significant adverse events related to procedure.

Very few patients required lighter conversion to a surgical fistula and a fewer percentage of patients required superfistulization, I think an important concept with a percutaneous fistula. You'll also noted, average maturation time only four weeks. Next slide.

I thought these images were interesting. The one on the right is the cover of the journal of vascular surgery recently showing ellipses percutaneous fistula. This happens to be a patient that had a high bifurcation of the radial artery and this was a well-functioning fistula with a lovely image suitable for a cover picture.

The images on the left Dr. Mallios, so this is not a published case. But it was interesting, a patient with increasing peripheral vascular disease and slowly lower flow in the Ellipsys proximal radial artery fistula that he planned to do in-flow proximalization, so he dissected out the fistula and you can see, it is simply a fistula that looks like any other surgical fistula that we have ever made.

There's nothing peculiar or unusual about it. It's revisable and functional just like a regular fistula. This one was treated with an inflow proximalization to avoid the risk of steal with distal disease progressive downstream.

I also listed a couple of papers. Early cannulation, we reviewed a series of patients with Ellipsys fistulas that had early cannulation, defined by 1 to 14 days, 13 to 14 were successful without complication, suggesting that this may play a role in avoiding prolonged maturation problems.

These were all patients that had problematic catheters and an early cannulation was used with the plastic needles available in Europe to avoid new catheter replacement.

And the number two reference was a recently published, a series of four patients that had deep communicating veins of adequate size at the risk and the Ellipsys device was used to create a percutaneous classics amino radial-cephalic fistula. Next slide.

So, this kind of parallels Dr. Wasse's comments about the long and winding road to a functional fistula. Time for referrals. A lot of surgeons don't do their own vessel mapping, our group does. And we think that saves a lot of time and then time to surgery, busy schedules and delays their post-RPF time for follow up and maturation.

So, as we open up the opportunity for access creation to many other doctors, but I would suggest including surgeons in this use of this device. We are going to save a dramatic amount of catheter time.

Interventions required more time. And again, just like Dr. Wasse mentioned, there's a large variation among surgeons in their success rate and long-term patency.

And you are going to bump into some patients who say I'm simply not going to have a surgical operation but are willing to consider a percutaneous procedure. Next slide.

Woman: And doctor, we are down to one minute.

Dr. William Jennings: Okay. This just characterizes why percutaneous fistulas may be better. You are going to have fewer technical misadventures less opportunity for a rotation or

twisting of the vein, proximal radial artery fistulas. Just whether they are surgical or Ellipsys are going to have lower pressures and lower flow versus brachial access and therefore less risks of stenosis and aneurisms.

You are going to have fewer fistulas that are lost from steel or cardiac high flow issues. Cannulation zones extended that's a very real outcome from percutaneous fistulas. And then I mentioned the cannulation that may be earlier.

So, and lastly, a radial-cephalic fistula is not precluded, if vessel dimensions change or improve because of bidirectional flow that doesn't mean you couldn't do a radial-cephalic fistula later. Next slide.

So that's the end of my talk. Thank you very much.

Dr. Haug Dr. Jennings, thank you very much. A couple of questions or comments. You've been a big proponent of the proximal radial artery fistula surgically created. It's been somewhat overlooked in the past. Are you now out of the surgical proximal radial artery fistula business?

Dr. William Jennings: No, we've, you just could - I couldn't list all the studies that have been done, but we've also done some studies looking at how many of these patients are going to be candidates for a percutaneous fistula. And it maybe 60%, it may be more or less depending on your patient population. So there still are going to be a role, you are going to have patients that don't have a good deep communicating vein, you are going to have patients that don't have an easy access.

And some providers may not adopt percutaneous fistulas right away or at all. So, there's going to always be a role for that. I emphasize the benefit of either proximal radial or proximal owner access in avoiding so many complications associated with high flow brachial artery fistulas.

So, there's going to be always a need for a surgical approach in a very real number of patients. But yes, I think this is probably going to replace a lot of the surgical cases.

Dr. Haug I know your focus has been mostly on the Ellipsys system I think. So, anyway, have you had any experience with the WavelinQ system?

Dr. William Jennings: My own, I have no personal experience. I helped (Robert Civerdian) the surgeon in Hamburg, with his paper that has just recently been accepted. And it compares the two devices. So, I think that will come out and there was a difference in cumulative patency at the end of follow-up and there was a difference, favoring Ellipsys also in the number of adverse events.

So, again, I'm biased. And I've had experience physically only with the one with the Ellipsys device. So, for what it's worth.

Dr. Haug So, going back to your prior comment, if you had those 40% that may not be a candidate for Ellipsys, would you consider a WavelinQ approach before an open surgical approach and if some of them were not?

Dr. William Jennings: No, they would not be a candidate for Ellipsys because the deep communicating vein is either too far away or inadequate. So, it might be possible that a WavelinQ would be appropriate. In that paper I just mentioned that's now - just now coming out and available.

The majority of patients were, something like 70% were candidates for an Ellipsys fistula, but only 20% or 30% candidates, anatomically by ultrasound examination for the WavelinQ.

So, you are right, there will be occasional patients that are appropriate for a WavelinQ and not Ellipsys. But on the other hand, the most are going to be candidates for ellipses.

Dr. Haug So, if you did have a patient that was not a candidate for Ellipsys, would you now as of today pursue the WavelinQ before you did an open surgical approach or not?

Dr. William Jennings: I would not, I would do a surgical course. A surgical proximal radial artery fistula is not a huge operation. So, it's a pretty minimal operation. But I would do that before the WavelinQ due to the adverse events that have been reported with the other device.

Dr. Haug Dr. Jennings, thank you for your comments.

Dr. William Jennings: You are welcome.

Dr. Haug Our next registered speaker is Dr. Hentschel. Operator, if you could open his line.

Dr. Dirk Hentschel: Hello, this is Dirk Hentschel. Can you hear me?

Dr. Haug Yes.

Dr. Dirk Hentschel: Excellent. Thank you for allowing me to be part of this panel. I am Director of Interventional Nephrology at the Brigham Women's Hospital in Boston and I'm also on the Board of VASA (Vascular Access Society of the Americas) as well as ASDIN. Next slide, please.

My disclosures listed here. I, you know, work with a variety of companies as this, that (Unintelligible) access space until relatively recently has seen a paucity of innovation and a lot of innovation comes from industry and so, I've worked with a lot of companies on different aspects. Next slide, please.

As Dr. Wasse and Dr. Jennings expanded on the thousand access space, I think it's characterized by a huge variation in maturation success, that varies wildly some centers and physicians have 80% success, others less than 20. And we also know that different types of accesses forearm cephalic versus upper arm, cephalic and upper arm transpose cephalic veins have different failure modes.

And if you think of patients that are on dialysis with a capital versus patients that are still in the PSRD phase, it often is very important to take into account the time until they may use the access and what complications they may experience in that interim.

That may be pulmonary hypertension due to longstanding high access flows, repeated angioplasties from stenosis, thrombosis or violent access may not even be used.

There also is uncertainty with progression of ESRD. So, having dialysis access types that are relatively complication free in particularly for the PSRD period, which is where as a system we are trying to create accuracy so that patients don't crash into dialysis with the need for tunnel catheter.

What are the options there? So locally, we have made a very conscious decision to kind of push radial artery risk near-based accesses as they have the lowest flow and the lowest complication number in the long-term and they can often just sit there and mature.

But we have recently also found that endovascularly created arteriovenous fistula maintain relatively low flows and can also sit there in a PSRD fashion, mature arterial inflow as well as the venous outflow options with - to date a few observed complications. So, next slide please.

You saw the slide before, so we can move on. So this is the Ellipsys device, this is the device that we currently, all hospitals are certified to use. We are working on having the WavelinQ device also approved. And I'll talk a little bit more about why we want both devices later on. Next slide, please.

So, this is just a general timeline of how accesses are created at our center. You've heard before the timelines can be very, very long and we have a very active collaboration with our vascular surgeons, so that we really rapidly transition patients

through. But I also show this to show that there's a lot that goes into access creation beyond the procedure.

So there's ultrasonic variational in our case, we do a lot of vein mapping monography. We put into context, the anatomy that we discuss as a team, is a risk access possible, is there a mid-form option? Is there an unusual form vein option something using the basilic. Jennings fistula that we sometimes create.

We take into account the patient's comorbidities, can they actually have? Do we really want to push a forearm fistula with relatively lower flow in somebody with heart failure? Are there unknown central vein occlusions that also would push us to create really a low flow access. And then obviously, the life expectancy.

As you heard from Dr. Wasse, most accesses require some kind of additional procedure. And Dr. Jennings has talked about the epidemic of obesity in many parts of the US where the upper arm access that now makes up by and large over 75% of accesses in the United States. They almost universally need some kind of super-fistulization or lipectomy to really offer a great difference for usability.

And so, in our ranking, we really start at the risk with a snuffbox and then work our way up and would view EndoAVF procedures kind of in between the risk and the proximal radial artery to cephalic vein options either standard upper arm cephalic vein access or Jennings type access. Next slide please.

Here as an example, the criteria for endovascular access creation using the Ellipsys. These are the ultrasound criteria. As was alluded to the theoretical suitability for Elliypses type accesses is about two thirds of patients. You know, the WavelinQ studies, the newer one that Dr. Jennings referred to has slightly lower in the hands of (unintelligible) in Germany. But other studies also show kind of 60% suitability in theory.

While in our local clinical setting with a very concerted team effort and an absolute kind of focus on risk-based accesses, we end up with about 10% of patients that go

into the procedure room with a potential for EndoAVF candidacy. But then, after a regional or general anesthesia, we find that there are still several patients that show their veins at the risk and within half the surgical creation of a risk fistula rather than an EndoAVF in mid-arm.

And even though we aggressively pursue risk fistulas, I think 75% of our fistulas now newly created our risk-based radial artery fistulas. We still have maturation successes that are kind of around 90%.

So, for us the question what type of access we create, since they all give us about a maturation in the high 80% or 90% range is really what is the best anatomy to support this patient? How does it best fit into the patient's morbidity, mortality and life plans? Next slide, please.

So, the next seven slides is really a rundown through the Ellipsys technology that's the one that we currently have access to in the hospital. And this is just to kind of bring home the realization that there is actually a skill involved in guiding the needle through the vessels.

So in the studies you've seen the data that the time for the procedure is between seven and 35 minutes if Dr. Mallios does, who doesn't relatively frequently with an average of 15 minutes. But not every operator who's capable of creating surgical fistulas or who's able to wield dialysis angioplasty balloons necessarily has the skill set readymade to do this.

So, there's a learning curve and some people may never be completely comfortable with this. And similarly, if you look at the WavelinQ technique that I think Dr. Berland will speak to as a final speaker today. Also, that is a technology that requires a different skill set that not every operator has.

There are surgeons that create accesses surgically that don't have endovascular training maybe general surgeons or it may be transplant surgeons that don't have that training.

And so, it's often provider driven, which technologies, which approach is the one that gets you to successful access creation. So, we can just run through the next slide here. You know, you plan the anastomosis, you measure and make sure that the distance is okay that way you can cannulate the vein. Next slide please.

Advance under ultrasound guidance. Next slide. And then, place a sheet. Next slide. And then, you know, the wire, next slide, deploy the device and that we can go next slide. You see here that actually fusing of the vessels. Then use a balloon to post dilate. Next slide.

And then you have…

Woman: We are down one minute, please.

Dr. Dirk Hentschel: Yes, fistula created. Yes. And so, next slide please.

And so, this is actually my last slide. The local systems of availability of expertise, determine often what kind of access is created. And we don't have real, true long-term outcomes in the dialysis access space, I would say that's five or 10 years or more to see what are the long-term consequences of creating a fistula by endovascular means.

And so, in my mind the two available technologies are relatively equivalent in terms of uncertainty how the long-term works. Clearly, they both successfully can create accesses.

I think the fact that the wavelength device is now in its third evolution of a technology shows also that there is a lot of development still in this space. There's responsiveness to things that are being observed that I think over time will affect suitability and safety.

And you heard that now, even direct risk based radial-cephalic fistula has been created using the Ellipsys device. So, there are still a lot of movement in this space and it would be fantastic to allow this variety as there are many other new technologies in this space as you can see here, human side, human cell derived vessels, biographs that are used as early cannulation things. Other early cannulation catheters, novel tunneled catheters.

Thank you very much on the last slide for allowing me to share our experience here.

Dr. Haug Dr. Hentschel, thank you for your comment. Some similar questions that I had for Dr. Jennings. Do you personally have any experience with the WavelinQ system?

Dr. William Jennings: So, our hospital took about six months to nine months to let us use the Ellipsys device. And which we now used and we are in the process of getting the WavelinQ device approved for use. But I don't have any WavelinQ experience. But I, in my daily life, I use wires every day. And so, I feel that's kind of a lovely comfortable transition to go to that because it's much more free floating to do an ultrasound guided fistula creation

Dr. Haug Ultrasound, which is the Ellipsys is not the…

Dr. William Jennings: Yes, correct. I mean, it's more of it for somebody who works a lot wire and catheter based, the WavelinQ seems intuitively safer because you kind of know where you are. While if you go through three-dimensional space on the ultrasound guidance that's kind of a, you know, we do that a lot by getting central venous access for tunnel dialysis catheters.

But in this case, going from one vessel into another vessel. That's kind of the jump that I had to learn. But it can be learned very quickly if you have a basic set of skills there. But I know that a lot of providers that are very experienced with guidewires and with catheters, they feel an intuitive transition into the WavelinQ device. So, I have not worked with it. So, I don't have any personal experience with it.

Dr. Haug Dr. Hentschel, thank you for your comments.

Dr. Dirk Hentschel: Yes.

Dr. Haug Our next registered speaker is Dr. Berland. Operator, if you could open his line. Thanks.

Dr. Todd Berland: Hello. Hey, can you guys hear me?

Dr. Haug Yes.

Dr. Todd Berland: Great. Hey, guys, I'm Dr. Todd Berland. I'm a Vascular Surgeon based out of New York. I've been creating these fistulas for about five years. I was the first vascular surgeon to use this latest generation or this four fits generation device to create a fistula and this was several years ago. Next slide, please.

First closures, I have no conflicts of interest. I don't hold any equity in either company. I have no stock. I have no financial, nothing financially to gain by any decision that is made. I am a Medicare provider and practice within this NGS jurisdiction. I am a consultant for BD and presenting for them. But really on behalf of my practice and my experience.

And our last disclosure is, I'm also a SiriusXM radio host, Doctor Radio is a direct to patient. You guys may have heard it in your car going to and from work when you are not on lockdown. But it is an opportunity where we have a two-hour show dedicated to vascular surgery patients can call in.

And a number of times we've talked about this technology and the excitement and the interest in patients and from the patient advocacy groups. It's pretty significant. Next slide please.

I will go an overview of surgical fistula that's been talked about already. I'll discuss WavelinQ and then some of the concerns with the proposed LCD changes. Next slide.

Now, this is a slide really kind of setting the stage. We've heard from the previous presenters that surgical fistulas, which are the standard of care are also fraught with their own issues. You can see on the Y-axis there AV Fistulas, AV Grafts and central venous catheters.

And mortality rates, although favorable for AV fistulas are real in this patient group. And if you look at infection rates, 2% for AV fistulas and then 13 and 18 for the graft and catheters. Still better for fistulas but this is a real problem.

Moving on to the primary patency in the last column. Again, favoring AV fistulas. This is our gold standard. This is what we are trying to compare EndoAVF both Ellipsys and WavelinQ too. So, this is really the unmet need here. The fact that surgical fistulas are not despite being done since the 1960s. There's not been a lot of evolution and innovation in this space. Next slide, please.

We need an alternative to surgical fistulas. Only about one in five patients initiate dialysis with a fistula. Failure rates are high. It can take months to mature. And then this last point is really my favorite point when I'm talking to patients about surgical fistulas. And to date, I still create more surgical facilities than I do EndoAVF.

So, I'm a big fan of EndoAVF. It does have a role in lots of patients. But when I'm talking about patients, I am talking about surgical fistulas needing on average two to three re-interventions per year to keep those fistulas open. The body just tries to shut those down. So, we are constantly trying to balloon angioplasty and open these fistulas. And these high failure rates and long maturation times really have prompted some innovation. Next slide.

So, if you look at the surgical fistula that hasn't really evolved in half a century, that's a valid name is transected. The other end is over stone and we swing that vein over

on the artery, we make an incision, we use a scalpel to open up that artery and manually so the vessel on. This, we think may be causing some of the issues that we are seeing longer term that we are not really seen with Ellipsys and WavelinQ devices.

Essentially, what we have is a traumatic fistula creation, for lack of better words, when I asked the inventor of WavelinQ how he came up with this idea, it was really quite ingenious. He was a surgical resident and noticed that trauma patients who were shot or stabbed, when that bullet or knife nicked an artery or vein those patients would develop AV fistulas.

And when you follow these patients up in the office, these fistulas would never close. Contrast that to surgical fistulas that you are constantly battling with re-interventions to keep them open for the life of that fistula. The traumatic fistulas just didn't seem to close down.

So, what WavelinQ, and really to a degree ellipses does is it's almost akin to a traumatic fistula where we are creating energy and going through an artery or vein either in the radial or owner positions to create this fistula in the deep veins to get flow superficially into the upper arm veins for dialysis.

So, where's the Ellipsys has the option for a radial fistula creation, WavelinQ is similar to that but also as the owner option as well. Next slide.

Sorry. Can you guys see the slides?

Dr. Haug Yes, we can.

Dr. Todd Berland: I'm sorry. My screen just went off here. There it is. Okay, I've got 6 French device on my screen. I hope you guys can see that. Well, this device is the one that really paved the way for the innovation. This is the first generation device. It's been discontinued a lot of the data that we are looking at evolves around this 6 French device.

It involved the brachial artery access. But this did really pave the way for an endovascular fistula. Next slide please.

The second generation device which we've been using since last year, is much smaller, 50% smaller. The (4-French device) much smaller hole in the artery. So, as a vascular surgeon, I've been taught to really appreciate and respect the brachial artery.

It's usually a very thin walled artery. Any pseudo aneurysm or bleeding is fraught with lots of trouble. Patients can have lots of problems with hematoma, pseudo aneurysms from brachial artery bleeding. So we really like this idea of a smaller, more streamlined catheter with a (4-French device).

And while we are talking about the device, we have two catheters, one goes inside the artery, one inside the vein. Magnets, pull them together. And then once we confirm under Poroscopy, that everything looks good that the fistula creation will be in the location that we want. We hooked the back end of the catheter up to a RF generator off the field, we press the button and we burn a hole from the venous side into the arterial side.

So, we create a traumatic fistula and create a fistula between the artery and vein in that deep system. Next slide, please.

So, really what we have here is two catheters in the vessels, we create about a five by two millimeters hole which is similar to a surgical. And anastomosis when we actually physically saw an artery to a vein and we get communication or flow from the artery into the venous side. Next slide.

So looking at the studies to date, really what we have is the flex study and the neat study which were the 6 French device. I'm the first author and primary author of the East study where we were going down to Paraguay and really performing these procedures on patients.

There were four of us that did these studies. They were each of our first patients. So, I think I contributed about 10 of the patients. These were my first 10 procedures ever created. Contrast that to surgical fistula papers where some of the operators have done hundreds if not thousands of these before, you know, enrolling or studying these.

These were literally, the four of us who had done these had never done one before. And this first study was capturing that experience. So, early in the learning curve type of experience.

And we have very good safety and efficacy rates there with good maturation rates. Moving forward to the ease to and post market studies. Again, this is now just recently completed and being looked at and now the post market study will be starting soon. Again, looking at the (4-French device).

6 French device has now been discontinued. All of our efforts are 4 French device, 50% smaller device. Next slide, please.

There's also a paper that was recently published Journal of Vascular Access by Dr. Instien. Again, his first 30 patients, so early again on the learning curve, compared to 40 surgical fistulas.

Again, he's been doing this for 20 years. So, he's done hundreds of surgical fistulas, but just started a prospective study looking at 30 versus 40 and you can see the numbers there. I don't want to read them all out, but you can see that the procedural success, the primary patency, all very favorable. For WavelinQ mean patency was excellent. And that was statistically significant when compared to surgical fistulas with reasonable secondary patency as well.

So really to date, in these studies, we have about 214 studied patients including this 30 from instance, with very good data. We've got about 300 physicians that have been trained in our country to do this procedure over the last year and I'm involved

with some of this physician training. But a 100 of them are from this area that we are talking in this NGS jurisdiction. These hundred physicians will be affected by this. Next slide, please.

Really, what's interesting here is that the FDA and CMS and both supported EndoAVF with WavelinQ and Ellipsys, really from the get go. They cleared both on in June of 2018. They gave them both C-Codes in 2019. And in one week from today, there'll be now a G-Code again, for both WavelinQ and Ellipsys, establishing payment for physicians.

And in a rare move, CMS increased payment for 2020 for both of these technologies as well. So really, these two technologies have been lockstep the entire way. Next slide.

The MAUDE database. So, this is really one of the issues with the LCG projection that we know that the FDA concedes that MAUDE data has limitations.

The data is incomplete. It's inaccurate, it's biased. And the FDA even warns that MAUDE data should not be used to evaluate adverse events. We don't have a denominator, it's hard to compare rates across events.

And when you look at a big company like BD that acquired a company Bard that acquired TVA Medical, a small device company that first had the WavelinQ device. You've got a big company that has a big regulatory and compliance department, who is really going to try and report every little thing.

If you look at the MAUDE database, the 70 or so, entries in there, the majority are from BD employees. And still the majority of cases had a successful fistula created even though there may have been some type of event and really at the end of the day, there have been no limb threatening or life-threatening events from either of these devices.

So really what we are saying is that the MAUDE database has significant limitations and really should not be used to make a decision, especially of a comparative decision between devices. Next slide please?

Woman 1: And Doctor, we are down to one minute please.

Dr. Todd Berland: Okay, great. Now looking at - really focused on that bottom line for one moment here. Looking at all of these studies, again, this is pulling all the data 4 French and 6 French, technical success rate high similar to what you see with Ellipsys, device-related (FAs) 2.2%, again similar to what the retrospective Ellipsys study would show.

And then procedural related (FAs), I think inappropriately higher secondary to those initial 6 French device studies. We had brachial artery hematomas and then people tried to get smart and use closure devices. The closure devices themselves in the brachial artery are an off label procedure. Physicians were using those and not having very good results. So we have the highest complication in that initial NEAT study which was that 6 French device, again no longer available.

Next slide? Looking at the studies to-date, again, similar age. If you look at patency, very similar at six and 12 months and then median or mean time to needle cannulation. Again similar in these days, this is a metric that's hard to follow, because if it's a pre-dialysis patient, you may not be cannulating them if they don't yet need to be on dialysis. They may have fistula that's ready to go, but they don't need dialysis, so hard to look at that number.

Next slide? So really in conclusion, now this is my last slide. Both technologies have comparable safety and clinical profiles. Lots of procedures have been done to-date. This is a field that has had very little to no innovation and to try and stop this now would be like pulling the plug and pulling the energy out of a grassroots movement here where patients are finally having an option for something else. Instead of a surgical fistula being thrown up on them, they're finally now having an option that is not a surgical procedure.

And neither of these procedures burn any bridges. We're creating fistulas between that radial artery and radial vein or ulnar artery and ulnar vein and not obviating any kind of future access issues. This is simply giving another option, another space to create a fistula in a very difficult patient population.

And finally I'll just end with that, relying on the MAUDE database is really contradicting the FDA's warning to not rely on this to compare devices because of all those inherent inaccuracies. So really limiting the access to just Ellipsys or just wavelength or to both would really hurt patient's ability to provide alternative access care to their patient. Just like Dr. Hentschel was saying, these procedures complement each other. Not everybody's anatomy is conducive to one or the other and not every operator is familiar or as easily able to perform one procedure or the other. So these are very complementary procedures that are both adding another option for patients. That's all I have.

Dr. Haug Dr. Berland, thank you. As noted in the LCD, I mean there is two - the basis for the non-coverage at the moment was the shorter follow up. We don't have the two-year follow up on Ellipsys and only one year follow up and actually if you talk about the 4 French, it's even more limited than that really in any large numbers anyway.

But the other issue is and you mentioned that the modern - the manufacturing user facility device experience database which as you mentioned actually as of yesterday was 75 reported issues for wavelength and zero for Ellipsys. Now that's hard to ignore as you can probably imagine the - not all of the issues in 75 issues and I should say that, you know, last year most of them are related to the 4 French, not the legacy 6 French. Various problems with the device like failure to align, failure to cut, material deformation, maybe not all those lead to a complication, maybe some of them went on to successful procedure. But they - at least they had those issues.

((Crosstalk))

Dr. Haug Are you suggesting that the Ellipsys - that there are similar number of Ellipsys issues, but they're just not being reported?

Dr. Todd Berland: Well, I wouldn't dare to say it is a similar number, because you have to look at the denominator. I think the CMS database, SAF database demonstrates that more wavelength procedures are being done than Ellipsys. So I would not expect that numerator, that 75 to be similar with…

Dr. Haug Okay, percent wise and percentage wise it's not that…

((Crosstalk))

Dr. Todd Berland: If you look retrospectively at the data, they both have between 2% and 3% SAE rate. So I do think that they are inherently similar from that standpoint, but I do think if you look at Ellipsys or Avenu Medical as a company compared to TVA which was a small company that got bought by a bigger company that got bought by an even bigger company that has this over regulatory basic want the need for compliance, you're going to have some inherent over reporting in that bigger company. And I think that's what we're seeing here.

And again, I have nothing to disclose. I don't have anything to gain from your decision with this, but you can easily see that a bigger company is liable to over report this. So if you look at this data, I think you really need to look at the published data where both of these devices are very similar.

And more for your first question, when you really look at the Ellipsys study, that's a retrospective study. And it really doesn't involve their newest generation where they're doing that secondary procedure as part of the first which I think is a great move on their part to kind of condense it and move things forward. I don't know that two-year data even includes that type of procedure, that evolution of procedure. The wavelength data is all prospective studies that have moved out and again we got six and 12 months data which in most spaces in the device world is sufficient for coverage in FDA approval et cetera.

Dr. Haug Well, on the other hand, one of our prior speakers said that they prefer five to 10-year and has said from that standpoint one or two-year is relatively the same, but…

Dr. Todd Berland: But – and it will get there I think. But when you rip out reimbursement and coverage then physicians won't be able to do that and we will never have those studies, but it will be great. It took 15 years, 20 years before aneurysms had a study comparing EVAR to open surgery. You really have to have it available, have the technology out there and the option for physicians to use it to then get this data.

Dr. Haug Yes. I wonder if - operator, if you could just open up the lines on our prior three, Dr. Wasse, Dr. Jennings and Dr. Hentschel? If you have - if any of them have any comments on this MAUDE issue, because that frankly is a large impediment that we're seeing and I'd appreciate if they had any insights into how much we should or shouldn't value that.

Dr. William Jennings: Hi. This is Dr. Jennings, can you hear me?

Dr. Haug Yes, Dr. Jennings.

Dr. William Jennings: So in the new study from Germany, Dr. Shebardian, the adverse events including a brachial artery bleed that required stenting and those things were I think in his experience four for wavelength and one for Ellipsys. I also would - want to comment on the question of long-term data on the immediate balloon maturation in the Ellipsys. Dr. Mallios's series that was 240 cases, only the very first few like the first 20 were with bringing them back for an angioplasty, so 95% of those were done with - or at least 90% of those were done with immediate balloon maturation. So that does have the long-term or at least the mid-term data available.

Dr. Haug And as far as the MAUDE database, how much should we credit that?

Dr. William Jennings: Well, I think that whether you look at the original study with wavelength or not. But there is just not a lot of published data about the new wavelength and those are

real things. They're brachial artery entries or failure to complete the procedure, those kind of things. So - and I think Dr. Berland is able to talk to those as he already has better than I because of his experience with wavelength. But some of them are real and I don't…

Dr. Haug And do you feel - so if you're somewhat affiliated with the Ellipsys company, do you feel that there is potential for under reporting because the company smaller than BD?

Dr. William Jennings: I don't know of that. I don't know anything. I don't have knowledge of that.

Dr. Haug Okay. Dr. (Lafayette) or Dr. (Hentschel), do you have any comments on the MAUDE database and how much that should be waited in general or ignored?

Woman 2: You know, I think that's a difficult question. I mean we all are aware of - at our institutions and out in the community of some of the misfiring and some of the issues.

You know, Dr. Berland brings up a point of saying that it's more likely that things are getting reported because there are more number of users with wavelength. But I don't know that that's necessarily the point that I would make. I think that this is a different skill set that's used for each one of these devices and different anatomy is required and ensuring that the patients are being selected appropriately and have anatomy that actually fits with the devices, you know, really are key issues here.

So I think maybe it's just because there is some care that's clearly practitioners are taking care in terms of selecting patients, but because they're, you know, dual sheaths and ensuring that there is a proximity to - with the two vessels with one another and, you know, avoiding calcifications and things like that that might contribute to misfiring. Maybe those are issues that are arising that might be contributing to some of the complexities.

Dr. Haug So in other words, do you think the database is - the reporting is somewhat real, it's not to be discounted altogether? Doctor…

Woman 2: Well, I mean I would say that simply on the basis of seeing what's happened at my own institution, seeing - not being aware of what happened at other institutions with the devices. But again, I'm less about comparing this is being apples and oranges and more about just saying that these are - these employ different vascular anatomy and required different skill sets that need to be optimized to ensure that complications are avoided.

Dr. Haug Thank you. Dr. Berland, I know you're about to stop, but let me just get Dr. Hentschel in here. Do you have anything to add Dr. Hentschel?

Dr. Hentschel: I have. I just want to - so I think that the point that Dr. Wasse was making about skill sets and anatomy, I think that's kind of what I would also focus on. And I just want to put this into the greater context. So for instance, we use PTFE grafts as an alternative to fistula and they have infection rates that, you know, are in the 10 to - 10%, that's kind of accepted in the first year and we still use them, right.

And so I think one of the things here is disclosure, right? So if you talk to a patient, I think the disclosure that there is this risk of vascular complications, but there is the benefit of having a fistula created in a specific location in a way that otherwise doesn't have surgery, I think that's something that should go into this process, right. And I appreciate that the company is working on updated technology to reduce the rate of complications, but the MAUDE database is what it is, right? I mean you can't discuss - you can't really argue a way that people are reporting things and we may at some point see more reports for the Ellipsys technology if that is more widely used. But, you know, we don't know it's speculative at this point.

Dr. Haug Thank you. Dr. Berland, I wasn't sure where you trying to get in some last words.

Dr. Todd Berland: No, I mean I will just say that, you know, from all the biases that go into the self-reporting, I think we just have to be careful. And I just want to reiterate that the majority of those reports were from BD employees and the majority of patients still have a successful fistula created. I think there were only six reported patient injuries,

so we're talking very few with, you know, 3,000 devices sold already across the country.

So I think these numbers are very small relatively speaking and I think that they shouldn't be used and that when the committee makes their decision, they should really look at the published data and particularly the newer, safer 4 French devices that make smaller holes in the access arteries.

Dr. Haug Thank you Dr. Berland for your comments. Operator, if we could ask if there are any other comments on this policy at this point?

Coordinator: Absolutely. As a reminder, if you have a comment or a question, please press star-1. You'll be prompted to record your name. Once again if you have a comment or a question, please press star-1. It'll take just a moment for those to come through. Once again, if you have a comment or a question, please press. It looks like we have nothing coming through at this time.

Dr. Haug Thank you operator. Open meeting comments on this policy will now be closed.

The next policy or a comment is again a current policy that is we've made some revisions to percutaneous vertebral augmentation for osteoporotic vertebral compression fracture. There were two changes made. The - in addition to acute six to - zero to six week fractures, sub-acute fractures, six to 12 weeks were added to the inclusion criteria.

Also, the multidisciplinary referral segment was clarified along with the education requirements with more of an emphasis on ensuring the continuous care and preventing medical under treatment of the overarching systemic disease, osteoporosis of which VCF is a symptom. So the two requirements here all patients presenting with VCF should be referred for evaluation of bone marrow density and osteoporosis education for subsequent treatment as indicated in all patients with VCF should be instructed to take part in an osteoporosis prevention treatment program.

These changes were made on the basis of concerns about real world barriers to both multidisciplinary referral and time to surgery. We have three registered presented today. The first is Dr. Levy. Operator, if you could open his line?

Dr. Jason Levy: Hello. Am I here?

Dr. Haug Dr. Levy, we can hear you, yes.

Dr. Jason Levy: Yes. There was a request for Dr. Beall to go first. I believe he has another meeting. If that's not okay, then I'll go. But if it's okay then can we defer to him?

Dr. Haug That's fine. That's okay with me. I hadn't seen that request, so Dr. Beall.

Dr. Jason Levy: I'll go after him.

Dr. Haug Sure. Operator, if you could Dr. Beall's line?

Dr. Doug Beall: Was (unintelligible).

Dr. Haug And before we - operator, if we could move ahead to Dr. Beall's line. We only have this conflict of interest slides. It's already there, thanks. Go ahead Dr. Beall.

Dr. Doug Beall: Okay. Thank you very much (unintelligible). Go on the next slide. I'm Doug Beall, Interventional Radiologist. Next slide?

I'm Author of - next slide please? Just go ahead and click through all the disclosure slides if you want. I'm the primary Author of The Comprehensive Guide for Vertebral Augmentation. I've been doing vertebral augmentation treating patients for underlying osteoporosis and dealing with vertebral fractures since the early 90s.

As we're looking for my slides, we'll just go ahead and start. First of all, I'd like to save the changes have been optimal. I liked the changes to the LCD. These have been very much well needed. I'm glad the changes have been made.

I'm going to deal with an issue on timeline and if we can find my slides and click down to slide 9 that would be good. As was mentioned…

Dr. Haug And Dr. Beall, as I told you the slides didn't make it in time to be on the deck.

Dr. Doug Beall: But I had the original slides submitted previously for the presentation before the last LCD.

Dr. Haug Right. Well, those were before the new LCD was published, so they didn't…

Dr. Doug Beall: Well, it's not what was communicated to me, but let me continue. All right, so the issue about adding acute fractures is fine. Acute fractures have a good amount of information. Sub-acute fractures have more information. And the issues with chronic fractures have about the same amount of as acute fractures, but these were excluded from the LCD.

So there is - and The Comprehensive Guide of Vertebral Augmentation, we wrote a whole book chapter about it. It has 24 references and I will submit all my slides with all the supporting data of this. It also has a presented, but as of yet unpublished new sham trial called VERTOS V. VERTOS IV was submitted as the LCD in terms of the supporting information and is all over the document for the supporting information. This is VERTOS V and this is the treatment of chronic fractures that has been previously presented and has concluded vertebroplasty is safe and effective for the treatment of chronic fractures with a statistically significant improvement in pain and quality of life.

So the question really is if there is the same amount of data supporting chronic fraction treatment for painful vertebral compression fractures as acute fracture treatment, why is this not being allowed?

Moving on to the next topic, the infiltration for periosteal infiltration, the option to do that prior to treatment. As I mentioned previously, this is completely unsupported by literature at all. In the all five sham trials, none of them had infiltration of the pedicle with anesthetic as an option for treatment. 01 had document pedicles in the outside of the (views) and the outside of pedicles. (Unintelligible) infiltration scanning subcutaneous tissue, it doesn't have infiltration over the lambda, but none of them had infiltration around the pedicle used in isolation.

And the trials by (Wilson M and Wang) had infiltration of the facet joint, not the pedicle. So recommendation to do this came through the evidence that's referenced in the seventh paragraph, the opinions in VERTOS IV this was (unintelligible) article. I contacted these authors and confirm that this is just author opinion and the senior author whom I spoke to, Dr. (Paul Lolli) confirmed that an author opinion is nothing more than just unsubstantiated evidence that should not provide as a surrogate for evidence based medicine and evidence based information.

Also, the fracture levels are also arbitrarily limited from T5 to L5 and there is no reason for this limitation. Again, we wrote a whole book chapter about treatment of fractures beyond this limit and this has 42 references. This also involves people that are very sick and ill such as people with metastatic cancer, which I will touch on in a second, people with glucocorticoid induced osteoporosis and people with severe osteoporosis and multiple myeloma.

So these are - this is clearly an arbitrary distinction that we really should not do, because there are plenty of evidence. In addition to the 42 references in the book chapter, there are 12 level 1 and level 2 data and I have - I had that on my slide, but I have all this information including with PDFs with articles manuscripts for each one of these 12 articles that involve treatment beyond the levels of T5 to L5.

And finally, for the exclusion criteria, the exclusion criteria is listed as no more than three fractures and it's my understanding that this was a misunderstanding that this was meant to be no more than three fractures at a time. But one of the - at least one

of the medical directors that I've spoken with has said that his opinion was that this was limited to three fractures in a lifetime. So that's a very big discrepancy in this and not only - that will be like treating somebody's one hip fracture and not treating the second broken hip and somebody like them. Also, that's not a contraindication at all.

UCLA/RAND methodology for appropriateness criteria methodology does not list treating more than three fractures at all in either absolute strong, usually contraindicated or relative contraindications. So this should not be listed at all. This is a relative safety limitation, but if this is limited, if you do limited this more than three fractures as I mentioned, there is data with multiple myeloma to deal with glucocorticoid induced osteoporosis.

There is one level 1 trial that had an average of 3.36 patients enroll in their incredible cancer data most recently by an author named (Lulin) that presented this as - for publication this year, was out.

So I'm going to summarize it up. So there is extensive data that supports treating patients from outside the limitation of T5 to L5. And this limitation is arbitrary and should not be kept. This is something that will limit people, probably the most vulnerable to the patient population that have fractures outside this area, most commonly from T1 to T4.

Periosteal infiltration should be removed even as a recommendation. This is unsubstantiated opinion and this is not replicated in any level 1 trials nor in any of the poster element trials. Treatment of chronic fractures has the same evidence as treatment of acute factures with now the new sham trial. So this really should be considered for patients with painful chronic fractures, because what else are you going to do if they're not candidates for screws and rods, if they have persistent severe pain then this should be allowed.

And then treating more than three fractures is the limitation is - that it is a bad idea. That will limit arbitrarily and inadvertently the most severely affected patients from treatment.

And finally, almost as a parenthetic comment, but I want to make this as a distinct point. There is no cancer codes in here. So the treatment of patients with the cancer diagnosis and that's 100,000 fractures a year, I'm just going to assume that that's an oversight, because there is good level 1 data on this for the treatment of neoplastic fractures. There is an extensive number of - there is meta-analysis, there is level 1 data, we wrote a whole book chapter about this. So I'm going to assume that this is an oversight.

With that, I will stop right there. Thank you very much.

Dr. Haug: Dr. Beall, thank you for your comments. Just to go over a few of them, the cancer, that's out of the scope of the policy. So as I think I mentioned to you that I pointed out in the billing and coding section, it addresses this and says that that's out of scope and the coverage will remain available for medically necessary procedures for other conditions not included in this article LCD. So that's that point.

The T5, L5 and three fracture limit that basically mirrors the inclusion criteria as most of the main studies. My interpretation of the three fracture was always at the same time, not a lifetime limitation. So I think that's what was meant in the studies themselves and that certainly was my interpretation of it. So I don't think that's going to be much of an issue there. I'm not sure about…

((Crosstalk))

Dr. Doug Beall: Well, that will be an issue. I mean there is significant literature on this and just to…

Dr. Haug): Well, I mean if we - it's not an issue if we clarify that.

Dr. Doug Beall: Well, I mean limited to three fractures is not - should not be a contraindication. This is - that's a relative safety limitation. It's just going to limit (unintelligible) cancer patients and multiple myeloma and severe osteoporosis.

Dr. Haug Right.

Dr. Doug Beall: And then there is level 1, level 2 data associated with this.

Dr. Haug Okay. It seems there is two issues there. One was the potential misunderstanding, the lifetime versus, you know, at the same time and the other is whether it should be a relative or absolute contraindication. And, you know, that's something we could put together.

Dr. Doug Beall: Agree, yes. They're two issues.

Dr. Haug Okay. And as far as the T5 to L5, again, that was included in - most of the inclusion criteria, most of the studies you mentioned it was arbitrary. I mean, I - as you know, I mean there is hardly ever something that's completely arbitrary that goes into these studies. There is probably some reason for it. They may not agree those are reasons or we may think that despite those reasons, it shouldn't apply to the real world beyond the study. But are you - I think you are aware that that was included in most of these studies. Do you – are you aware of a reason for having that limitation and not just saying T1 to L5?

Dr. Doug Beall: Yes, tradition and inertia. For example, the largest type of plastic trial ever done is the EVOLVED trial. And I was the PI of the EVOLVED trial. We had a limitation of T5 to L5. Do you know why? Because we were asked to buy the Noridian jurisdiction, (E&F), because they wanted to test out their LCD, they wanted information to see within their LCD did this work under their existing local coverage determination or not. And that's why it was limited to T5 and L5, because it was done specifically with their criteria inclusion - as inclusion exclusion criteria. We have a whole list of people that were denied based on fractures above T5…

((Crosstalk))

Dr. Haug Well, Dr. Beall, there were several major studies, RCTs vapor, VERTOS II, the free trial that predated I think that discussion that also had that limitation.

Dr. Doug Beall: I understand. But there is also Riesner, Evans, Peris, Vogel, Comstock, Martinez Ferrer, Blasco. I mean there is numerous ones that do not use that as an inclusion and exclusion…

Dr. Haug Okay. All I'm asking is why did some of them do you think?

Dr. Doug Beall: This tradition inertia - I mean mostly these are the most common fractures absolutely happen from T5 to L5. The most common rhetorical lumbar junctions, T10 to L2 by far, by far two-thirds rhetorical lumbar junction fractures. But to limit it to T5, my advice is as an expert, is it if you limit it to T5 and excluded from T1 to T4, you're going to be excluding the people that are severely affected.

Glucocorticoid induced osteoporosis, myeloma, severe osteoporosis and cancer and this will not be well. And there is a known incidence of fractures from T1 to T4. And I have information, can speak to that, can submit the data on this and this is not unusual. I won't disagree with the fact that the most common limiter is T5 to L5, but this is primarily for conducting randomized control trials and - but this is real world though and this…

Dr. Haug So unlike the three fracture limitation which I think we would both agree had certain safety concerns associated with doing more than three at a time. In the case of the T5 to L5, you don't see any real substantive reason beyond tradition that that was included in the trials?

Dr. Doug Beall: No, I have firsthand experience. I mean, not only do I seen no reasons, I know why that is. That's inertia and tradition. And that's with the most commonly treated patients. And so whatever we developed, these protocols back - you know, I did - I started doing this in the early 90s and so this is just kind of came out and repeated. And the other authors that I mentioned to you, these are people that I know and they wanted to test outside of this ramification which is this limitation which is totally appropriate. And whatever we apply this to the general population, the Medicare

population, there - you know, I treat T1 to T4 two to three times a week. So this is something that really comes up.

Dr. Haug And what about that event?

Dr. Doug Beall: Well that, you know, above that - that's a very good question. That's a very, very good question. Above that, it doesn't really apply necessarily, because we have the ability to do vertebroplasty is defined as cervical thoracic. So vertebroplasty is defined cervical thoracic and lumbosacral. So the ability to treat the patients in terms of a vertebroplasty of the cervical spine still seems to be supported. And however, this is done that I also agree with that. These are not very common. Cervical vertebroplasties, in my career, I've done 1000s and 1000s of general, but maybe only about 25 cervical cases.

But when you do them, they're typically myeloma. I mean these are patients that have very severe problems. So they don't happen very often, but they do happen. And typically they're recovered by the cervical thoracic vertebroplasty code, because you don't do vertebral augmentation necessarily in the cervical spine.

Dr. Haug Got you. Dr. Beall, thank you for your comments.

Dr. Doug Beall: Very well, thank you.

Dr. Haug Operator, if we could now go to Dr. Levy and open his line?

Dr. Jason Levy: Hi there. I am Dr. Dr. Jason Levy and I am representing the Society of Interventional Radiology. I appreciate the ability to speak regarding the proposed LCD and I also appreciate the changes getting rid of the multidisciplinary requirement which was really unnecessary. I do want to address some shortcomings in the existing LCD.

If we could go to the next slide, briefly my disclosures are listed here. The only one that's really relative - relevant is the Medtronic disclosure.

Next slide? So I'm going to be focusing on what we're supposed to be discussing during the comment period, but I will address some of the things that Dr. Beall discussed as well. I'm going to start with the age of the fracture.

Next slide? So unfortunately right now we have it on the proposed LCD at up to 12 weeks. The challenge with this is there is really two to three things that are problematic. 1, it's unclear, 2, it's unrealistic and 3, it's essentially unsupported.

So from a clear clarity standpoint and a realistic standpoint, there is not always a defining event. So we have to look at this clinically and from imaging. From a clinical perspective, we do not have a defined event in many times. This is not a motor vehicle accident. It is a low impact trauma. Sometimes it can be elicited simply by a cough. The patients are elderly and don't always give us a specific date. So timing of this is really truly unrealistic.

What's the other challenge with this is we know we have definitive data from VERTOS II, VERTOS IV, vapor trial, Papanastasiou meta-analysis that these fractures aren't a onetime event. They fracture and then they fracture again in the same vertebral body. That further challenges any type of dating.

When we look at most of the literature, we should be focusing on advanced imaging and that is one of the criteria that came out of the RAND study, okay. We should be focusing on criteria. Attached to this are seven references looking at a DEMA on advanced MRI as really the most important feature or one of many important features rather than focusing on time.

So the next slide. So I looked - the LCD refer to six references and I looked at each of these references as far as where is your source for this. So if you're going to exclude older fractures, I request the source. Now Dr. Beall mentioned a bunch of sources that support chronic fracture treatment, but I don't really see a source that doesn't. So the bar, no, there was only mentioned against the initial mandatory waiting period which you have got rid of.

The RAND study in fact went the exact opposite direction and I highlighted this, the panel's treatment recommendation did not vary substantially with time. In fact, they focused on what I suggest is focusing more on advanced imaging findings rather than timing.

Next slide, please? The McConnell, again, on the contrary, I'd actually suggest sub-acute. Again, no timing described. I will get to the Clark reference in a second, (unintelligible) which is actually the (SERC) guidelines on the contrary supports chronic nonunion fracture similar to what we would do with a nonunion fracture anywhere else in the body.

So again, that is one out of six and this one, let's look at that further in depth, because it's not really a supporting an exclusion. It actually was not a study, but instead a response to an (Aaron)'s Cochrane database. And it certainly didn't suggest that fractures can't be treated greater than 12 weeks, but instead suggested that potentially fracture in the three failed sham trials which is not what these patients are getting, they're getting nonsurgical management, but those three failed sham trials that was related to - including chronic fractures.

Now, you have to remember in one of those sham trials they did not include MRIs and another one of the sham trials, the MRI's timing related to the fracture was unclear.

Let's go to the next slide please. There certainly is evidence out there to the contrary. Here is a sampling of that. Dr. Beall mentioned more, but these are randomized control trials and as well as single-arm prospective trial that should say greater than three months on the bottom, that is a typo on my part, excuse me for that. But the bottom line is there is certainly evidence to the contrary.

So I'm going to skip on to some of the other topics that are not part of this comment period, but I do think that there are important enough to discuss. The first is the exclusion of T1 through T4. This is completely unsupported and I assume again this may be a concern related to safety concerns, but again that is unsupported as well.

So I would ask the NGS to be giving us support for why that it was excluded than I did hear that it wasn't included in some of the trials although there are trials where it has been included although not as frequently and that is in part because it doesn't happen as often in that area.

Having said that, there were six references that the LCD included. Did those references mention exclusion of T1 through T4 and that was zero for six and not a single one mentioned it is an exclusion and in fact the (SERC)'s recommendation was given and the procedural approaches for the upper T spine.

The next item I want to address is the number of fractures. We've already talked about how unclear this wording is. For instance, if a patient has a report in a chronic MRI - and MRI with three chronic fractures and a fourth acute fracture, this would exclude this patient.

And I did hear you say and I agree with you, there are some safety concerns. However, that number three is sort of somewhat arbitrary number and there are safety concerns with nonsurgical management. We know that patients go onto fracture. In fact, some of the patients in the VERTOS IV study went on to fracture and became paralyzed related to that. There are significant risks to nonsurgical management such as de-conditioning. So we have to balance the cardio pulmonary risk of treating multiple levels versus the risks of treating nonsurgical management.

So like I said, the six references that were - I'm sorry on this, there were five references. Again, zero for five excluded the number of fractures. In fact, the (SERC) recommendation was five, not three. So we have to balance these patients. There are studies we have looked at and you can see that in my slide deck that is not shown here, but there are studies that have looked at this and have shown very similar safety profiles.

There has been a suggestion of no more than five or six. There has been a suggestion of no more than 30 CC (unintelligible), but we need to, 1, clarify that it's not more than three, we need to - that cannot be an absolute contraindication. There

may be a way to get around this by suggesting stage to procedures were three at - three or four at a time are treated. But we can't let the most high risk population for complications related to de-conditioning go untreated. This exclusion leaves a large portion of the Medicare population untreated.

So the final comment that I want to make is we're in an opioid epidemic and this wasn't listed here. But we are in an opioid epidemic. The fact that opioids which is the alternative here is not listed as one of the indication. So if somebody is on chronic opioid and having unacceptable side effects, that is mentioned in every single society guidelines that is one of the LCD references and every one of them had mentioned for a patient with a weakened or fractured vertebra body unacceptable side effects such as excessive sedation, confusion or constipation should be an indication.

So in that table where you list progression of vertebral body height loss greater than 25%, we need to add that as a fourth possible indication, allowing for two of the four rather than two of the three indications.

So to sum it up, we need to get rid of the – sorry, we need to allow for more chronic fractures, especially if they have a DEMA, we need to get rid of the exclusion from T1 through T4, we need to get rid of the three vertebral fractures, we need to clarify the language and allow for treatment in the sick population, allow for the physicians to balance the risks. And then finally, I think we need to concern ourselves with our opioid use and the alternative of what these patients are really getting and allow that to be an indication for this procedure.

So I thank you for your time. And if there are any questions, I'm happy to answer them.

Dr. Haug Absolutely. Thanks for your comments. Just a few things, I think - as far as the three fracture limit in the T5 to L5, that's - those were the inclusion criteria on virtually every major study. I'll take these references that you looked at, one specifically coupled to those they may have been nearby, but they weren't specifically coupled to

those things. If you look at vapor, VERTOS IV or VERTOS II in (unintelligible) and even in upcoming VERTOS V, they all have those same limitations, so better or worse.

And as I already spoke to, I think the three fracture is somewhat of a misunderstanding and that my interpretation was it wasn't any lifetime, it was at the same time issue. Yes, there are - maybe beyond that there is a case to be made that even at the same time more than three, but that's a different issue.

The T5 to L5, again, that's in all the studies. The reasons for Dr. Beall unlike the fracture limitation and safety, there wasn't a cogent explanation. I'll have to see why all those studies did the same thing. Again, usually things aren't arbitrary in these studies. They do it for a reason.

The - and one thing I would - going to the - your first comment that you made as far as these things aren't a momentous event, they can be just as a cough or something like that. That's true. And so it's not as memorable in that respect. But I was a little surprised by this, because it's frankly never occurred to me that that was going to be a big issue to note the onset of the fracture, because usually that's associated with symptoms. And I think virtually all the studies accounted that way, the onset of symptoms.

So - and that, even if the cough wasn't memorable, the onset of symptoms probably are. So I'm not sure that that's as much of an issue. We could certainly clarify that that's related to the onset of symptoms that may have been that. It seemed so obviously, we didn't even specify it.

One thing I also want to mention was and I should have mentioned this to Dr. Beall, he made a big case of the data for the chronic being equivalent to the acute and sub-acute and he put a lot of weight on the VERTOS V. VERTOS V is not yet published. And my discussion with the actual authors on that, they're not giving out any information on that and they recommend not acting anything like that until it's published. And certainly we don't take into consideration any evidence that isn't

published in peer review journal, so there is that. That's going to be published probably later this year or early next year, but it's certainly not published yet. And I don't think I brought that out with Dr. Beall's comments and it's certainly important.

When that does come out, that will have some of the same limitations that were held against VERTOS IV and we'll see what that data shows. It's an important study and that we certainly look forward to getting that information.

I think that's all I had as far as in response. Did you have anything you wanted to say?

Dr. Jason Levy: Yes, I'd like to respond to some of those. First, starters, one of the common themes here is you are referring to absolute contraindications and you're saying these are absolute contraindications, because in some of the studies they were not - in many of the studies they were not included. That is never an absolute contraindication which is what you were suggesting here. And that is a dangerous implication in setting where there is definitive mortality benefits from this procedure. So I think that is an unfair comment when we're saying that it is in absolute contraindications. Let's start with that.

Second, as a person who has treated 1000s of patients, you are well off the mark on the timing perspective. You cannot time these fractures. And we have definitive evidence that these fractures like I said earlier, there is VERTOS II, VERTOS IV, vapor trial. We know these fractures will fracture and fracture again. So the - even if you try the onset of symptoms, that can't happen. Your alternative, you're putting these patients on opioid and that's not going to help us remember these fracture timing.

So if a patient comes in and we think the timing was 10 weeks or 11 weeks and six days ago, we have one day to get this patient on the tape. It is absurd to think in a real world population that that is relevant.

Finally, the reference that the levels. Some of these studies did not - they just said thoracic or lumbar, they did not always indicate whether it was T5. I believe one of the major randomized controlled studies did include T4, but again you are leaving the highest at risk population. They're very rare when you compare it to junctional areas between T9 and L3, but they happen. And right now we have seen significant information on mortality.

So I think we need to take a step back and we're calling something an absolute contraindication or leaving it completely out, completely uncovered when there is really no support to use it as a risk. And that goes again for the number of three levels. You know, all of the society recommendations, there is no three levels in there, that's fairly arbitrary.

So I would - I will leave my comments in that and finally with the mortality discussion when we look at that and I will submit the references for mortality, there was just another one published in radiology earlier this year so that will be included as well. But when you look at that, that's looking at Medicare data, so that's not necessarily stopping at three levels. I have personally treated multiple patients with many more than three levels, as I'm sure every speaker that's going to discuss has as well. So those are my comments.

Dr. Haug Thank you Dr. Levy. Our next registered speaker is Dr.Shonnard. Operator, if you could open his line? Dr. Shonnard, are you there?

Dr. Shonnard: Is the line open? Can you hear me?

Dr. Haug: Yes we can hear you.

Dr. Shonnard Great. Thank you for the opportunity to speak. I just wanted to ask Craig if you remind me at the end of my presentation, I can address a cogent explanation for each of the issues that you raised, because really what you're trying to do is find objective criteria for indications. That's what you're trying to do. You're looking for onset of symptoms, you're looking for acuity, you're trying to figure out T5 to L5 and

three levels or why not all fractures. What is this business with chronic fracture? You're just looking for indications and I can understand that.

So let me - so I'm an Orthopedic Fellowship-Trained Spine Surgeon. I'm the Founding Clinician who is responsible for the vertebral compression fracture registry done in collaboration with Bernice Hecker, (Dick Whitten), (Gary Oaks) and (Eileen), you know, in conjunction with the data vendor to develop the registry. And this collaboration has produced the largest VCF registry in the world and it has given significant insight into healthcare utilization.

And since the VCF registry and the healthcare utilization data reflect Noridian's 2014 LCD, it applies to all max, because this is your data. These are your beneficiaries.

So let me click and go next slide. And I'll just power through this. So you know where it was done. Those are the - it was in jurisdictions you know. You know who the principles are.

The next slide, the authorization criteria did address acuity and I can tell you how. That's what you're looking for is an objective measure and I can tell you how to get that done. Well, the three levels was arbitrary and capricious as others have said and it was based on the two collaborating physicians in the original collaboration, me and Bernice.

So remember, Bernice Hecker, the Medical Director of Noridian at the time and since married and now retired. Bernice was anesthesia trained and I'm a fellowship-trained spine surgeon. So both Bernice and I knew that when you turn a patient prone, you're going to have blood pressure problems. And in this age group which is almost always dehydrated. Our concern was safety.

So Bernice and I agreed that you should not do more than three for safety purposes. And that's three per episode. She and I did not have any valid scientific justification for it, but we thought it clinically wise. Both she and I are senior clinicians. So that was an arbitrary and that's what we did and that's the cogent understanding. As I

understand your implication that as a safety measure we might retain the three levels per treatment episode and then leave to the clinician - treating clinician the decision when to proceed with the others. I could align with that. But I also understand that this is not scientifically based, the three levels is capricious and arbitrary as Doug and Jason have mentioned.

So I'm going to go to the next slide on mine and intended - remember, this was covered with evidence development, a purpose that we collaborated around and it involves surveillance tracking and it gave insights. It actually resolved the controversy.

The next slide will show that the immediate impacts were a restriction of access. It's important to understand this, because your proposed LCD will do this. In Washington, only six out of 310 were authorized, in Montana zero out of a 100 were authorized in the early 2014 and there was also a claw back, but I'm not going to go into claw back.

Next slide? So what you see the intended results of this where the world's largest VCF registry, the resolution of controversy around treatment and now the Europeans are approaching us to help them understand that more completely.

What you find and you'll see in the data slides that this is the most beneficial and a treatment option for these patients with the greatest amount of pain and function improvement.

Next slide? There is the data. Embedded in the slides are the red zone at the top of each graph line, that's your MCID, that's your Minimal Clinically Important Difference. And although these are slides that are showing populations rather than individuals, I put the MCID in there so that you can realize, my God, the pain improvement is five times the MCID and the functional improvement is three times the MCID. So these are hugely beneficial and this is for the largest population recorded.

So let's go to the next slide. When you look at healthcare utilizations, these were done, all of these patients are registry patients, all of them are reflected in the outcomes. And what you see is all costs affiliated with the index ICD 9 vertebral compression fracture code.

And the next slide shows that it breaks into three categories early, intermediate and late. And when you look at the next slide, you'll see the early and the late. And this is the important thing to understand here is the benefits of this collaboration are hugely insightful for you as a MAC. What you see here is if the patient is diagnosed early and treated promptly, the dysfunction in their role in (Morris) which is significant 20, improves to three. That is grandma dancing across the floor. 20 is grandma bedridden hospice level care. So there is dramatic improvement. The pain improvement from eight goes to one.

Now look at if you delay care. The LCD will delay care. So what happens? So this is - 171 is - days is six months. Your cost triples mostly because of return to ED, readmission, MRI, CT. Notice they're still severely disabled, so nonsurgical care isn't working. And they improve dramatically, two times MCID, but not as much as if you did their treatment immediately. Their pain improvement is dramatic, but not as much. So what does that mean? That means that the patient who waits is harmed, measurably harmed by the objective criteria that we collaborated to demonstrate whether this was covered with evidence.

And let's go to the next slide. Unintended and intended consequences. 1, PVA is the safest, most beneficial treatment you can do. And every level responded, even those were - I did three and then I waited a week, made sure patient was doing well cardiovascularly and then did the next two afterwards. They all responded beautifully. So every level of vertebral compression fraction independent of cervical, thoracic, lumbar, sacral, every level responds to appropriate treatment reproducibly. The prompt treatment is the greatest benefit at the lowest cost and delayed treatment results in debility, destitution, death and the highest cost for the (MAC).

Next slide please? So unintended consequences, if you use LCD the way that you have it now outlined, you are going to delay care. So the periosteal infiltration violates all orthopedic fracture principles. It should be discarded.

Last slide. What happens with this? So yes, you are familiar with a class of individuals, vulnerable individuals. And the reference to this is the smoking lawsuits, the breast implant lawsuits, the contaminated community water supply.

If you have a whole class of vulnerable beneficiaries whose care is delayed, you're exposing the (MAC) to enormous liability. And the findings of the Noridian LCD are now public knowledge. I'll sort of say this in other way. The unintended consequences of the Noridian LCD in 2014 was that Noridian discovered a resoundingly beneficial way to treat the painful osteoporotic vertebral compression fracture and it resolved a treatment controversy.

Secondly, Noridian discovered an expedited pathway for compassionate care for their beneficiaries. And thirdly, Noridian received the opportunity to achieve massive healthcare utilization cost savings by improving efficiency of care. The LCD is a barrier through the improvement of efficiency of care.

And now lastly, let me reflect back on some of the concerns you had. Cogent explanations you were seeking, because really that's - it give me objective criteria for indications and Bernice and I were committed to accomplishing this and (didn't let) participate it in some of these discussions.

So acuity cannot be defined by date of injury, because these women have been reflected earlier - independent of the studies that you were quoting, Craig, these women do not have a grasp of when this started. And their husbands, if they are still alive and still with them, they don't remember when this started. And their daughters who are usually taking care of them, they're the ones who bring them in, they don't know but grandma just started deteriorating.

So what Bernice and I did is we said look, what's the MRI or the bone scan, because some of these folks are on pacers, then you can't MRI them. What is the criteria for acuity radiologically? But for MRI, acute fractures remain positive on stir for four to six months. So notice in the Noridian LCD, treatment was allowed up to six months and that's based on our agreement around an objective criteria.

Doug and Jason are precisely correct that the chronic fractures respond, but they don't have a stir signal abnormality. So if you use MRI as a hard definer of indication, you will fail to get to those patients. So what Bernice and I came up with is actually (Courtney Brown) from Denver came up with this and then I shared it with Bernice is we used a localizing X-ray, I use a paper clip. And part of the physical exam as I put the paper clip where the patient is painful and every single time it's on top of the vertebral compression fracture except the older female who has spondylolisthesis, because she also hurts at L4 and L5 and it'll end up down there.

But if there is no vertebral compression fracture down there, that problem is mechanical back pain from spinal stenosis and spondylolisthesis. But the localizing X-ray is an objective measure of the location of pain. And if it's over a chronic vertebral compression fracture, that fraction needs to be treated.

And T5, L5, that arises from (Alex Vaccaro)'s pedicle screw fixation technique. In the late 90s, (Alex) was my junior resident while I was a fellow at Rothman. And pedicle screw fixation from T1 to T5, really T1 to T4, because that's where Bernice and I settled on T4 as the upper limit. And that was because of safety using fluoroscopy, you cannot see the upper pedicles as easily, so you have to be skilled which is why Doug Beall does it, that's why Jason does it, that's why I do it. We're skilled at doing this. We know how to do it. The scapula of the shoulder blades gets in the way, particularly in the obese patient, but that was a safety issue.

Woman 1: And Doctor, we've exceeded time.

Dr. Shonnard All right. Well then, cogent explanations if you wish. Dr. Haug I'll leave that to you.

Dr. Haug Cogent explanation for?

Dr. Shonnard So the points that I have marked out is chronic vertebral compression fracture and I addressed that with the localizing X-ray. For levels cervical, thoracic, lumbar, sacral, I addressed that by saying that all fractures are painful and all fractures should be promptly treated. The three levels I addressed that with the conversation of Bernice and I around the safety of elderly women being prone.

The T5, L5, I just got finished explaining and the objective criteria is with regard to onset of symptoms was something that Bernice and I struggled with and so we settle on a radiographic criteria for MRI, but the radio graphic criteria for MRI will not allow you the flexibility to treat the chronically painful vertebral compression fractures, because the stir image will have gone cold by then, just as the bone scan will have gone cold by then and that's where you can substitute a localizing X-ray indicating the level of the painful vertebral compression fracture and that will allow you to treat the chronic vertebral compression fracture based on objective criteria for indications.

That's why I'm reliving the conversations that Bernice and I had when we first set (unintelligible 01:03:55) and I had when we first set up the vertebral compression fracture registry.

Dr. Haug And Dr. Shonnard, I mean virtually every study gauged acuity by time from pain onset.

Dr. Shonnard Yes. And this is the largest study in the world and I can tell you that a little old lady doesn't have a firm date of onset. And Jason inferred it that they go through an initial vertebral compression fracture, they develop pain, they don't get to see their doctor for four to six weeks, they get in and I'm feeling better now and they then go onto subsequently compress and develop what's called vertebra plana. Think of it as a recycled can of Coke. If you step on a partially, it partially collapses. If you shift your full weight onto it, it flattens like a pancake. That's what happens to these women sequentially. So putting a date of onset is irrational and the registry proved that is not reliable.

Dr. Haug Dr. Shonnard, thank you for your comments.

Dr. Shonnard Glad to help.

Dr. Haug Operator, if we could see if there is anybody else who has comments on this policy.

Coordinator: Absolutely. If you do have comments or questions, please press star-1. Once again, if you do have comments or questions, please press star-1. We do have a question from Heather. Your line is open.

Heather Heicher Hi, thanks for the opportunity to get some clarification on this new policy or the revision of this policy. My question has to do with the four diagnosis, all saying osteoporosis. Prior to this change we - a good majority of the patients we saw were osteopenia by classification. Is osteopenia no longer included as an acceptable diagnosis? And the reason I asked this, when I was reviewing the VERTOS IV criteria, they included T-scores negative one and half, negative 2.5.

Dr. Haug Thank you for that comment. I really haven't had any comments related to that. I think I had one and it may have been from you via email. So that's - it's sort of a unique comment. I - my impression was that that the data has been related to osteoporosis, not osteopenia. But I'd be interested to have you send in a comment that includes references to the studies that you think included osteopenia.

Heather Heicher So the VERTOS IV, they asked that I clarify on my email, they actually - so what I did when I sent this second email, I cited the - I used the same VERTOS IV citation from the policy list. And in their criteria it spells out like the T-score they used was negative 1 being the cut off, but that in fact is osteopenia by definition. So how - I guess then my next question would be how do I just resend that email for them to reconsider that diagnosis?

Dr. Haug Well, I would say, you know, the one thing VERTOS IV didn't show a benefit, so that's one. Secondly, you know, if that's one study, if you could look at some of the

other major studies and see if they also included those patients. Again, this is sort of an isolated comment from my perspective and not that it's not valid, but I just haven't looked into it. But I will…

((Crosstalk))

Heather Heicher No, absolutely. I will.

Dr. Jason Levy: Craig, can I answer a little of that?

Dr. Haug Who is speaking?

Dr. Jason Levy: It's Dr. Levy. Can I answer a little of that?

Dr. Haug Sure. Go ahead Dr. Levy.

Dr. Jason Levy: Sure, so two things. VERTOS IV actually did show a benefit. You're just comparing - it didn't show a benefit compared to a sham which we don't know what the…

Dr. Haug Dr. Levy, if we could just stick to the osteopenia versus osteoporosis question.

Dr. Jason Levy: Sure. I think most people believe that - well, you had said that, so I wanted to clarify a misstatement. But I think most people…

Dr. Haug I don't think that's a misstatement. I think that's - that was - those will be official published results, but let's stick with the osteopenia versus osteoporosis.

Dr. Jason Levy: Okay. Well, the official published result did show a benefit in that population. But the difference between osteopenia and osteoporosis and I think Dr. Shonnard would agree in a low impact situation regardless of what the bone density study shows that that typically an osteoporosis defining event.

So a low impact vertebral compression deformity or a fracture is - you know, obviously in the absence of a cancer or other diagnosis that you guys have already talked about is an osteoporosis defining event. I don't think that the majority of these patients have had a definitive osteoporosis diagnosis based on bone densitometry. In fact, the vast majority of them have not and that's not currently an indication. So I think that's how I would personally read this and I would be interested to hear Dr. Shonnard's opinion.

Heather Heicher May I add to that what you just said. So in our clinic, the majority of our patients have in fact had DEXA scan and if they come to me with a fracture, that's one of the first things I do in addition to further work up is to get a DEXA scan. And what I've seen over the past - well, since December especially, I'm having patients return who've had kyphoplasty prior to or vertebral augmentation prior to the December change. They're returning with a new fracture, their DEXA scan says osteopenia and now they no longer qualify. So I am seeing them show with osteopenia just to add that. I know that doesn't have to do with our question, but I'm seeing them with osteopenia with fractures.

So my second question based on what you just said, if - I don't want to misdiagnose anyone because I don't want to be audited and on the hot seat in a case where they show with osteopenia and they have a fracture, is it acceptable for me to use the osteoporosis diagnosis code for these women for vertebral augmentation?

Dr. Haug The osteoporosis code or osteopenia code?

Heather Heicher Well, there are no osteopenia codes. The only two or four options I have, two - what, one is osteoporosis - initial one is osteoporosis subsequent and then the other two are other osteoporosis.

Dr. Haug Yes. Again, this is a first time I've really been exposed to this comment or request. If you could survey these studies out there and see if the majority of the studies support your - support coverage of osteopenia, I think that's where I'd recommend you start.

Heather Heicher (Heather): No, I'm happy to do that. I appreciate you entertaining my question.

Dr. Haug Yes. Thank you for your comment.

Heather Heicher No, thank you.

Dr. Haug Operator, do we have any others operator?

Coordinator: We have no other questions or comments at this time.

Dr. Haug Okay, then we will be closing the meeting comments on percutaneous vertebral augmentation for osteoporosis vertebral compression fractions.

The next policy is revision to the existing water vapor thermal therapy, select BPH policy. This is as I said existing LCD related to minimally invasive thermal treatment of BPH in which we made this simple revision of leading urinary retention as a contraindication. This change is made secondary to the publication of retrospective analysis showing the procedure to be a viable alternative for treatment of capital dependent urinary retention, especially in elderly and frail patients at higher risk for anesthesia and more invasive surgical approaches.

We don't have any registered commenters for this policy. Operator, can you ask if there are any other comments on this?

Coordinator: Yes, absolutely. Once again, if there are any comments, please press star-1 and I will open your line. Once again, if there are any comments, please press star-1. Once again, as a reminder, if you have any comments or questions, please press star-1. And we have nothing coming through at this time Doctor.

Dr. Haug Okay, thank you. If there are no comments on this - the comments for this policy during this open meeting will now be closed.

The next policy up for discussion is a new policy, computed tomography, cerebral perfusion analysis CTP. CT - cerebral perfusion analysis, CTP uses a sequence in head CT after a contract (goes 01:13:55) to measure various human genetic parameters related to cerebral blood flow. These metrics help distinguish brain regions with a high probability of irreversible infarction, so called ischemic core from areas with potentially reversible ischemic, so called penumbra.

Two recent major RCTs, both published in the New England Journal found that CTP help determine eligibility for endovascular thrombectomy in the late time period that being six to 24 hours after acute ischemic stroke. Both trials demonstrated a large clinical benefit with numbers needed to treat of three to four (to prevent 01:14:33) functional dependence.

Next slide please? These are the key inclusion criteria of the two studies. Both focus on those patients who seemed to have either clinical symptoms, a reversible ischemia out of proportion to the volume of irreversible infarction, a clinical core or a penumbra core mismatch, so to speak. In other words, those patients that may have more salvageable brain if the thrombectomy is performed and profusion restored.

Epidemiologic data suggests that about one-third of acute ischemic stroke patients present during this late time period six to 24 hours and only 9.2% of these or 2.7% overall meet either DAWN or DEFUSE 3 inclusion criteria.

Next slide? This slide shows the draft coverage criteria which basically requires strict adherence to either the DAWN or DEFUSE protocol as recommended by the latest AHA/ASA guidelines.

Other stroke or non-stroke indications for CTP lack level 1 evidence and are not considered medically reasonable necessary at this time. Again, we don’t have any registered commenters on this policy. Operator, can you see if there are any other comments?

Coordinator: If you have any comments on this policy, please press star-1. Once again, if you would like to comment on this, please press star-1. Again, as a reminder, if you would like to make a comment, please press star-1 and record your name. Doctor, we have no questions or comments coming through at this time.

Dr. Haug Thank you, operator. So the comments on this policy for this open meeting are now closed.

If you can go to the next slide? The official comment period ends on July 18 this year for these five policies.

And next slide? That may be the last one. Actually, that's the last slide. So thank you all the presenters and other commenters today for attending our open meeting. And operator, I think that's the - that will be the end of our open meeting.

Coordinator: Thank you. That concludes today's conference. Thank you for participating. You may now disconnect.

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