CENTERS FOR MEDICARE & MEDICAID SERVICES

Moderator: Patricia Brooks
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12:30 p.m. CT

Operator: Good afternoon, ladies and gentlemen. My name is Laurie and I will be your conference operator today. At this time I would like to welcome everyone to the ICD-9-CM Coordination and Maintenance conference call. All lines have been placed on mute to prevent any background noise.

After the speaker's remarks there will be a question and answer session. If you would like to ask a question during this time, press star, then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key.

Pat Brooks, you may begin your conference.

Patricia Brooks: Thank you very much. I would now like to introduce Ann Fagan from CMS' staff, who is going to be doing the next two topics, number eight and nine. The next topic she will be doing is Endovascular Embolization with Head or Neck Vessel Reconstruction.

Ann Fagan: Thank you Pat. OK, what we need to talk about this afternoon then is the issue of whether or not the ICD-9 coding system contains a code that will specifically identify embolization of an intracranial artery aneurysm via endovascular insertion of a stent-like device. And we have had a lot of internal chat about this topic and about describing it.

So if I could ask you to listen with many ears and with an eye towards how do we code this, how do we document it, how do we make it so that everybody

understands what it is language-wise in the coding book et cetera, then I'd really appreciate that because I think we're going to have a lot of discussion about this topic. OK, my speaker today is Dr. Giuseppe Lanzino, Professor of Neurosurgery, currently from the Mayo Clinic, formerly from Italy, but you would have been able to figure that out. Thank you.

Dr. Giuseppe Lanzino: Thank you, good afternoon. Thank you for giving me this opportunity to present today. My name is Giuseppe Lanzino. I'm a Neurosurgeon with training and who performs both so open surgery and endovascular procedure for treatment of intracranial aneurysms. Before we start, I'd like to note that in the past I've received educational grants from ev3. Before we go through the concept of vessel reconstruction I'd like to briefly review the disease that we are trying to treat.

An aneurysm as you know is an out-pouching of the blood vessel and it occurs usually at the site of that blood vessel where there is an area of underlying weakness and this is a very important concept to understand the reconstruction that we will be discussing about. Many aneurysms might be silent, some don't need any treatment, other aneurysms might grow and might compress different structures like cranial nerves and [the patient might] present with visual loss, double vision, pain behind their eye or numbness on one side of the face. A number of aneurysms unfortunately go on to burst and that causes an intracranial hemorrhage and that can have catastrophic consequences.

For reasons that are not completely clear, this disease tend to involve primarily women, especially middle aged women during the prime of their life. Now there are different ways that we can classify aneurysms. Aneurysm can be classified by size and so often we talk about small aneurysms that are equal or less than 10 millimeters, large aneurysms up to 25 millimeters and giant aneurysms, those that are 25 millimeters or greater.

The majority of aneurysms that we treat and we encounter are usually small aneurysms but 15 percent are either large or giant and those are the type of aneurysms where we have a lot of problems with the current existing treatment. Another way we classify aneurysms is also based on their shape.

So the most common aneurysm is the circular aneurysm, that's in a nice round shape, almost like a small balloon. Then there are wide neck aneurysms that are defined based on the size of their neck. When we talk about the neck – the neck of the aneurysm is the site of attachment to the blood vessel. And then there are a few simple aneurysms that, as you can see at the bottom left [of the slide] these aneurysms are – they involve circumferentially the entire vessel wall and they are extremely difficult to treat.

What are the current available treatments? The most traditional way of treating intracranial aneurysms has been surgery. With surgical clipping we need to perform a brain surgery, it's maximally invasive, but we are able, once we find the aneurysm, to place a small aneurysm clip to actually close the aneurysm.

In the early '90s, the treatment of intracranial aneurysms was revolutionized by the availability of endovascular coils. With the coils which are delivered through the endovascular route, therefore there is no need for open surgery, what we do is we try – we do our best to actually pack the space of the aneurysms with these metallic stents.

As we recognized some of the limitations of coils we start developing techniques like the so-called coil retention stent, where you can see at the bottom [slide] a stent is deployed so that the primary function of that stent is to keep the coils inside the aneurysm and prevent those coils from protruding or even escaping into the normal vessel and of causing the stroke. Now different patients can be treated with this different treatment paradigm but some of them will see there are some aneurysms where we really did not have a good treatment option until recently.

Now each of the treatment I discussed has significant limitations. Open surgery is of course maximally invasive and the majority of patients would rather have an endovascular procedure through a simple needle stick than having a major brain surgery to achieve the same goal. The other problem for brain surgery for aneurysms is that it is extremely technically a very demanding procedure and the results likely are good in the majority but not all in all patients.

Endovascular coiling as well as the concept of a coil retention stent has also limitations because if you try to imagine in your mind the three dimension of space of this balloon, you can see how it's virtually impossible with the coils to completely fill that space because there will be micro spaces in between the different coil loops. In addition for those aneurysms that are large and they have a wide neck, over time we observe the phenomenon where part of the aneurysm tends to come back because the coils are all compacted; they're all pushed together and therefore there is a need for additional treatment.

All these limitations push the people to try to think about new completely different treatment paradigm because each one of these treatments including coils that now have reached their maturity since they have been around for almost 20 years, they have very definite limitations, that we have not been able to address and therefore investigate or start thinking literally outside of the sack, outside of the sack of the aneurysms.

And therefore the attention shifted from the aneurysm to the vessel. That's why the concept I introduced before, that the aneurysm is a consequence of a weakness of the vessel from which the aneurysm itself arises, that's why that concept becomes very important because now we are not so focused on the final expression of the disease, i.e., the aneurysm, but we are trying to go at the root of the problem and therefore try to establish a procedure that will fully result in a permanent cure for the patient.

Here is where the vessel reconstruction device comes into play and you can see here a prototype of one of these devices, so called Pipeline™ is the brand name. And this device has several characteristics; it may look like a stent at the first very superficial look, but it's actually not a stent. It does have completely different engineering, it does have completely [different] characteristics that we need for this device to serve the purpose, and the other issue is that the disease we are trying to treat, i.e., the aneurysm or the weakness of the blood vessel, it’s completely different from the disease for which traditional stents have been used for, like occlusion of the blood vessel because of atherosclerosis.

One of the main properties of this device that differentiates it from a common stent is that it adapts to the curvatures of the intracranial vasculature in a way that no other available device or stent can do. How is this device deployed? Well, the procedure is done in the angiography suite or in the cath lab and it's done through a percutaneous approach through a simple puncture of the femoral artery at the level of the groin. The delivery catheter under radiography guidance is placed across the neck of the aneurysm as you can see and then the way the device is delivered it's very different than most other devices that are used in the endovascular arena.

This is the delivery through a combination of a pull and push mechanism depending on the type of [aneurysm] – and the type of curve you are working in and then the results where rotation is required in order to expose the device as it comes out from the catheter itself and also eventually to deliver the device itself from the guide wire.

What is revolutionary with this technique, and you will see clearly in some of the example, is what happens to the aneurysm. The device, because it has a very high metal in it, what it does, it disrupts flow in and out of the aneurysm and since the aneurysm is a closed pouch, if you slow a flow going into the aneurysm, that slowing of flow eventually will promote a blood clot and thrombosis inside the aneurysm.

That clot will show two functions, number one it will close the aneurysm temporarily but number two more importantly as the clot organizes, it acts like a scar and the scar what it does, it retracts. So what we have observed with this technique that we have never seen before with the current endovascular techniques is that over time if we do MRI in these patients, the aneurysm, it actually disappears and the normal vessel as you will see tends to have its normal natural native form.

So it's a completely different technology and it's completely different concept from the techniques that we had available until now which were based on trying to address the end product of the disease, the aneurysm while now we are trying to act right at the root of the problem which is an underlying vessel weakness.

As you can see in this micro photograph which is taken from the inside of the blood vessel, the reconstruction device acts as a scaffold so that a continuous layer of endothelium is formed across the device and that blocks access of blood into and out of the aneurysm. And you can see in the areas circled in yellow where there is the edge of the vessel that is now literally reinforced by the presence of the metal of the device.

More importantly there are vessels which arise from the segment that we are treating and of course we like for those vessels to stay open. These vessels indeed stay open and the reason is that those vessels, unlike the aneurysm that is a dead pouch so you slow blood into the aneurysm and eventually form a blood clot, there is a flow into these vessels because there is a distal flow of blood and as you can see in these pictures of the rabbit hole where a stent – a reconstruction device was placed, the actual side branches stay open overtime.

So that was very important for us before we start the clinical trials because we want to make sure yes, they increase the metal density of the device. It's useful to take care of the aneurysm but we need to make sure that it does not interfere with the flow into the normal vessels. Who are the patients that we think are good candidates for this reconstruction, concept reconstruction device? These are at this stage, these are patients where we don't have very good alternatives, patients with large, giant wide-neck aneurysms, patients with the shallow aneurysms, where the current technologies fail in most of these cases.

Patients who have a previous coiling and I will show you some examples, they have incomplete closure of the aneurysm, might also be candidate for these procedure. These are some of the examples and some of the results which we have seen consistently in greater than 90 percent of these patients over a period of six months to a year.

It's also important to realize that this concept is a concept which works gradually in closing the aneurysm. So aneurysm closure does not occur immediately after placement of the device because it's, as I said before, it's a slow process that takes weeks to months.

So you can see in the case of a small wide-neck aneurysm which was in a curvature of the internal carotid artery. It is a very difficult place to reach with surgery and also a place, a location and configuration which would have been very hard to treat with coils or coiling plus stenting. Placement of the reconstruction device achieves the goal of taking care of the aneurysm while reconstructing the normal shape and the physiology of the blood vessel. For the large aneurysm that I showed before, placement of the device after six months, again the aneurysm is gone and you can see that the shape of the normal vessel is maintained and reconstructed.

Same thing for this giant aneurysm, where not too long ago, about 10 years ago, we would have done surgery with the risk of morbidity or mortality to the patient in the range of 20 percent, 30 percent. Now we can treat this by simply reconstructing the normal anatomy, reinforcing that area of the vessel where the aneurysm takes place, with the results like this that as I said that we have seen a 90 plus percent of cases. This is a little bit of a different situation. This is a giant aneurysm in a patient who was progressively becoming blind, losing vision because this aneurysm is compressing on the optic nerve.

The aneurysm was treated with the coiling and the initial treatment you can see in the MRI, it was actually not that bad considering the complexity of the aneurysm with the coils filling the entire aneurysm, but you can see what happens on the left side after a few months, those coils are pushed together by the hemodynamic forces and therefore they are compacted together and now there is some space that has formed again at the base of this aneurysm.

For this specific aneurysm, coiling was a good treatment because it might have protected the patient from a hemorrhage because the aneurysm did not bleed but this treatment, the coiling, did very little to the pressure that the aneurysm was exerting against the optic nerve and because we treated the aneurysm itself with more coils which are metal so that pressure effect persisted. And on this patient, placement of the reconstruction device results in a complete occlusion of the neck of the aneurysm and treatment of that vessel as well as of the aneurysm.

At the time this patient was in treatment, the reconstruction device was not available, probably this patient would have regained a vision with two months after the treatment because not only we were able to close the aneurysm but they showed in those examples before the aneurysm actually starts shrinking after treatment because we are reconstructing the vessel. Now there are some key documentation points and I am not guilty but I am told that physicians, we don't do a great job in precisely describing what we do.

We think we are describing very detail what we do but I know very well that when you go and try to extract from our dictation what you need for documentation it's a nightmare. So the potential keywords that coders might find for this type of disease and for this type of treatment which again this is revolutionary treatment. It's completely different from what we have been doing until now. It could be aneurysm and repair, embolization, endovascular reconstruction, then it's important again to stress that the device is used alone as a standalone device in the majority of patients.

There is no association with coiling as we saw in the use of the coil retaining stent. There is a very clear cut difference between this procedure, this device and the traditional stents that we used to reopen occluded blood vessels because the disease is aneurysm and in the other case it’s atherosclerosis. There is no need of when we – use a so-called dilatation stent to reopen a blood vessel. That is usually needed for angioplasty before deployment of the stent or immediately thereafter because there is that (inaudible).

With this device occasionally, there might be need for a balloon but that's not to do an angioplasty. That [balloon] has been used occasionally as a salvage procedure, because as you can understand with any device as we start our experience we find out that not every device might deploy perfectly to conform to that curvature of the vessel. In the initial experience occasionally, as a salvage procedure, there was a need for a balloon or other tricks to try to reopen a device that had incompletely deployed.

My experience has been one case out of 40 plus devices deployed, in almost all, close to 20 patients now. I suspect and I foresee that as we gain more experience and the devices will improve, this issue of needing a balloon in a

small percentage of case will become less and less, but again, even when the balloon is needed it's a salvage procedure to deal with the technical complication. [This is] different from the balloon angioplasty that you are used to seeing when we reopen blood vessels.

Other words that you might find in the charts are Pipeline, which is the brand name for the devices that approval is pending or PED which is an abbreviation for Pipeline™ Embolization Device or PVR (Pipeline) Vessel Reconstruction. Occasionally, you might see the word embolization stent but as you have seen there is a significant and key difference in the type of disease we are treating and the type of device.

And here just let's briefly discuss the issue and the use of the word stent because it does – it's such a common procedure that as physician we have become very used to generically label and talk about stent for any tubular structure that we place in or around a blood vessel but as you can see in this slide there is a significant difference between what I would call a dilatation stent that is used for Atherosclerotic disease usually or to treat an occluded blood vessel.

It's a coil retention stent which for intracranial aneurysms has been used but it's not a standalone procedure. Those stents like the Enterprise or the Neuroform they have significant differences between them and the reconstruction device. The metal ratio it's much completely different, the density of the straps is completely different. The Neuroform and the Enterprise they perform rather poorly around curvatures and it's not been significant the incidental delayed movement of the stent, because the stent tends to slowly bounce back to the straighter segment of the vessel.

With the embolization so-called stent, but I will not use that word because it is an embolization reconstruction device. We are number one treating the underlying weakness of the blood vessel. We are not trying to reopen an obstructed blood vessel. It's a standalone procedure, it does not require the use of additional coils and unless a very few cases where we might run into a complication and you might need a balloon to open an incompletely deploy the device. There is really no balloon angioplasty.

I think that it is very important to especially since we are I think at the beginning of an era where we have a new revolutionary treatment for intracranial aneurysms, it would be extremely important to add a separate code also so that we are clearly able to track down the use of the procedure which aneurysm this procedure is used, to track outcome both short and long-terms, otherwise this procedure might be bundled together with other procedures which as you have seen and now you're clearly recognize our completely different from a methodological and also from a conceptual point of view.

I'll be happy to answer any questions if you have.

Operator: I would like to remind everyone if you would like to ask a question star one on your telephone keypad.

Dr. John Cooper: Hi I am John Cooper, a medical officer here at CMS. I have two brief questions. I was just curious; in your descriptions about other types of therapies for the aneurysms you described the clipping of circular aneurysms. Could you give us a little bit of description on what happens to the native vessel and once in terms of remodeling once the aneurysm is clipped?

And then the second question is what was the, I am noticing in your notes that sometimes you referred to what the Pipeline device does as a being a support for vessel remodeling and also being described as a reconstruction device. I just wonder if you could bring some clarity on the decision between the distinction, how you see this distinction between the two?

Dr. Giuseppe Lanzino: Sure. The question – the first question is what happens to the vessel after surgical clipping. The principle of surgical clipping is to place a clip, to clip together the base of the aneurysm so there is no blood flowing into the aneurysm. The clipping itself does very little to the native vessel.

As a matter of fact it's not unusual especially in those patients who have an aneurysm and they are young, especially if they are smoker and they have hypertension, not uncommonly after 10, 15, 20 years. We see a recurrent

aneurysm in the vicinity of the clip which is not their original native aneurysm. It's a different one that has formed because the clip does little to address that intrinsic weakness of the blood vessel.

As far as the second question about the PED being used, addressed as a reconstruction device and as also to perform to add the structural strength to the vessel wall. I think that those are complimentary characteristics of the device as it applies to this disease because the remodeling of the vessel, it's actually a remodeling of flow inside the vessel, so that flow follows more the normal natural pathways and it's diverted away from the aneurysm.

So that characteristics is very important to promote aneurysm thrombosis and eventually shrinking of the aneurysm and then there is the other component which is related to the characteristics of the device itself, that by placing an endovascular device across a weaken segment by the nature of the device itself you provide not only a structural stability to the vessel wall which is weak to start with but also provides a scaffold so that new endothelium can (hold with that) device and further promote exclusion of the aneurysm.

So I would view those characteristics are often used to describe the device because they are complimentary futures of the device as it applies to the specific treatment.

Ann Fagan: Are there additional clinical questions in the house? Operator, do we have any questions on the phone?

Operator: There are no questions in the queue at this time.

Ann Fagan: OK, thank you so much. OK, you can see that we started with option two that's just because some of the technology is a little (inaudible) and I was telling trouble just creating these slides and whatever. So option one always is and has nothing to do with the device, is don't do anything, leave the system as it is. Option two, create a new code. OK, basically, excuse me; what we've got at 39.7 is an existing code at 39.72 endovascular embolization or occlusion of head and neck vessel.

If we go with the new code what we would do would be to add an exclusion note that excludes the endovascular embolization with vessel reconstruction. Then same thing at 39.75 which talks about the bare coil and adding the same note to exclude vessel reconstruction at 39.77 a new code and again at 39.76, which we had just created these codes are bare and bioactive coils. So leaving the coil type in fact we want to exclude codes that would be – that people like confused about, OK.

So then the option is to create a code at 39.77 endovascular embolization with head or neck vessel reconstruction, this isn't right, OK, let me get my notes. We remodeled these slides again and again. The new code would actually read – I'll do it slow in case anybody wants to write these codes down.. Endovascular embolization with head or neck vessel, vascular remodeling support, and then we do not have a note that says it's not performed with angioplasty or atherectomy and then we do have inclusion notes as shown embolization stent, a stent-like device and that for repair of aneurysm.

All of those are just to help the coder understand that yes they are in the right spot. Additional tabular changes that we would make and this looks to be OK, at 00.6 procedures on blood vessel at 00.63 percutaneous insertion of carotid artery stents, we would exclude that for head or neck vessel reconstruction and send them into 39.77, likewise the 00.64 same note and 00.65 which would be probably more the code that would be that of choice for a coder - percutaneous insertion of intracranial vascular stents.

OK, now here is the thing. The documentation in the record is everything and when the coder reads that some sort of angioplasty or balloon device may have been used, they know what that means. And they go to what that means which is atherectomy and they code that and then they code 00.65.

So this is a bit of a problem, if we're going to differentiate this particular code from the other things that are going out there and those of you who have suffered with me through the cardiac issues know that there is an awful lot of very similar out there and they have different names and different intents and different applications but they are very, very similar and it's up to the coder to kind of figure out with the best documentation that they've got, what exactly

was done for the patient and what is the best code and you know all the things that go along with data collection et cetera.

So we really want to hear from you about this proposal, what do you think in terms of language and includes notes. We've had a long standing tradition of not putting where it's like the name of the device Pipeline™ in the tabular. So people who code, go shopping in the tabular, you wouldn't see that, they would have to shopping in the index first where we do put the names of devices. And so we will do that, we'll put Pipeline™ in the index and hope that it translates into the coders the way of coding, and make as many modifications to the index as we can.

If you think that we can do better with the title of proposed code 39.77 vascular remodeling support, then fine, please suggest that we look forward to your -Nelly.

Nelly: No, it's just question because I am not sure if I missed it. I think on the slide that you had for 39.77.

Ann Fagan: Right.

Nelly: There was a note on the screen that you said there was a mistake, right?

Ann Fagan: Yes.

Nelly: But I think there was note at, I am not sure if it was 39.75 or 39.76 and I wonder if you meant that that was also…

Ann Fagan: What I meant that was that the note at.

Nelly: No, I think it was the slide before this one, yes at 39.75 and 76 those notes, is that correct or because this is not on my handout.

Ann Fagan: Thank you that shouldn't have been there either.

Nelly: OK.

Ann Fagan: We meant to mention that too. OK, we there is a company out there (inaudible) and they have a product called Neuroform which is a stent that holds the coils in the aneurysms. This is kind of new news and so we said well we'll make this little change, (inaudible) has prevailed and said well let's get that company on any decisions we make about their products and so let's yes those notes should not be there too.

Here is what I propose. I propose that you all flood me with information and good ideas about where we should go with this, that we will talk to the Neuroform people and say this is what we want to do with identifying your device and as a coil retention stent and then we'll try and make sure that anything that's done with the proposed code at 39.77 is more easily understood by coders and it's really able to they just say yes that's one of those new devices and what not and here is what's going to happen. You'll see this again in March.

When you look at the proposed rule, I know everybody here reads it. When you look at table 6B for the new codes, you're not going to see 39.77 as a new code because we're going to discuss it again in March and the only new codes that show up in our proposed rule for IPPS, DRG proposed rule in March are real codes that are firm and ready to be implemented next October. This one is still under discussions.

We won't have a full fledged presentation because we've already done it here but we will discuss it again and try and come up with synopsis or summation of what you all have told me that you think is a good idea that you wanted to look like the language, et cetera.

We were also have given (inaudible) another opportunity to comment. OK, are there any questions about that or any other comments on the coding portion? Say your name.

Linda Holtzman: Hi Ann, this is Linda Holtzman Clarity Coding, you may have missed this Ann, but I worked on this proposal just, full disclosure. I might of had a brilliant idea last night. Could you just go to 39.77 again? OK, actually I might have had two brilliant ideas I am not sure if they are brilliant are not

though, on 39.77 if there is some kind of salvage ballooning that's taking place just to try to get the device to open or whatever it is, maybe we could have an inclusion note that says something like includes any ballooning performed or something like that.

There is on the CPT side just for what it's worth, on the CPT side they sometimes will have notes that say something like you know includes any ballooning during within the target zone and maybe that's a concept that could be transferred here. So perhaps an inclusion note on 39.77 that says includes any ballooning performed in the area.

Ann Fagan: OK.

Linda Holtzman: Something like that and then on the next slide which had the 00 right.

Ann Fagan: Right.

Linda Holtzman: The second potentially brilliant idea that I had is that there is notes, there is current notes in ICD-9-CM on stent code 00.55 and 39.90 that say those are the peripheral stenting codes and they say excludes that for aneurysm repair and that might be a good note to put on here because we already know those notes help the coders get redirected with its peripheral vessel, so it could work just as well here with the carotid precerebral and intracranial. It's already a precedent.

Ann Fagan: OK. Duly noted.

Lisa Brooks Taylor: Lisa Taylor from Resolution health. If you could go to the 39.77 slide.

Ann Fagan: Let's see if I can get this right.

Lisa Brooks Taylor: When I see the term reconstruction there in this title, it implies to me that an actual physical reconstruction of the vessel is occurring during that procedure event and so the wording that you've verbalized for changing it to remodeling which is the stent is inserted and the body remodels the vessel, I think is more appropriate than using the word reconstruction.

Ann Fagan: OK, thank you. Are there any more comments in-house? Operator, do we have any comments on the phone?

Operator: If you would like to ask a question star one on your telephone keypad. There are no questions in the queue at this time.

Ann Fagan: Thank you operator. OK, Lisa.

Lisa Brooks Taylor: Lisa Taylor from Resolution health. Also I am wondering looking forward, are we going to start seeing that these codes will be expanded because these stents are now bioactive, I mean are we going to end up with a great, an expansion due to the further evolution of the technology.

Dr. Giuseppe Lanzino: Well at this stage we don't have prototypes that are reconstruction devices that are modified biologically but it is possible that the technology above that could be a possibility in the future, sure.

Ann Fagan: OK, is that it then? Well thank you very much and please, please, please write to me. OK, I am still standing here so I am just going to go ahead. The next topic which is on page 44 of your handout talks about the Fenestrated Endograft Repair of Abdominal Aortic Aneurysms and it is my distinct pleasure to introduce to you Dr. Tara Mastracci, Assistant Professor of Surgery at the Cleveland Clinic.

Tara Mastracci: Got it. Hello, thank you very much. It is truly an honor to be here to talk about fenestrated endografting and the treatments of complex aortic aneurysms using an endovascular approach. I work at the Cleveland Clinic where I have the distinct pleasure with two other partners of performing quite a few of these procedures and so I hope I can walk you through how it is that they are different from a common infrarenal aneurysm and also the settle piece in the technique itself.

I must tell you for full disclosure that I am here at the expense of Cook [Medical] and I do consultation for them on a regular basis as they are the only really fully developed fenestrated stents currently being used. So I want to start very simply and discuss the whole concept of the aortic aneurysm, as

you know the aorta is the main blood vessel that comes out of the heart, arches around through the chest left off blood vessels to the head and arms.

And then at the level of the diaphragm or the diaphragmatic crest it also puts our vessels to the visceral organs such as the gut and the kidneys where then it becomes a straight shot to propel this and it splits into two and goes down through the pelvis into the legs. An aneurysm of the aorta is when that big blood vessel becomes bigger than it should be and the ideology of that is multi factorial.

We usually attribute it to people who have smoked but certainly there are genetic predispositions and genetic factors that can cause an aneurysm to occur. Now it is actually a relative prevalent disease and we know this because there has been four large randomized control trials in North America, Europe and Australia looking at the prevalent in men and some women over the age of 65. And in men over the age of 65 it occurs approximately six percent of the time and certainly within that group are more commonly smokers and people who have first degree relative with aneurysms.

It seems to occur less commonly in women and when it does occur it occurs in women at an older age group. The rational for surgical intervention on an elective basis or on a non-urgent basis is a 100 percent to prevent the risk of rupture and spontaneous death and so we always treat an asymptomatic condition in this case in order to prevent death or ultimate mortality.

It would be somewhat unethical to carryout aneurysm to the course of their natural history at 15 age, but luckily many years ago some scientists actually did that and surgeons observed to their patients till the end of their disease and found that it is truly a fatal disease, in fact your likelihood of dying with your aneurysm is far more likely if it's not treated.

So we do know that we have a very good surgical intervention that changes the natural history of this disease and therefore it's something that we offer to our patients quite routinely. The risk of rupture is somewhat difficult to quantify but we know that it's non linear and the best technique we have to determine the risk of rupture is really measuring the maximum diameter of the

aneurysm. So imagine like a balloon, the larger it is, the more likely it is to rupture or pop and that doesn't seem to get bigger as the vessels goes from four centimeters and we assume in vascular surgery circles that anything below three centimeters is normal.

So as the aneurysm goes from four centimeters up to seven centimeters the risk of rupture increases in a non-linear fashion. And ruptures are indeed lethal, there is a very good reason to treat these patients before they rupture. It's the most, it's most common cause of death in this country, 66 percent of patients who rupture will die at home or on route to the hospital.

Once they get to the hospital the treatment of the disease becomes a lot more lethal, if a patient is already ruptured, half or 30 percent to 50 percent of patients who actually rupture and are treated and make it to the operating room will die within 30 days of their surgery. Contrast of that with elective surgery who are non-urgent surgery in a setting where a patient has not ruptured and the risk of death within the 30 days of surgery is usually one to five percent. So much lower.

There is a lot of good reasons to catch these patients early and to treat them if we can in a non-urgent manner. Now discussing aneurysm is intrinsic in discussing the anatomy of the aorta, because where an aneurysm lies in the aorta really makes a big difference in how we're going to treat it and you can imagine that an aneurysm that lies in the branched segments of aorta either in the visceral segment or up in the arch becomes a lot more complex because we have to worry about not only the aorta itself but all the associated pluming that comes with it and so there is major reconstruction that's required.

Our field at the clinic and people who developed complex endovascular devices really deal with the entire aorta and learning to fix an aneurysm and replum the entire body as you would imagine. Now there is a certain size at which we know aneurysm repair is beneficial and this is because there has been two randomized control trials looking at surveillance of aneurysms over time versus intervention as soon as we find the aneurysm and really there is no benefit in intervening in an infrarenal aneurysm, so an aneurysm in the lower portion of the aorta before it's about five or 5.5 centimeters.

Similar trials have not been done for thoraco-abdominal aneurysms. So all that's left for us to extrapolate and because the complexity of the disease is a lot greater when we have to include the visceral aorta or the thoracic component of the aorta. We usually assume that the threshold for intervention is a little bit bigger. So we treat patients who are six or 6.5 centimeters when the aneurysms become more complex. We let them grow a little bit bigger.

So currently our treatment option for aneurysms are too full, open and endovascular repair. Open repair has been done since the mid 1950s and is a very robust and good operation, however you can imagine it's one of the largest operations we could do on a human being because it really does require opening both the chest and the abdomen in order to get to the aneurysm where it lives just resting along the spine so way in the back of the body and we can do open repair in the thorax alone and the abdomen alone and then bundle when it comes a thoracoabdominal aneurysm in both cavities together.

Endovascular repair has been really around since the early 1990s and its development has followed similar course. It started in the infrarenal abdomen and so endovascular repair can be done there alone, it's very quickly been adopted for the thoracic aneurysm because you can imagine not opening the chest or something that helps a lot of patients with this disease.

And then finally and where we are right now is developing something that will bridge that vascular or visceral segments of the aorta where we bundle both abdominal and thoracic procedures together, however it adds a great deal of complexities to create a endovascular stent that has branches on it and that's where really our discussion for today begins.

So as I said up until now the historical goal standards for open – for aneurysms repair and the infrarenal aorta has been open surgical repair. However now that endovascular devices has been developed, really since 2006 in this country there are more endovascular repairs being done in the infrarenal aorta compared with open repairs and it's really the standard of care now in vascular surgeons minds across the globe.

So what we've seen is the burgeoning of endovascular devices and the infrarenal aorta and it's really been great for patients because we've taken the mortality of a procedure from five to six percent down to one and two percent in most people's hands in far sicker patients who may have been just not allowed care before.

So really endovascular repair is a lot better for infrarenal aorta and this is just further evidence of that, the number of procedures done according to MedPAR data seriously has slipped scale since 2006. Now to explain to you the difference between an infrarenal aorta and juxtarenal aortic aneurysm really talks about what we look for when we define an aneurysm. So a normal aorta has nice parallel walls- aorta, it looks like a host something that you would expect an aorta to look like.

When an aorta becomes aneurysmal the walls are no longer parallel, they become thrombus lines, they become quite disease looking. So really the critical definition or difference between a juxtarenal and infrarenal aneurysm is how much of that normal wall is below the renal artery, because that makes a difference in for open repair whether or not we're going to have to re-implant the renal arteries so take them off the aorta and then subsequently reset them on to our repair or if we can just kind of cut the aorta below the renal arteries and leave everything else the way god made it and that's the difference between infrarenal and juxtarenal Aneurysm.

Juxtarenal repair is obviously a great deal more complex even the open cousin of juxtarenal repair. We need to re-implant the renal arteries; it comes with a five to seven percent risk of renal failure. So it is a lot more morbid for a patient and therefore more complex. In some patients, we even need to enter the chest in order to get good exposure of the aorta. So the link that possible stay and the entire procedure becomes quite longer.

Thank you. For endovascular repair the common infrarenal kind and this is what I've been describing as becoming standard of care in this country, you'll notice that there is a nice area of parallel walled aorta below the renal arteries, so our stent graph goes in along the railroad wire that we put in there and

we're able to deploy it hopefully if the video runs. As you see here within the aorta and in a modular fashion realign the inside of the aorta so that we redirect blood flow, protecting these fragile walled of aneurysm and allowing the blood to flow really in atomic way through the stent itself.

You'll notice that there are numerous pieces of this stent being put in and that allows us to kind of tailor it to what the patients different sizes are and you'll notice that up here the stent has landed in the parallel walled aorta in what we call the ceiling zone so that no blood can seep around the edges. There is an area of stent above the main stent-graft that's uncovered with little barbs in it to hold it in place. So this is our active sensation to hold it in place and the blood can still flow through to the renal arteries as needed.

This is a perfectly repaired infrarenal endovascular repair and you can see that the principles of this might be carried through to the visceral aorta, if we could figure out a way to make little holes in the stent-graft itself. And in fact that's exactly what happened. We noticed as infrarenal aortic devices became more and more used and people started pushing the limits of what kind of aortas they could implant them in, the next that some physicians were accepting we're getting shorter and shorter and as a result the complications of endovascular repair were starting to be seen more where we would get flow around the devices.

So we had to do something to help extend the repair upwards so that we could pick whatever ceiling zone we wanted to make it a good repair. And in fact that's how endovascular devices were born. If you can make out this middle diagram here we can pick parallel walled aorta that's above branched vessels because the main body of the device itself have little holes in it that we can accommodate a stent in as you see here in this model. And within the body here you could see that the stent goes up and extend beyond the vascular or visceral portion of the aorta but it still allows blood flow.

Now it's beautiful and we've been doing it first in dogs in 1994 and since then in humans and it works very, very well, but it adds intense degree of complexity to the procedure itself. First of all the more stents that need to be placed, so depending on how much of the aorta is covered, the pieces are

modular and they come in pieces and it does require more time to implant them and also some more technical skills to be able to manipulate the area of the aorta that's branched because each of those little holes have to be made with the smaller stent that directly lines up with the holes in the aorta. And here is just the cartoon diagram of what it would look like if we put a fenestrated in.

Same thing we'll have a wired railroad but now you'll notice that our stent-graft is deployed above where the renal arteries are and in the operating room under x-ray vision I have to align this stent-graft so that the hole directly match up with all the kidney arteries, it takes a bit of siblings and once we do that though we're able to place a wire up from the other side and stent into both of the visceral portions of the aorta here, so that it stays in place and then the stents themselves you'll see in a sec, or actually deployed so that they act as little (pivots) to hold the main body in place and also allows blood flow to occur into the visceral portion of the aorta.

A phenomenal advance in technology that also quite a bit of an advanced in the skill set needed for the surgeon who is placing this in you cath lab. And here we are placing it uncovered stent in and the balloon is flaring it in place. Same thing on the other side and you can imagine if this was extended up to the SMA or celiac artery, it would be the same process over again but the more process does take a bit longer.

Once we've gotten this portion done and there is good flow to the kidneys, we then need to go back and do the rest of our routine, infrarenal repair which includes placing a bifurcated piece just like in the old system and then additional modular limb pieces so that we can exclude the common iliac arteries as well, a brilliant fix for a very complex aneurysm in patients who have a great deal of comorbidities.

However it is considerably more complex than a simple infrarenal repair. This is the example of one of my patients in whom this procedure was done. You'll notice that there is stents for both renal arteries for the SMA and I left just a simple fenestration for the celiac so that they would blood flow but no stent was needed and you can tell by the overlapping segments of stent-graft

that there are modules of other stents placed in here. This is a 3D reconstruction of one of our post-op CT scans.

So just to kind of make the point further, there is clearly a difference in the procedures. If you look at the procedural time fluoroscopic time and the x-ray contrast needed for both endovascular repair versus a fenestrated aneurysm repair, there is a significant difference. Now these numbers are little bit old and we've been able to whittle away all of these parameters with new technology and better contrast but the bottom line is the difference still exist. It does take longer to do a fenestrated repair and it does take more materials.

In summary, aneurysms are a major cause of morbidity and mortality in the Medicare population and I think it will become a bigger cause as our screening becomes better and endovascular repair is certainly becoming the standard of care for infrarenal aneurysms and likely so, because there is clearly a benefit, a survival benefit for patients who have this compared with open surgery.

There are a significant number of patients who do not fall within the standard infrarenal endovascular parameters and therefore need a different device in order to accommodate their anatomy and that device what we've been finding has been the fenestrated repair and so therefore fenestrated endovascular repair really offers treatment options for patients who would otherwise have to have a much larger open surgery and these patients are often quite sick or at least sicker than their infrarenal counterparts and the procedure is certainly a little bit more complicated.

So that's all I have to present, but I am happy to answer any questions if there are any from the audience.

Operator: At this time if anyone would like to queue up for a question star one on your telephone keypad.

Ann Fagan: OK, thank you so much. That was excellent; apparently there is no questions because you described it so well. OK. So here is the deal. Option one again,

no new code because we have one at 39.7,1 Endovascular implantation graft in abdominal aorta.

However, this is a pretty different device because it's got a lot of branches and of what not so we've suggested that we create a new code as follows, that we take a look at the category 39.7 endovascular repair, I am sorry, endovascular procedures on vessel or vessels and revise the code title at 39.71 to say endovascular implantation of non fenestrated graph in abdominal aorta that the underlying parties to revision. And adding an excluded note that says don't go here go over here to 39.78 to the fenestrated graft.

The new code would look like this; 39.78, Endovascular implantation of fenestrated graft or grafts in abdominal aorta and then has the code also, yes, code also any insertion of the peripheral stents and non-drug-eluting, et cetera that you've seen on other stent applications. So that is what the new code would look like. There is actually also a couple of inclusion notes that didn't get to this particular slide that would be also infrarenal or IR repair which is something that coders might see in the records or juxtarenal JR repair which coders might, excuse me, might see in the medical records.

So for the interim coding use the existing code at 39.71, which describes the standard procedure of endovascular implantation graft in the abdominal aorta. Our recommendation is to, our recommendation is missing, our recommendation is to go with option two. Now for those of you that are on the phone and in the audience and who printed out your background papers, they look a little different from this slideshow. The printout is correct, the slideshow is not correct.

So that's our recommendation at to create a new code at 39.71. I saw a little bit of head nodding agreement.

Nelly Leon-Chisen: Can you clarify what part of this slide is incorrect because I think on your slide 39.71 the code title actually includes non fenestrated? Is that correct or not?

Ann Fagan: Let me …

Nelly Leon-Chisen: Because part of my question is going to be then what would the default code be when this documentation doesn't tell you whether it's fenestrated or non-fenestrated. So we need to know an, we'll need an NOS option because I can't see hospitals having to ask the doctor every single time this is fenestrated or non-fenestrated?

Ann Fagan: Would operative notes say fenestrated?

Tara Mastracci: Likely it would say complex endovascular repair or fenestrated, but you will know just by the presence of all the additional stents into the small vessels that's really not present in infrarenal repair.

Nelly Leon-Chisen: It's going to be very difficult for the coders to do that plus we're not allowed to interpret like that so I mean I think we'll need some little more guidance or if you think most of the time it's going to be non-fenestrated that maybe you put the NOS option under 39.71.

Ann Fagan: OK.

Linda Holtzman: Linda Holtzman. I am confused on what we're supposed to do with the stents in the branches; because what's on the slide says has notes. Could we move to next slide? Right, on the slides the note says to go ahead and code the stent separately within in the package, it doesn't have this. So I am not sure which one is.

Ann Fagan: This is wrong.

Linda Holtzman: That's wrong.

Ann Fagan: Yours is right. Yes, first time ever.

Linda Holtzman: So then the question becomes what do you want us to do with the peripheral stents. Do you want us to code the stents in the renal separately or you now want us to put them separately?

Ann Fagan: We have I think at 39.7 there is an instruction about at the top of the coding that she is going to look up. OK, so Nelly what you were asking about your which one would be the other is default 39.71, Endovascular implantation of

other graft in abdominal aorta, would be the default. And we can make that more clear in the index.

Lina Holtzman: So it's 39.7.

Ann Fagan: 39.71 is other and 39.78 is the proposed new code. At 39.71 we would add an excludes note that says don't go here, exclude the endovascular implantation of fenestrated graft in abdominal aorta.

Linda Holtzman: So at 39.7 if category level there has an exclusion note for insertion of peripheral stent and also for angioplasty, so we would not code that separately. Is that correct?

Ann Fagan: OK. I apologize for the confusion about what you're looking at if you didn't print the background paper.

Lisa Brooks Taylor: Lisa Taylor, Resolution Health. I have a question with the extended length of time that is required. Is it because of the insertion of the peripheral stents into those other vessels and therefore with the code that exists works now for the abdominal deployment of the graft and then the addition of the peripheral stent could, would that take care of that length of time issue that is required or is insertion of the fenestrated stent in the abdominal aorta portion, is there a significant difference in the amount of work required.

Tara Mastracci: It is more complex to put in a fenestrated graft compared with an infrarenal graft there are no branch vessels that we have to worry about cannulating for an infrarenal graft. Does that answer your question?

Lisa Brooks Taylor: What explains the additional length of time?

Tara Mastracci: What explains the additional length of time, is the use of more procedures, more stents. So imagine a separate renal artery stenting times to plus an SMA stenting and then the replacement of a main body of an aortic graft, so all of those procedures take extra time.

Lisa Brooks Taylor: All right so what I am thinking is just keep the endovascular implantation of the abdominal aorta for that component whether it's fenestrated or not and then add the codes for the insertion of the peripheral vessel stent.

Ann Fagan: I understand what you're saying, OK. Keep 39.71 as it is and then add on additional code for other stents that are inserted at the time.

Lisa Brooks Taylor: Which would then impact the DRG assignments, probably showing?

Ann Fagan: We don't talk of it, no, no.

Lisa Brooks Taylor: But additional work in that procedure event.

Ann Fagan: OK and in your mind it is more elegant to have several codes than to have one code to describe the fenestrated.

Lisa Brooks Taylor: You're showing code also all of those other stents.

Ann Fagan: And I told you that was wrong.

Lisa Brooks Taylor: That's right.

Ann Fagan: Let's turn that off.

Jeanne Yoder: To consider if you are going with that method is that when you are trying to do the fenestrated one, evidently as according to the document there is a lot of additional preparation time because you have to go in and map the aorta to find out we're all of the little openings and so you have to do that an extra mapping which is involved in just the regular process stents in there and then you have to get it in their position correctly, so I think there is still more work involved in just getting the basic fenestrated stent in as opposed to just putting in a stent and then there is also more time during the OK, good she is saying yes.

Ann Fagan: OK, for the transcriptionist that was Jeanne Yoder.

Tara Mastracci: Yes, you're correct it's a completely different device. It is custom made for the patient itself. It's very different than putting in a simple tube graft for an infrarenal you are totally right, it's a very different device.

Ann Fagan: Are there any other comments in-house? So you'll write to me on this one too. OK, operator, are there comments on the phone lines?

Operator: There are no questions at this time.

Ann Fagan: Thank you very much operator. OK, thank you.

Pat Brooks: OK, we'll now go to the last two ICD-9 topics for the day then hopefully we're going to have time to let CDC start her, their diagnosis issue then we can close. Mady Hue is going to come up and do item number 10, Contrast Dye Removal, and item number 11, Addenda.

Mady Hue: For those of you following along, we're on page 48 of the agenda and handout packet. We're going to discuss removal of contrast dye and the issue is that currently there is not a procedure code to describe the removal of dye. I'd like to present Dr. Robert Van Tassel from the Minneapolis Heart Institute to discuss the clinical portion.

Dr. Robert Van Tassel: OK, thank you. Well I certainly appreciate the opportunity to present to the committee today a very novel technology to address the field, address the problem in a field that we have not had before. The problem is been there for over 30 years but without a good solution and what I would like to discuss with you is this solution to a very old and chronic problem.

Just to introduce myself. I've been in the cath lab for 26 years at the Minneapolis Heart Institute. I've served as Senior Consultant in Cardiology at the Abbott Northwestern Hospital in Minneapolis and at the Minneapolis Heart Institute and served as a Clinical Professor of Medicine at the University of Minnesota. During that time I found at the Minneapolis Heart Institute and I say all of that I served because I retired in January.

So I am no longer in the clinical practice of medicine and during that time I worked with a variety of startup ventures and developing tools that we used in

the cath lab and as you heard earlier today a lot of the things we do in the cath lab and as the surgeons do in the endovascular repair, require tools and devices and frequently the companies will come to those of us that are doing that is they have at Cleveland and we saw earlier today and I've had the opportunity to work with them and as a point of disclosure I am working as a consultation with Osprey Medical, the company that is developing this device.

This is contrast-induced nephropathy and if you think of contrast, that's really a clear liquid. If you look at it, it looks like a glass of water, but in that glass of water is iodine and the iodine is connected to the molecules and they are such that when we put it in the body and then expose the body to radiation to x-ray, the x-rays are deflected off from that and they give us an image and it's that image that we use to look at the aorta as in the previous presentation or my own field in cardiology, the heart.

So this dye is injected into the heart and here in this little panel on the right, we have the left coronary artery and we've injected dye and as I said the x-rays are reflected off from that and it gives us that image but that dye has to go some place. There is only two places that it can go, either the – the liver can metabolize it or it has to be excreted by the kidneys and in the case of a contrast or some people use the word dye that's excreted in the kidneys and for most of us in this room that would be absolutely not problem at all.

You would feel a little warm when we injected that dye but the kidneys would get rid of it, you would pass it and it would be out of your system. Unfortunately, if we have any preexisting risk factors that make the kidneys susceptible that dye can be toxic and the dye is toxic in a couple of ways. The best way to think about is if you put a little acid on your hand and it would burn your hand, well contrast is tubules in the kidneys the same way. It actually is a direct (inaudible), a direct irritant to the kidney and it affects the tubules.

But perhaps more important, one of the other things it does is it causes the vessels to constrict. Think of putting your hand in ice water and you pull your hand out your hand, your fingertips are white, that's because the blood vessels have constricted down and when that blood or that contrast leaves the artery

of the host it's excreted through the kidney, it’s directly toxic and it causes just constriction which causes further damage.

Now we use this contrast media and you saw several just in the previous presentation of the dye that's used so that they can place those graft, we use that in the heart in order to outline the coronary anatomy, we could do a coronary angiograms, angioplasty which is the biggest field for us right now in cardiology and of course coronary stenting.

And as I mentioned, contrast is very, very well tolerated and 97 percent of people is absolutely no problem, but it's not well problem in people, it's not well tolerated in people with high risk. Now, what are the high risks? Now one of the things we have to do in the hospital in our field of cardiology when a patient comes in for an angiogram or stenting we have to sort of (shift and sort) a little bit.

We have to pick out that 97 percent that we're certainly going to do pretty well and pick out that three percent that might have problems and so we know that certain people if they have chronic kidney disease they are very high on the list, they have problems, people with diabetes and probably that relates to their kidney disease as well but there is a variety of other things that also play a role.

Congestive heart failure for the patients is heart failure that plays a major role. If they are hypotensive, their blood pressure is low, that plays a role. There are certain medications, high blood pressure pills, that you may be taking and if our nurse clinicians note that they quickly tell us about that and we treat those patients differently, not all blood pressure pills but certainly some of them called ACE inhibitors. There are certain pain medications that make it more likely. So there is a variety of things that cause and when we see those things light up on our chart we then treat that patient a little bit differently.

Now does it make any difference if that small percentage of people we make matters worse for them or I'll just show some slides all of these now are within eight years so these are up-to-date studies. And if you look here and if you

look at the people in blue, these are the people with contrast-induced nephropathy.

The mortality rate at one year is about three to four times that that if they don't have it. So the people that developed kidney problem secondary to the dye that we use in the catheterization lab have a three to four times risk of dying in that first year. Now if you carry that out to five years, that goes up to almost 50 percent mortality rate in that group. So we can make matters in off a lot worse when we use that dye on people who don't tolerate it.

Now in addition to the mortality rate, it makes difference to other people as well, certainly those of us that are involved in healthcare to healthcare delivery and costs, it's a very high cost as you might imagine. There is an average of just the average case of four additional days of hospital stay and during that time we're monitoring kidney function, we're hydrating the patient, treating them, make sure his blood pressure is satisfactory because we don't want that kidney disease to get worse.

And as I mentioned they are more likely not only to die in a year but those that survive are more likely to have long-term kidney disease. Well what do we do about it, I had mentioned we try to pick these people out that are at risk and we find those people at risk, what do we do and I think the interesting thing and the thing that intrigues me about this entire device, this entire field is that I was in the cath lab for 26 years and what we're doing today is pretty much exactly what we were doing 26 years ago.

We really don't have a device to take care of this. What we do is we try to manipulate things in the patient. One probably, the two most important things are hydration management. If you are dehydrated and we put that dye in, the concentration of the dye in the kidneys is higher; if the concentration is higher it does more direct damage. So that's an important thing. So we hydrate these patients either with intravenous saline or sometimes we use bicarbonate some tricky patients we might use some isotonic glucose.

A very important part is what we call contrast management. Normally, we might use a 120 to 150 CC of contrast on a case. If somebody lights up on our

chart and we say this is patient at a high risk, we'll dilute that contrast with saline. So instead of using a 150, we'll use 75 still the same much same contrast or amount of injection, but the contrast is less. So it doesn't give us quite the quality of study we'd like, but it helps us reduce the risk to the patient. We also use what's called non-ionic contrast which has a little bit of affect not a lot, but it makes it somewhat better and so we do use that as well.

Certainly if there aren't any of these medications that I talked about, we would get rid of those medications. So if they are ACE inhibitors or it's around like a drug like Motrin or Advil, we would take them off from that. There are certain drugs that seem to have a role. And I say seemed to have a role because if you look back at the meta-analysis that is a combination of the studies, these make things a little better in some studies, a little worse in others. We still use it but we don't have quite the confidence level. At our hospital we use the N-acetyl-L-Cysteine which is Mucomyst and that seems to have an antioxidant effect, seems to protect the kidneys and reuse it.

We don't use the others although there are centers and it would be interest to know if the other speakers today might use that ascorbic acid or statins or prostaglandins we cannot use it but that's on our radar screen of possibilities. The end of the spectrum would be to remove that contrast with hemodialysis or ultra filtration. So this would be to take – you do the study on the patient but then try to get rid of that dye with hemodialysis like you would with somebody with renal failure.

If you look at the studies that in some cases that made it worse, not better and so we tend not to do that except in, sort of exceptional cases. I think the most important part of this slide is what I started out with and there is nothing on this slide that's new. I was doing this 26 years ago and I bet they're doing that today six months after I retired. What I want to talk about today is this novel approach of actually removing this contrast before it gets to the kidneys.

Now the heart is sort of a unique organ its because the major blood flow in the heart comes from two vessels, the left coronary artery and the right coronary artery. The left coronary artery which carries 75 percent of the blood flow all drains into one vein of the heart, we call that the coronary sinus. Because it

all drains into that one vein, if we can catch that blood in that vein after it goes through the heart, we can remove that contrast before it ever gets to the kidneys. So the kidney's never exposed to it. It doesn't have that direct toxic effect; it doesn't have the vasoconstriction effect.

This would be removing the contrast as an adjunctive procedure. So we would do the procedure exactly as we're doing it today. We would still use less contrast, we would still remove the pending medications, we would still hydrate the patient but at the time of the study we would try to remove that dye. What we do is we take a catheter a long tube, not that long, we put it either through the artery or the vein in the neck called the jugular vein or the vein in the leg called the femoral vein and we inserted up into that special vein called the coronary sinus in the heart. That's not a difficult thing to do for an experienced operator.

That's in there and then at the time we inject we connect this catheter here is the heart, here is that tip of that catheter in the coronary sinus which is going to collect all of the blood that that left coronary artery is going to drain into, after we inject the dye. This little pump here is going to suck on this blood, remove it with the vacuum and deposit it here. We turn that pump on only when we inject the dye because we just want to take out that small amount of blood, so the pump is only turned on eight to ten seconds. So just removing a relatively small amount of blood. Therefore the dye is removed, or the majority of the dye is removed and it does not reach the kidneys.

Now this is a little video, this is the pump. This is really sort of an elegantly simple device. It really is not complex. This is a device which is a vacuum, it's connected to the wall, it's connected to the catheter and we have a little device here that collects the blood. This is the little catheter, the little tube about the size of a straw with a balloon on the end. Here is the beating heart, we bring this up through the femoral vein, put it into this little vein, the coronary or the coronary sinus. Here is the blood coming back from the left coronary artery. We use the guide wires so it's placed in safely.

We then use the centering catheter which keeps us from hitting either wall of this thing and now we blow up a balloon to slow our nearly stop the flow of

blood through there and then when we inject dye into the coronary artery-here is dye into that left coronary artery, when that contrast or dye is in the artery, then it comes back and collects it in this vein. And while it's being in this vein we turn down this pump and remove the dye. Obviously, there is blood and dye and not all of it's collected but the majority of it is.

When we're through with that, then we dispose of that and move on. So this is all removed. This takes 10 or 15 minutes for this to be placed in place. The pump is on for about eight seconds in order to remove the contrast and the blood at this time and then this whole system is removed. Here is the actual angiogram. Here you are in the cath lab, here is this catheter in the coronary sinus, here is a Judkins catheter, a diagnostic catheter in the left main coronary artery and that injects, goes down through the coronary vein at the coronary sinus and is collected.

The system's status, where are we today. I described to you what the problem is, what we treat it with today and what we're proposing we treat it with tomorrow. The company is a small startup company, it now has developed this system again and I think it's very elaborate but I think it's sort of elegantly simple to tell you the truth. They have FDA approval which they received in June of this year to begin a U.S. IDE clinical trial, which shall begin in about the second quarter of next year.

The clinical investigators are now being recruited with the U.S. randomized trial scheduled to begin next year. A feasibility trial was done outside of the U.S. on 41 patients that primarily assesses safety. It's just a safe thing to do. What we are doing here is nothing that we haven't done for a long time, putting artery or catheters in a coronary sinus, we've done for over 30 years, our electrophysiologist do it every day in the cath lab, now they do it for a different reason, but they are in exactly the same place.

So there is not a steep learning curve here for either the cardiologist or electro-physiologist. The procedure itself is quite simple, just removing a very relatively small amount of blood which we hope will have the majority of the contrast in it. The feasibility trial has been done outside the U.S., has proven the device safe. There were no device complications in 41 patients.

There were complications that we always encounter while when we do any interventional or invasive study in the heart. And then, I am going to leave this to people much more skilled than I am of why we need an ICD-9-CM procedure code.

I will say that the majority of these patients will be sicker than normal; these will not be the standard case that we do coronary angiograms or diagnostic angiograms. These will be patients that need intervention and we expect some more between 25 percent of these will have the high risk factors for developing contrast-induced nephropathy and the majority of these people well over half, probably well over 70 percent will in fact be Medicare patients.

The Medicare procedure code is needed for Medicare category B billing during this IDE clinical trial and the procedure code as was mentioned in the previous presentations, is needed for utilization tracking and hopefully cost containment.

I'd be happy to answer any questions on this topic.

Operator: Again if you would like to ask a question star one on your telephone keypad.

Dr. Robert Van Tassel: Yes ma'am.

Claudia Bonnell: Hi Claudia Bonnell from Blue Cross and Blue Shield Association. I just wondered how long the trial was supposed to go, the IDE trial. When would you anticipate it being ending, since it's supposed to being in 2011?

Dr. Robert Van Tassel: It begins in 2011 and there are 500 patients and maybe Doug, is Doug here? Yes Doug, could you answer what your estimation or length of the trial is?

Douglas Schoenberg: Doug Schoenberg with Osprey Medical. Yes, the trial will start we're anticipating in the middle of next year and the complete trial with enrollment, we're expecting about 12 to 18 months, so about the middle of 2012.

Claudia Bonnell: Thank you.

Dr. Robert Van Tassel: Thank you very much.

Mady Hue: OK, we'll now go over to the coding options at the bottom on page 49. Option one is do not create a new code, that removal of contrast media should not be coded separately, we could update the alphabetic index or tabular section to provide instruction to coders about that.

Option two includes adding an inclusion term to identify the removal of cardiovascular contrast media at code 37.29, Other diagnostic procedures on the heart and pericardium, and we realize that the removal is not diagnostic in nature but it would place the procedure in the cardiovascular chapter of ICD-9-CM.

Option three, would be to create a new code in subcategory 17.7, Other diagnostic and therapeutic procedures, and if in fact the removal of contrast media would be utilized in other areas, it would not restrict it to just the cardiovascular section in the book. On page 50, we have our CMS recommendation and that's option one, do not create a new code at this time. Do we have any comments?

Jolayne Fisher: Jolayne Fisher, Argenta Advisors, for Osprey Medical. I think I just want to address a couple things. First of all, it’s probably the elephant in the room why this early? A number of reasons for that, obviously, the freeze period coming up and want to get in with this being the last meeting but also to be able to potentially differentiate this procedure, when it's done and when it's not done. As you heard Dr. Van Tassel say, this is not indicated for most of the patients with this condition.

But we also want to be able to capture the cost avoidance data that we believe will help us for really measuring some of that hospital cost that we're trying to avoid and really reign in. We're not really in a position to be able to extract this data manually being a startup company so that is a concern of ours, but also one thing I just wanted to address with the amount of discussion happening around Fluoro and the length of time that patients are exposed to Flouro as well as the hospitals and their employees, we think that this is maybe another solution in being able to capture some of those quality

measures that have the ability to significantly reduce the cost to the hospital systems.

So just a few comments to offer for thoughts. Thank you.

Linda Holtzman: Linda Holtzman. I have to say that this seems premature to me. I know that there is approval to go ahead with the trials but it's very early in the process and my understanding is that to create a new ICD-9-CM code which would of course be a permanent code, you're looking for true FDA approval in the year where the code would go into effect.

And so I don't really have a feeling or a preference on creating a new code or not creating a new code or any of those options because it just seems too early to make. This would set a precedent too, of creating new codes, permanent new codes, for anything that goes to clinical trial and not everything that goes clinical trial pans out.

So that's the reason to have a clinical trial. So I would just hold. There is still the option according to the freeze schedule that we discussed this morning that if does go to a new technology you still have the option of adding the code later. So the freeze wouldn't necessarily impact on this if a new technology add on is determined.

Mady Hue: Thank you Linda. Operator, can you check the phone lines for any comments?

Operator: There are no responses in the queue at this time.

Mady Hue: Do we have any other comments in-house? OK, on page 50, we have that, in the interim, assignment of diagnosis code V70.7, Examination of participant in clinical trial, along with the procedure codes for the cardiovascular procedure performed would be sufficient to track patients for the clinical trial. I would encourage you to send in additional comments that you might have on this topic. And we'll move on to the addenda now.

OK, on page 51 of your handout under the tabular section, our very first issue deals with code 33.24 and some of you might remember that at the previous

meeting we just discussed this to index it at 33.29. We received a comment that was a little late in the period but they asked us to bring it back to give consideration to indexing the mini-BAL at 33.24 , instead of 33.29.

Moving down the page, there is a folio error at the 68.4, the header category, when we expanded the codes. That excludes note should be placed at 68.49, so we're proposing to fix that. And then lastly at 99.09, Transfusion of other substance, this was another folio issue where we needed to expand the range so we have to revise the exclusion term for those codes.

Moving on to the index. We had a request to try and clarify the laparoscopic hysterectomy codes, so here is the proposal. It's a lot to look at right now. So I would encourage you to look it over and send in comments, if you feel that it helps to clarify current coding. Turn to page 52, this would just be the revised tabular, if we went ahead and complemented the mini-BAL request. So do we have any comments on the addenda?

Operator, are there any comments on the phone?

Operator: There are no questions or responses in the queue at this time.

Mady Hue: OK, I am going to turn it back over to Pat.

Pat Brooks: I would like to thank everyone. In particularly our speakers today, very informative on the procedure code issues. Remind everyone that some of those topics were extremely difficult. We recognize that and we would like to have your written comments by November 19th for the ICD-9 codes. We will now turn the meeting over to Donna Pickett, who is going to start the diagnosis code issues today. Try to get a little jump start on things.

Donna Pickett: Good afternoon everyone. For those of you who have been up on the Web site, you saw that there are a large number of topics being presented. So NCHS staff is absolutely delighted to be able to present some of the topics this afternoon and I'll try to do all 42 in one day tomorrow. I am joined, I will be joined by Beth Fisher and David Berglund in doing some of the presentations, the presentations we'll be doing this afternoon are those where we don't have a presenter either that needs to be online or in the audience.

OK, I'd like to start. If you would go to page 24 in your handout and that would be part one of the handout. NCHS received a request to add details for dementia that's unspecified and include with or without behavioral disturbance. I am not going to read through the entire proposal because you do have a basically what the Veterans Affairs Medical Center was indicating was that many times in documentation there will be documentation that the patient has dementia but they are not specifying what the underlying etiology of that dementia is, but they will indicate that there is or is not disturbance associated with that dementia.

So the request is to create new codes for Dementia unspecified with or without behavioral disturbance, and while this is a documentation issue, I've spoken with other facilities and sought input from the American Psychiatric Association and the American Academy of Neurology regarding the need for this expansion, and they indicate support for the concept.

So what we would be proposing is at category 294, Persistent mental disorders due to conditions classified elsewhere, we would create a new subcategory 294.2 Dementia unspecified and then two new codes under that subcategory for Dementia unspecified without behavioral disturbance and Dementia unspecified with behavioral disturbance. These codes parallel with codes that already exist at 294.1.

Are there any questions from the floor on this proposal? I think it's fairly straight forward but we always have like to get input because we never know which ones are going to be the complex issues.

Linda Holtzman: Just want to comment I think it's a really good idea, we do see dementia documented quite a bit on inpatient Medicare patients and many times it's being documented by a vascular surgeon or someone who doesn't have the same background to be able to give you specifics on the type of dementia. So it would be very nice to be able to identify it distinctly as opposed to just sticking it in with 294.8. So I do – I like the proposal very much.

Donna Pickett: OK, thank you. Any other comments or questions from the floor? Operator, are there any questions on the line?

Operator: There are no questions in the queue at this time.

Donna Pickett: OK, thank you. The next item will be on page 40 of part one of the topic packet. We've had a request from Avanir Pharmaceuticals to create a unique code for pseudobulbar affect. Several years ago we created an index entry for pseudobulbar affect (PBA), sending it to code 310.8. The requestor now is asking for a unique code. They provided a great deal of detail regarding the condition and you see that outlined here in the proposal along with information about how it is secondary to a number of conditions and also related to traumatic brain injury.

The proposal is to expand 310.8 and create a new code at 310.81 for PBA and to have a code first note for those incidences where the underlying etiology of the PBA has been identified and of course in doing this expansion we would also need to create a new code 310.89 for all the other conditions that were classified at 310.8. Fairly straight forward proposal. Comments or questions from the floor?

Sue Bowman: Well, I don't know a lot about, this is Sue Bowman from AHIMA I don't know a lot about the condition but I assume there will be times when it's documented without an underlying cause, so the way the note is worded it might be better to say it's applicable or something to say if you know the underlying cause, code it first but otherwise people might be stuck into trying to figure out an underlying cause that's not known.

Donna Pickett: And Dr. Powers is stepping to the microphone and I would ask her to comment on that because it was something we had discussed previously.

Dr. Laura Powers: It would be hard to call it pseudobulbar affect unless you knew there was an underlying cause but it might happen, I can understand that might happen but it would be hard to call it that because you almost have to know that there is something else going on vascular disease or MS or something else to call it that, but the American Academy of Neurology does support a separate code for this. In the past, we might not have because it was – the name of it was supposed to be involuntary emotional expression disorder which is not a commonly used term but pseudobulbar affect is and I think in a number of the

diseases that we treat including MS - it's becoming more and more obvious that it occurs in those diseases, so we do support that.

Donna Pickett: Thank you Dr. Powers and you raised a good point that I didn't cover in the overview. The involuntary emotional expression disorder is currently indexed to 310.8 but it's part of the expansion, it would be included at the new code 310.81. Because the terms are used interchangeably. Operator, are there any questions or comments on the line?

Operator: There are no responses in the queue at this time.

Donna Pickett: OK, we'll now turn to page 39 in part one of the handout. And it's complications of stem cell transplant. Currently ICD-9-CM does not have a unique code for complications of stem cell transplant. The coding of complications of stem cell transplant recently was discussed at an Editorial Advisory Board meeting and there were several thoughts on how to code the condition and which was the best way to go with this and so we're bringing two options to your attention for this. One train of thought was that stem cell transplant complications should go to the existing code 996.85, Bone marrow.

There were others however who really felt that a new and unique code would be necessary and so in option one, we show a new code, 996.88, for Stem cell which would include transplanted stem cells from either bone marrow or from peripheral blood or umbilical cord; they would all be there together. Option two again is to have stem cell transplant be included at the bone marrow code, and again all of the different ways of collecting stem cells would be included there, so bone marrow, peripheral blood and umbilical cord.

It was a very lively debate trying to figure out which way to go, I see Nelly smiling. I think for – Nelly are we having Coding Clinic advice published on that in the interim? I know it was discussed and that was 996.89 but, OK, didn't mean to put you on the spot but I know we had discussed it and we kind of went around and around on this one.

Any questions or comments from the floor on either of the proposals, is there an accepted I mean, do you prefer option one or do you prefer option two.

And with the new code, 996.88, that would be using the last code in that range. So there would be no other opportunities to add codes, new codes, to that section and anything else that would come about what has to be coded at the .89.

Questions, comments from the floor? Preferences, you need to think about it OK. Operator, are there any questions or comments on the phone lines?

Operator: There are no questions or comments in the queue at this time.

Donna Pickett: Well we encourage everyone to think about this. We've been raising concerns in the past about judicious use of the codes in the remaining years of ICD-9-CM, so this might be something to consider or for tracking purposes when you're trying to identifying complications whether having the unique code would be beneficial separating it out from bone marrow.

So with that I am now going to turn the floor over to Dr. David Berglund who will cover arteriovenous malformation and he is going to do a little bit of setup over here.

Dr. David Berglund: Do you hear me? Testing one, two, three. Testing one, two, three, yes that worked. OK, let me, I am trying to see if I can get the system to show over here too, let me see oh boy. I should have tried testing this earlier too, trying to – OK, let's see. Is it going to work? I am having a hard time in actually getting this to actually – yes, usually something that works below it. OK. We need to start getting this display, usually is it that one here we go – yes it's a different one.

Male: Here we go.

Dr. David Berglund: All right.

Male: Could change the properties, right.

Dr. David Berglund: Yes. Let's see, which one are we doing, hold on a second. OK, this one not that (inaudible) 800 by 600 right?

Male: Yes.

Dr. David Berglund: There you go. OK, that's changed. Well all right let's check that up. What is that – OK, maybe just change everything to it. Like that?

Male: Yes.

Dr. David Berglund: That looks better. All right, that looks better, OK. We've heard a little bit about aneurysms today, on procedures and how to fix them and we're going to talk now a little about another kind of aneurysm that sometimes occurs or Pulmonary Arteriovenous Malformation which can sometimes be called Pulmonary Arteriovenous Aneurysms also. And this is just a communication between pulmonary arteries and pulmonary veins; they do not handle those as well.

Now most of the time either small, they're most often congenital, can be acquired though. When these becomes a serious problem and they can cause some pretty serious morbidity - it can cause cyanosis, heart failure, respiratory failure. We don't have pulmonary arteriovenous malformation indexed in ICD-9-CM. We do have pulmonary arteriovenous aneurysm included at 747.3 which is anomalies of pulmonary artery. Now we do have a number of other disorders there including particularly types of narrowing of the pulmonary artery coarctation or stenosis also pulmonary atresia or agenesis congenital pulmonary artery problems.

And we've gotten the question on how to code pulmonary AVMs through our Coding Clinic Editorial Advisory Board we looked at this and we did state that it would be best to have a separate code for it. Now we are, let's see, we are also proposing some other changes to exclude at 417 exclude congenital arteriovenous fistula to the new codes in 473.2. Now that's 747.3 we're proposing to change the title for Anomalies of pulmonary artery to add Anomalies of pulmonary artery and pulmonary circulation.

And we would create new codes 747.31 for Pulmonary artery coarctation and atresia and we would include a number of terms there that are currently included at the.3 already all things such as agenesis, atresia, coarctation, hyperplasia and stenosis involving the pulmonary artery. We would also

create a code 747.32, Pulmonary arteriovenous malformation with the inclusion Pulmonary arteriovenous aneurysm.

However this would exclude Acquired pulmonary arteriovenous fistulas at the 417.0 in existing code for acquired, and we would also create a new code 747.39, Other anomalies of pulmonary artery and pulmonary circulation, which would include Anomaly of pulmonary artery and for that matter it would also include an Aneurysm of the pulmonary artery, if it wasn't described as arteriovenous.

As you may recall from the different pictures that we just saw earlier, not all aneurysms go from the artery to the vein as the ones we are talking about now do. And we would also include other changes in the notes, just to assure that we're excluding things to the proper locations, and those are also shown in our handouts on pages 37 to 38. OK, any – I think that covers this proposal. Let me see if we've got any comments, questions or thoughts from the floor first.

Nelly Leon-Chisen: Can you scroll down the old 42 there is a new note use additional code…

Dr. David Berglund: That was an additional note that I had gotten in at least this copy and that one was actually related to a completely different topic.

Nelly Leon-Chisen: OK, not related to …

Dr. David Berglund: My apologies.

Nelly Leon-Chisen: No problem. So OK, so I was trying to kind of think, find …

Dr. David Berglund: Why was that here... It was misplaced, my apologies, yes. And we'll hear about that tomorrow, it's a way of foreshadowing. OK, no other questions or comments on this topic at this time. Glad to see Nelly was awake anyway and I would like to see if there are any questions from the phone line at this time. Operator, can you check the phone lines for us please.

Operator: Again if you would like to ask a question press star and the number one on your telephone keypad. There are no questions at this time.

Dr. David Berglund: Thank you. And we have another comment or question here.

Linda Holtzman: Linda Holtzman, I just wanted to say first I like very much the proposal of creating a distinct code for a pulmonary AVM. For some reason I do see the code - that's an awful lot and it's – I would thought it was not the best solution to have it just go in with all the other types of anomalies.

I am wondering if there has been any thought to creating a specific code for AVM of the cerebral circulation because I see that a lot also and right now that's in a code for just anomalies of cerebral vascular system and it might be worthwhile to create that distinctly as well.

Dr. David Berglund: We haven't actually received a request for that but we'll certainly take this thought under advisement that is certainly something that happens and can be a big problem when it does. So I appreciate the comment. Other comments or questions? All right, Donna which topic do we want to go to next? I can do that yes. Do you want to look at the things up there to or not, OK.

Beth Fisher: No that's OK. I am going to cover a couple of things that are kind of addenda type because they are not new codes and then I am going to go into the addenda. So right now on page 30, if you've got our topic packet, since David is going to sit there he can navigate the document.

This is related to a topic we presented quite a few times here and we're hoping we almost have it and maybe do have it and that's for acquired absence of joints as you know it's kind of morphed from one code called “waiting for joint prostheses” to two codes to playing with the titles and last March we presented what's on page 30, I mean this is really appears pretty much the same as you saw last March, except we did receive comments from the American Academy of Orthopedic Surgeons who specifically asked if we would add inclusion terms at the V88 code that we proposed for the acquired absence of joints and at the last half of the paragraph of the narrative explains the rationale of it.

I guess they wanted to be clear that there are many other causes for acquired absence of the joint- congenital, trauma, neoplasm, infections and they wanted

to have us -make sure that we included here specifically that, the acquired absence of joint primarily with any of the V codes and the codes would be that following explantation of a joint prostheses with our without presence of an antibiotic-impregnated spacer. So that is really primarily what we have changed from last March and so we wanted to present that here today for any comments on those changes.

So do we have any comments please, and you can comment on proposal in general if you want but this is primarily what has changed from last March. Any comments from the floor, if not I guess I'll ask the operator if they are comments from the telephone.

Operator: There are no questions or comments in the queue at this time.

Beth Fisher: OK. Further related to that request, and another part of the request - I sort of toyed with waiting to do all my 9-CM and all 10-CM but they also had a 10-CM request and that is back on page 78 in the document which is again really primarily addenda related but we've had a lot of – well we had some people write to us say could you change this code title, that code title and just give me the part we really should present these two for comments.

So we've decided to present this is not a major change but back when we created the prosthetic, joint prosthetic complications I think about four or five years ago, that were put in the 9-CM, we put their equivalents in the 10-CM at T84.0 and then T84.02 we have a dislocation of internal joint prosthesis and included there is the instability of internal joint prosthesis and the subluxation of internal joint prosthesis.

And then when we were breaking them out by the joints, AAOS again commented to us saying that for the knee prosthesis specifically they recommend that we title the codes instability of internal right knee prosthesis and left knee prosthesis rather than dislocation and the write up at the beginning of this topic in the packet. The dislocations of prosthetic knees are extremely rare; the instability of the prosthetic knee is common indication for the revision surgery. So they just recommended that we change those code titles, so that's a kind of an addenda type change.

Any comments about that, or from the phone?

Operator: There are no responses in the queue at this time.

Beth Fisher: OK, hope they are still listening. OK, then we'll go to the actual addenda for 9-CM which is on page 45 so that we cover this today and then we can just do our topics tomorrow and not have to worry about the addenda. So on page 45, with the tabular addenda and this is the proposed addenda items that would be proposed for a year from now October 1, in two weeks of course we have this year's addenda going into place so I may actually reference that at some point in here because we've already found, people already found mistakes in our addenda, it just always happens as soon as we publish it we get e-mails, we try.

On page 45 beginning with category 249 and 250, a couple of use additional code notes where we have the range of 707.10 through 707.9 and it was recommended to us to look at those ranges again and so what we're proposing is to take out after I think we implemented these use additional code notes. We implemented the new codes for the pressure ulcer stages. So we're proposing to revise these notes so that 707.2 would not be included in these use additional code notes, that was just taken in for the recommendation and so that's in here several times at 249, 250 and in then that 440.2 and 459.81.

Now I am just going to progress through these if you have comments step to the microphone and periodically I'll try to ask for phone comments. Moving on to chapter five title, it was requested that we revised the title right now in 9-CM to match the title that is in 10-CM so chapter five is proposed to revise the title to “Mental and Behavioral Disorders” that's exactly the title that's in 10-CM. Linda Holtzman.

Linda Holtzman: Linda Holtzman, quick comments, I love this. Thank you so much for adding “behavioral” to this chapter title because sometimes you really get pressure not to assign codes in chapter five, because then you are tagging the patient for life or whatever with the mental disorder so to know that it's possible in chapter five but it's not mental per se but it's also behavioral I think that will take some of the pressure off, thank you. It's a wonderful idea.

Beth Fisher: All right. Any other comments? OK. The next item is under category or actually code 430 for subarachnoid hemorrhage. I believe the Editorial Advisory Board for Coding Clinic had questions in how to code a non-ruptured berry aneurysm and the recommendation was to code 437.3 so we're adding an excludes note at code 430 and you'll see later where it has a couple of other entries for that to index appropriately.

Category 440 is what I was saying earlier about the range of codes of 707.10 to .9 as well on the next page the same thing- revising the use additional code note at code 459.81. Code 518.3, we're adding an excludes note again this actually came through the EAB for Pulmonary infiltrate NOS to go to code 793.1 which you'll see later in the next pages- the non-specific findings on radiological and other examinations for lungs fields rather than sending it to the pulmonary eosinophilia.

At code 536.3 this is part one of gastroparesis, the other part will be presented tomorrow in ICD-10-CM but it was recommended to add “if applicable” to the code first note because it is not always, you do not always have an underlying disease for the gastroparesis.

Linda Holtzman: Linda Holtzman, just a very small question. It's just a wording thing, why “if applicable”, why not just say “if known”.

Beth Fisher: You know that's a good - and we searched the CD and we have many ways of saying it, so we chose this one- but you know we can put “if known” too.

Linda Holtzman: I personally just, I personally prefer if known, because in many situations if they just don't know what caused the gastroparesis and so it's – to me it makes it more clear that if you don't know what it was caused by, then you don't have to worry about an underlying disorder -small things.

Beth Fisher: OK, thanks. All right, then on to let's see, code 569.49 and also the next one at 618.04 I think it was pointed out to us that our addenda in the CD yes, but somehow it was pointed out we weren't consistent with using the word “use additional code for any associated” so we'll add those words back in to that, “use additional code note” in both those places.

Turn now to the next page, at page 47, subcategories 718.6, someone sent us a list of codes, they said these codes aren't indexed. I commend them for finding that but in some cases they were right and this one, they said that code 718.60 isn't indexed. Well actually with the common fifth digits lot of times we don't index them to the fifth digit level, we index them to the subcategory level and then you go to the tabular and find out about the fifth digits and apply the appropriate one, but in this case it didn't seemed like that fifth digit zero applied at all because it's "unspecified site" which would make the code Unspecified intrapelvic protrusion of the acetabulum unspecified site.

So we are recommending actually to revise the fifth digit note and take that away which technically deletes the code which we don't usually like to do, but it doesn't – didn't seemed a like valid code. We would then end up only having 718.65 which actually we're going to take away both of them and we said no let's just stick with the one code that's there because that's probably been used for a number of years. Hopefully 718.60 really wasn't getting used.

Any comments on that? OK, then at code 793.1 I'm going to add the includes note, an inclusion term for pulmonary infiltrate not otherwise specified. And then to subcategory 999.6, I think it's a subcategory, I think it's not a code, I am going to revise the code 999.89 this year, actually in a couple of weeks we put in all those new codes for transfusion complications and we have forgot to change this one excludes note. So we need to change that.

And then the titles to our V codes supplementary classification we failed to acknowledge the addition of category V91, so we need to change the range of that code title range. So let me just stop for a moment to just check if there are any phone comments, I haven't had any comments on the floor.

Operator: If you have a comment or if you would like to ask a question press star and the number one on your telephone keypad.

Beth Fisher: No comments again, OK.

Operator: There are no questions or comments at this time on the phone.

Beth Fisher: So we'll move onto page 48 which is the index, proposed index addenda of ICD-9-CM. The first item is hard to explain in a text format but, it's actually we're fixing the indentation of this. It's probably correct in code books but on the CD it's not aligned properly, so we're just moving that line “brain” with the code over one level.

The next line we are adding to Automatism, we're adding “with temporal sclerosis” to code 348.81 and that came to use through EAB. OK, on the next line we're revising and you can't see what we’re revising it’s just so subtle - you can't even see it but that's because it somehow disappeared when we were spell checking our document.

We are trying to add an extra close parenthesis for infant over 28 days old - it's the little things that make a difference. We are adding the index item for Anaplasmosis, humans for code 082.49 which I believe is Ehrlichiosis, we're adding under Aneurysm for the berry non-ruptured in a couple of places to code 437.3. We're deleting an index entry for Herxheimer’s reaction*;* right now it’s 995.0, which I think is an anaphylactic reaction. Anyway, it’s David Berglund -brought this to our attention that it's really a type of sepsis, so we've got it later indexed to the appropriate code. So it doesn't belong under vaccination reactions.

Under Dense, breasts we had one entry that said “omit code” but it really should be 793.82 like all of the rest similar entries in the index. Under Disease we've been asked to add for Fournier’s disease for the female to 616.89 under iron metabolism this was this year's change, we mixed up a couple of codes so we're changing it from the 275.03 to 275.09, those are new codes this year. We're adding microvillus atrophy at 751.5, last year we added couple of entries like that with MVD and MVID and things like that and now we're just spelling it out a little bit better.

We're adding an index entry for polyethylene disease to 996.45, I forgot what that is David, is it the periprosthetic osteolysis?

Dr. David Berglund: Yes.

Beth Fisher: OK, we checked with AAOS on this and they agreed with it, the Orthopedic Surgeons Group. We're correcting this Sweeley-Klionsky index entry, the 272.27 that was inconsistent in the index. We're adding a couple of index entries for alcohol-induced mood disorder, it was suggested to us, it was kind of hard to find the way it was indexed, I mean it just you had to go to a lot of different terms to get to code 291.89 so we're just trying to make it easier to find.

At Embolism, vein this year, we've – this year just couple of weeks we changed the index so that it would default to "acute" in several places and we forgot to do the upper extremities, so this is to fix that to make it Embolism of the vein, upper extremity, default to "acute" and then there would be some "superficial" underneath that. Encephalopathy due to drugs, we are changing that from 348.39 to 349.82 and then also under Encephalopathy, metabolic adding the term "drug induced" to 349.82.

Again the index entry for Fournier's disease, female. Under Fracture, this was also in the list of codes somebody pointed out to us that we didn't index. These were new codes for stress fractures that we introduced in 2008 and we just completely missed putting them in the index. I think they were fast tracked, so fast that it just got past us, so these sites for the femoral neck and the shaft to the femur - they told us they just got overlooked so we're proposing to put them in.

Hemochromatosis to diabetic we're fixing the index entry there that was put in incorrectly for this October, or it will go here next October. Herxheimer's reaction we're revising this as I said earlier it went to 995.0 but it more appropriately needs to go down to 995.91. Hypertension, pulmonary- we received a request to add an index entry for right heart ventricular strain and then the acute I guess it was hard to get to it being kind of under cor pulmonale so that means we do have to move cor pulmonale down and then create another index entry under that in the table for the right heart ventricular strain.

The lung infiltrate and pulmonary infiltrate to 793.1. Aspiration, injury from lung aspiration we have been asked to add that to 507.0. Under the

Intrauterine contraceptive device, we inadvertently we put something under the wrong level in this, so we're fixing that, instead of saying reinsertion and reinsertion we're putting that second line under removal where it belongs. Leukoencephalopathy, arteriosclerotic - we're adding an index entry for 437.0. Lipodermatosclerosis-we're adding the 729.39, neurocutaneous melanocytosis adding an index entry for that to 757.33. The MVID, again, the microvillus inclusion disease to 751.5, adding an entry for oncogenic osteomalacia at 275.8.

Back I think last spring when we presented jaw pain and related entries we heard from the maxillofacial surgeons that we really should take out the entry for temporomaxillary joint at 524.62. They commonted that is an archaic term and they think it confuses, it adds to confusion with things like maxillary pain and joint pain. So they asked us to remove that entry.

Under Pancytopenia we're adding with myelodysplastic syndrome to see the Syndrome, myelodysplastic so there is range of codes that could be applied so we couldn't come up with one, so we're just asking you to go see that term. Prognathism is indexed to 524.00 but it's actually included at 524.10, so we're changing that so that it reflects what the tabular has.

Revising again the Herxheimer's reaction to the 995.91. Septate uterus this year we introduced a lot of new codes for I think it was Müllerian anomalies and one of them was changing the code somewhat - well for septate uterus it used to go to 752.2 I believe and now it goes to the 752.35 so we're taking the "see also Double, uterus" out of there revising that.

Siderosis, CNS - realixed when I was proofing this it really should spell that out but would add that to 437.8. Adding an index entry for myelodysplastic lesion syndrome 238.72 and also an index entry for semicircular canal dehiscence to 386.8. An index, adding an index entry for annular fibrosis tear at 722.51 and then.

Linda Holtzman: Can I ask about that?

Beth Fisher: Go ahead Linda, sorry.

Linda Holtzman: The annular fibrosis tear to index to 722.51. So are you going to index an annular fibrosis tear to degeneration of the disc which I think makes sense but 722.51 is thoracic does it only happen to thoracic level?

Beth Fisher: I think I am going to defer to our medical officer because, he highly recommended that code. So we can look at it when we get back to it.

Linda Holtzman: If it happens at the cervical level and also at the lumbar level you would need to break that down; 722.51 is specifically thoracic and thoracolumbar.

Beth Fisher: OK.

Dr. David Berglund: Yes that can happen to another level.

Beth Fisher: So we need to look at that, OK. All right and then with main term Thrombosis we had some incorrect codes at "iliac" we I think that's unspecified and we should have put the 453.41 for the both the acute and the chronic, so wrong codes-we'll then revise those and then under the vein, it's the same fixes I talked about earlier creating the default of acute for upper extremity.

OK, and then on the next page, couple of things really minor in the External Cause of Injury Index. We're just adding the letter "s" to war operations so it's consistent with the rest of the "Blast" indexing, so it's plural. In the Table of Drugs and Chemicals from the same person that was catching unindexed codes, caught that the code E861.9 was not indexed. It's – I think the title is unspecified cleansing agent, et cetera, et cetera. So we're proposing to just include it as a line "type not specified" and then move down the NEC to underneath the cleaner.

And we're just actually changing that column, 2 codes, we're not changing any of the other codes for that either of those lines so, OK. And Linda?

Linda Holtzman: Linda Holtzman. Can we go back to the pain index entry for temporomaxillary joint, was the issue temporomandibular?

Beth Fisher: No it's actually temporomaxillary joint is the way it's in the index and actually I don't know if they said that that doesn't exist so it's in our CD anyway, so they didn't want to confuse it with maxillary pain.

Linda Holtzman: OK, thanks so I didn't understand what the issue was.

Beth Fisher: They just tell that it was just like a- I don't want to say -well I can't remember what their term was. It didn't exist but it just -basically they said it's not a term that really is ever used so…

Linda Holtzman: Thank you.

Dr. David Berglund: The temporomandibular joint of course is where the jaw meets the rest of the head but yes temporomaxillary joint doesn't make much sense I mean there would be some kind of a, I think a future line between the temporal bone and maxillary bone but that's not one that we really are thinking about here, I would say, so it's not quite clear what that was supposed to mean I think.

Beth Fisher: OK, so do we have any more comments on the addenda and I could ask also operator if there are any comments from the phone line, or questions.

Operator: If you have a question or comment please press star one on your telephone keypad. There are no questions on the phone at this time.

Beth Fisher: OK, then the last thing I'll cover right now is on page 80, we're at the end of the document. It's a few ICD-10-CM proposed addenda items that mostly came to us from the AAN, the American Academy of Neurology. On page 80, David?

Dr. David Berglund: What page?

Beth Fisher: Page 80, if you want to keep up.

Dr. David Berglund: There we go. Sorry.

Beth Fisher: OK, it was recommended to us in ICD-10-CM at G31.01 which is Pick's disease to remove – to the delete the term "Circumscribed brain atrophy" and

I hope I explained this right Dr. Powers - if not, you can correct me that it's the term not unique just the pick's disease, is that…?

Dr. Laura Powers: Historically, circumscribed brain atrophy was a synonym of Pick's disease but now it's frontotemporal circumscribed brain atrophy that is Pick's disease and there is a new definition or listing for Alzheimer's disease that would include other circumscribed atrophy or other type of localized atrophy.

So it's a little bit confusing if someone saw the other terms just circumscribed isn't enough, it needs to be frontotemporal circumscribed atrophy to refer to Pick's. So it's an older term, it was right when it was in there but it just, it's no longer correct and that's why we have asked for you to change.

Beth Fisher: OK, so they asked that we remove it from there and to add primary progressive aphasia to Pick's disease and then what you see related to that is right below that, is index proposed addenda item for ICD-10-CM is to modify as Dr. Powers was saying adding the word frontotemporal circumscribed to the entry for circumscribed brain atrophy which would still go to the Pick's disease.

Sue Bowman: Sue Bowman, I just wonder then if it wouldn't be – I guess better instead of deleting the inclusion term to just change it to be the same as the index entry to say frontal temporal.

Beth Fisher: I suppose we can leave them there, yes.

Beth Fisher: All right. And then a request to right now Gerstmann's syndrome, the way it's indexed in 10-CM, it just has the developmental Gerstmann's syndrome index to the F81.2 and so it was requested to revise that to R48.8 and have the developmental of course still indexed but just - it would be underneath Gerstmann's syndrome. So we would have both the developmental and the non-developmental indexed.

OK, and then the only other item for the 10-CM index addenda is probably very minor but isoimmunization not elsewhere classified to index all of these anti little c, big C, little e, big E to 036.09. We have the anti capital E going O36.19. So it's recommended to change that. So well that is all of the 10-CM

addenda items. So if there are no more comments, I'll turn it back over to Donna.

Donna Pickett: That's the end of the diagnosis proposals that we'll be able to do today. We will reconvene tomorrow morning at 9:00 AM sharp and we wish everybody a good evening. Pat, did you have any other announcements you wanted to make? OK, thank you everyone. Have a good evening and thank you everyone that was online.

Operator: This concludes today's conference. You may now disconnect.

END