

ICD-9-CM Coordination & Maintenance Committee Meeting

Co-Chairman: Pat Brooks
March 9, 2010
90:00 a.m. EST

Pat Brooks: I would like to begin the meeting by announcing some very sad news. Unfortunately, CMS has lost one of its valuable staff members. Joe Kelly, MD, a regular participant at the C&M meetings and the Editorial Advisory Board for Coding Clinic meetings was killed on February 27, 2010 in a plane crash. Joe Kelly was a valuable member of the coding and DRG team and assisted in the preparation of all the coding proposals presented at the meeting. The coding team and the rest of CMS greatly miss Joe. He always was working in the background reviewing the handouts, helping us streamline information, working on code titles, and he was just a real good advocate for coders, to help us speak to physicians, and to help explain to physicians what's a coding issue, and what's the clinical issue.

And I think I can speak to all of those in the Coding Clinic and the rest of the country who would say that we will greatly miss Joe Kelly. And we have a picture of him at one of our recent little parties down in CMM, and we want to say thank you, Joe for all those years. And we did want to give a few minutes to thinking about him today.

We had 200 people sign up for the meeting today, and we were, at the last minute, able to get funding for phone lines. And this time, we'll have 225 people, the first come first serve, who will be able to listen in to the meeting. And also, they will be able to ask questions and make comments after each one of the major presentations.

So we're going to change things a little bit today. We'll be doing presentations of the clinical issues followed immediately by presentations from one of the CMS staff on the coding options. And then we will ask the people in the audience here to ask your questions or to make a comment. And after that, we will be giving an opportunity for the people who called in today to make – ask their questions or to give their comments.

We are not sure yet whether we'll have funding for the calls for September. As you notice, we didn't share with you the information until very close to the meeting. It may happen that way again this fall. So, if you do not see information on our Web site about call-in numbers, that means there won't be any. And if we do get funding, then as soon as we get that information, we will post it on our ICD-9 Coordination and Maintenance Committee Web site for you.

Another big change that's happening for this meeting is we've decided to join the rest of the country in going green. We are no longer going to be making the huge stacks of handouts; and sometimes 200 of you may sign up but many of you have made your own copies anyway and you don't pick up the paper out front and so there was a huge waste of paper.

So, for this meeting, we did not make handouts and we posted that information on our website. We are facilitating your discussion thanks to the heroic efforts of Ann Fagan who did all the coding options and recommendations in suitable PowerPoint slides. So those of you who did not feel like bringing in your handout will be able to follow along hopefully.

Everything discussed today – this is the procedure part of the meeting. Tomorrow is the diagnosis part of the meeting, and there's Donna Pickett down there who'll be chairing tomorrow. Today, we're doing two things. We're doing procedure discussions, and we're starting the morning by doing ICD-10 information. And Donna and I will be leading those discussions.

We will ask you to – now, Donna will tell you tomorrow which of her topics will be for October, but all of our topics discussed today will be for consideration to be implemented this coming October. I'll go with you

through some of the important dates that we will consider. First of all, by April 2nd, we will need you to send in your comments on any issue discussed today.

We prefer e-mail because our snail mail will never get to us by April 2nd even if you mail it today, by the time it goes through the mail room and gets up to us. So please, after the meeting, send your comments but send them electronically. And on the timeline and in your handouts, you'll have our address, our e-mail address.

In April, thereabouts, you will see the inpatient proposed rule that will include Table Six which Amy Gruber prepares that will be all the new, revised and deleted diagnosis and procedure codes finalized in time to make the proposed rule. We will not be able to get the codes discussed today into the proposed rule because of the short turnaround. But any codes finalized today will be mentioned in the IPPS final rules in August.

In April, you'll see on your timeline, there will be a summary report of this meeting; the diagnosis part on CDC's website, the procedure part on CMS's website. And in June, you will see the addendum posted on CMS and CDC's website for all of the code changes that will go into effect October 1st.

Another important date – and this one is for the September meeting – we need – if you have a new code you want to request, you need to send us your request by July the 16th, July the 16th, two months prior to the next meeting on September 15th and 16th, so that we can address those at the fall meeting.

A couple more final dates; one is the August 13th, 2010 will be the date that our online registration site opens. Those of you who go to the site before August 13th, 2010 will think that it's full because – and it won't be open. It'll be closed, and you'll call (Mady) and you'll ask her, can I get on the meeting, and that is because the online system does not open until August the 13th. So do make a note of that and help us by signing up online.

And the last important date which we just mentioned was that our fall meeting is September 15th to 16th. Hopefully, we will get funding to let people participate by phones. We will have to let you know of that later.

Now, today's meeting is a public forum to discuss updates to ICD-9 CM but we're not going to make any final decisions here today. There are people listening on the phone. There are some of you in the audience who need to think things over. And so, we will give you till April 2nd to send in your additional comments.

It is only after all that that we would consider finalizing these codes. We want to give as many people an opportunity to comment on this as possible. And you'll know they're final when you see the IPPS proposed rules around April.

Now, just a few other points for those on the phone maybe who haven't been to these meetings, we do have an ICD-9 CM website. That's in your information. It gives you a lot of information. If you've never requested a new code before and you wonder what you have to do, we go through that whole process.

And, basically, you're just writing to us within the timeframe, telling us that issue with this new procedure, it doesn't have a code or it has a code and you don't think it works really well. And you write up a page, a background to describe what the procedure is all about, and you suggest code titles.

You send that to us and then we revise it, update it, and that's the handouts you see today are based from all that work. Now, the good news; on April 1st of this year, there will not be any mid-year code updates. So, if you were worried about having to update your system, there were no ICD-9 codes approved to be updated on April 1st.

OK. So, now, at this point, what we're going to do is we're going to turn over, and we're going to begin our ICD-10 discussions – and (Donna), if you don't mind coming up to the table up here. I'm going to go through a few things, and then we hope to have some discussions with you on ICD-10 topics.

The first topic is the ICD – the GEMs, the general equivalence mappings, and those are mappings that assist people in going from ICD-9 to ICD-10, and from ICD-10 back to ICD-9. We've had a number of presentations on this at

the past Coordination and Maintenance Committee meetings. At professional meetings, there are a lot of presentations so we're not going to do all that today.

But we are going to tell you that we did make updates for the 2010 version of the GEMs, and many of those updates came because, first of all, we added new ICD-9 codes. If we do that then we automatically add to ICD-10, and we have to update the maps.

But in addition, some of you are now actually beginning to convert your payment systems, your quality data, your codes or whatever, and you're using the GEMs, and you're finding issues or questions, and you're sending us questions about a particular issue. Some of those have led to small changes and updates to the GEMs, so that's a good thing.

We really appreciate those of you who are beginning to do this, and some of the private plan like Blue Cross plans identified some small issues with some left-right codes that we updated, the codes for this year. As you do that, we would really appreciate your sending in that in writing because some of these things are complicated. It's hard for us to react over the phone like Linda Holtzman just sent us some recently.

And it's very helpful if you say, here's the issue, here's how the GEMs work, which GEMs you're talking about, and ask if a certain other way would be appropriate. And then we can sit back and look at them and consider updates for the 2011 GEMs. So we hope that this year, we will have even more people using GEMs than previously because we are seeing some recent movement in that area.

To help you do that job well, Rhonda Butler has created a very nice fact sheet that we've included in your handout today. It's called the GEM Files Summary Sheet. It's like a cheat sheet, and you'll find it on page eight through twelve of your handouts this morning.

And obviously, you'd probably want to read the user guides before you use the GEMs, but sometimes you just need a quick reminder of things. One of the most important things it does on page eight of this fact sheet – it's not in

the paper handout, it's in your – the ones online. It tells you when you would use the GEM, this is for like big data projects, and it gives you suggestions of when it's appropriate to use the GEMs.

And it also says when you might just want to open a code book, an ICD-10 CM or PCS Code Book. And that would be – when you have a short list of things or when you're actually coding a medical record. One would want a code from the code books or encoder. One would not want to start coding from the GEMs. So that's helpful piece of information to get you started of when to use the GEMs.

On page nine of your handouts, there's a chart that you're using, the GEMs, you may want to look at. Extremely helpful. You wonder which one of those four files do I want to open, do I want to open the ICD-10 CM to ICD-9 file, the ICD-9 to ICD-10 CM file or the PCS to ICD-9 forward or backwards.

On page nine, you'll see that, the filename of each document. It tells you information about how that file is set up and what it contains. And at the bottom of the page, it gives you recommended use for each of the four GEM files. I think you'll find this extremely helpful.

Page ten of this same fact sheet describes some generic mapping projects, and maybe you can find something that you're going to work on that's very similar to that. And on this page, you'll find out which files you should use and how you should use them. And this is sort of an abbreviation of the 100-page paper we talked about undertaking a conversion project. That was extremely helpful. This gives you a shorthand version to help you remember.

And then the end of the document on page 12 simply gives you some glossary terms that we use in case – so we're all speaking the same thing when we're going through this task. And I think you would find this extremely helpful when you undertake your own project.

At this point, I'd like to ask the audience if any of you have anything you would like to share with us about projects that you have undertaken to convert ICD-9 codes to ICD-10 and any quick lessons you've learned or issues that you'd like to make us aware of. And if so, I would like you to come to the

microphone, because maybe we can all learn from this as we're all undergoing our project or maybe we'll see that there'd be some issues to work on that's from the GEMs that you've identified.

But is anyone here in the audience undergoing any or initiated any project that they'd like to share some of the lessons learned? OK, then I'm going to ask the same question in September, and hopefully, a few more of you will have been brave. We must now have a lot of the payer community here.

Operator, do you want to open the phone lines to see if there's anyone on the phone line that would share anything that they've learned by taking the GEMs and applying them to a conversion project?

Operator: If you would like to ask a question during this time, simply press star one on your telephone keypad. There are no questions at this time.

Pat Brooks: OK, thank you. And now we do have one from the audience.

Female: Just one thing...

Pat Brooks: Speak in to the microphone, please.

Female: Just one thing. Bone up on Access again. If you haven't used it for a couple of years, you know, get out your book because it's sure does make it easier; apparently, you can remember how to import those tables, and link them, and all that stuff. OK.

Pat Brooks: Thank you. There's a good practical tip for you. And just to mention again, and I should've done this earlier, we do have some fact sheets outside on the GEMs that are helpful. And also, I neglected to mention all the red bottles that we have everywhere.

Our CMS staff that are working on the 5010 conversion made these available, and I believe they have the website there too; 5010 will be happening very soon. More than likely we'll be accepting 5010 format next year. So, we have to have it ready so that we can accept ICD-10 codes. So we have bottles

for you to remember that important work that's happening on 5010. So, please, take one or more of the red bottles with you.

OK. Now, we're going to move to probably one of the more controversial topics of the day, and that's freezing of ICD-10 codes. I'm going to go through a summary of what's happened so far, and then what (Donna) and I would like to hear is additional comments from the floor when we're finished. And we would like for you after this meeting to send more comments.

Some of you have said that your thoughts on this are evolving over time. That's good. We've noticed that from the discussions of the meeting and from the comments coming in. But what if has taken place so far is that at our September 2009 Coordination and Maintenance Committee, we had an extensive discussion of whether or not we should freeze ICD-9 codes, and/or ICD-10 codes prior to the implementation of ICD-10 on October 1st, 2013.

People wrote to us afterwards on this issue. Overall, there has been considerable interest in dramatically reducing the number of code updates we do before that implementation period. It was suggested that we reduce those code updates for both systems; ICD-9 CM and ICD-10.

And many of us who have written in representing vendors, rebutters, system maintainers, payers, and educators have told us that if we will reduce those code updates, it would be so much easy to prepare, to develop systems, payment systems. Educational products are hard to update and prepare when the code's changed every year.

So, if you want to read detailed comments from that September meeting, it's in our summary report for that meeting. After the meeting, we have gotten a number of other written comments, and people stop me in meetings when I go places and say that they are very passionate about this issue. Based on that, we would like to tell you the recommendations we hear most commonly, and we would like to raise those today to get your input.

It seems like it's easier to have something to react to, some firm proposal. So, based on the comments we've gotten so far, we are recommending now that our last regular annual update to both ICD-9 and ICD-10 would be made on

October 1st, 2011, so we'd be business as usual for 2011. Then, on October 1st, 2012, there would be only limited code updates for both ICD-9 and ICD-10 to capture new technologies and new diseases.

And by new technologies, we're not going to totally restrict that just to people who are applying for new tech applications, that there's some new surgery, some really important new procedure, then a handful of those codes we would consider too. And if there were new flu outbreak that's only needed for CDC to capture, then, clearly, we need to have a handful of codes like that.

So, on October 1st, 2012, we'll begin the annual process with dramatically reduced number of code updates. And then on October 1st, 2013, once again, the first year – this ICD-10 implemented, we would have a very limited number of new updates once again to capture new technologies and diseases.

We would continue to have our Coordination and Maintenance Committee meetings throughout this time, and any other issues that didn't reach that mark after this group discussion on what's a new technology and new procedure; this would be held until October 1st, 2014. And October 1st, 2014 would be our first regular update for ICD-10 from there ongoing.

Obviously, we have the provision by law that we can make updates to capture new technology in the new technology provision in April 1st, those would continue too. Hopefully, as we are now, many of those are accomplished to the October 1st update. What we think should happen is that we need to come to groups with this issue. And if you agree, then we believe that if the September 15th to 16th meeting this fall, we should all come together again.

And we should all know and agree that we have finalized this issue. We know that there will be a freeze, there won't be a freeze, and we'll know how we're going to implement it so that we can discuss in September how we are going to begin to think about the criteria for this update around interim basis.

So I'd like now to open the floor for those of you to react to this date of October 1st, 2011 being the last major normal update for new codes – ICD-9, ICD-10 then we will open the microphone for those on the phone. And then equally important, we would ask you to send your written comments to us

throughout the fall and early summer so that we can really understand how you feel about it.

I think frequently hearing people make one comment; it has led people to change their minds. So hopefully now we can focus on this kind of approach that we can decide if it's workable or not. So I'll now open up the floor to those here in the room to have their comments if they agree or disagree with the October 1st, 2011 last regular update.

Darrel Regier: Good morning. I'm Darrel Regier from the American Psychiatric Association. And we are in the middle of a major revision of the diagnostic and statistical manual of mental disorders.

We have just released draft criteria on a website on February 10th at dsm5.org. And we'll be having a field trial starting in July of this year. We'll then have another revision based on field trial results going into a second revision or second field trial in July of 2011.

As a result, we will not have our final recommendations for the DSM-V probably until early 2011. So our clear recommendation would be to have the final freeze of the major classification for mental disorders, the chapter S in this case for October 1st, 2012.

The importance of this for us is that we had a complete conversion table (inaudible) as you will for DSM-IV and ICD-10 that was prepared back in about 1995 or so. So it's been sitting, waiting, ready to go for ICD-10 for quite some time. Our expectation is that we will be working with the central office at WHO on the mental health division throughout this time. They, of course, are working on ICD-11, which they hope to implement or approve in 2014.

Our expectation though is that ICD-10-CM will be the procedure – will be the diagnostic code for this country probably for the next 20 years. Maybe not as long as 36 years as ICD-9-CM has been, but our plan is to really have concordance between the proposed ICD-11 major categories and disease names in agreement and harmonization with the DSM-V by about October of 2012.

So, that's what we're working toward. From the ICD standpoint, this would give them really a wonderful field trial for their ICD-11 if we introduced the mental health codes into the ICD-10-CM that essentially will be going into ICD-11. So, it's a strange period of time with the revision of ICD-11 and now the revision of DSM-V being basically in synch.

What would be remarkably helpful is if we could basically hold on the firm freeze of the ICD-10-CM so that we could have this synchronization with DSM-V and then we would have a system that would be supportive of mental health diagnosis coding for probably a couple of decades.

Pat Brooks: Thank you. Do we have additional comments?

Nelly Leon-Chisen: Nelly Leon-Chisen, American Hospital Association. We're very, very pleased that you are considering the last regular update to both I9 and I10 to be October 1st, 2011.

We are hearing that especially payers and assistant vendors are doing a lot of work to get ready, and I think that it would be beneficial for everybody to have a stable system to work with and not have major changes anticipated as we get closer to actual implementation date, because it would mean having to touch all those systems, all those applications all over again, so we're very pleased with your recommendation.

Pat Brooks: Thank you. Linda?

Linda Holtzman: Linda Holtzman, Clarity Coding. I just want to second what Nelly said. I think you've done – I was here for the previous meeting. You're right. It was pretty controversial and there were a lot of comments and I think you've done a good job in balancing the concerns and the benefits to come to this particular recommendation.

I think it's a good idea to have a freeze on both systems at the same time for two years. I know there are people that would like it longer but I don't think that's practical. And I think something shorter just – doesn't give us any benefit of a freeze.

So I think two years is about right. It will make everybody equally happy and equally unhappy. And I would also like to thank you for allowing for these limited updates for new disease states that come to prominence and also for new procedures, because I do think that those types of exceptions are necessary. I don't think we can go two years or three years without having any kind of an update. So I appreciate that exception as well.

Pat Brooks: Thank you. Do we have additional comments?

John Shaw: Hi. John Shaw from Next Wave. I want to echo what Linda said. It's good to have a safety valve for limited updates where it's important and material. And wanted to just add a third category that might fit into there – we don't know but it might and that's new uses of data that uncover problems, particularly in the area of quality indicators.

You know, the kind of things that Pat Romano has been here refining the patient safety indicators. The code that comes to mind is dural tears breaking that out of the complication code. Many hospitals and doctors were not coding that at all and in looking at the real impact on measures that are being suggested for pay-for-performance.

That one code and difficulty in coding was as much as 20 to 40 percent of the entire variation of the entire pay-for-performance metric. And that to me is material, particularly since some of the reform proposals put in value-based purchasing pay-for-performance as much as five percent of the payments.

But again, I totally agree with, if it's material. And so speaking about September, coming up with what might be materiality thresholds and one suggestion is to look at what NQF is doing on their materiality thresholds for indicators.

Pat Brooks: Good point. All right. Next comment?

Laura Powers: Laura Powers, American Academy of Neurology. I want to say that your proposal is great. One of my jobs is to try to – I decided in looking at all this

is, it's important for me to explain to neurologists the changes in the system, you know, new things they need to know about using the coding system.

But what's more important is for me to get them familiar with the languages, the wording of the code so that when they answer documentation that they answer the appropriate wording so that the coders can take it up. And one year is not enough time to do that. I want to introduce it in groups by disease category and I think that your two years is great.

Pat Brooks: Thank you.

Nelly Leon-Chisen: Nelly Leon-Chisen, American Hospital Association. Again, I'd like to address John Shaw's comment about the NQF measures.

I had the pleasure of being part of an expert panel that NQF had convened to try to figure out a plan on how they will convert their measures. And it is a big deal for them to ask the measure maintainers to convert all their measures. And yes, they do rely on the codes but, actually, they were very concerned about their ability to process conversion of all their measures.

So I think there is a recommendation that they're working on, that they will be making public for comment. And in there, they have some timelines as far as when the measures will be converted. And I would say based on the more recent discussions that NQF would probably support an earlier freeze, because just the magnitude of the work involved in having to convert all the measures and take them through the process of public comment and everything, that, in reality, I have a feeling that they would probably not want new codes being introduced or swapped over because it would mean that these measures would need to be relooked at and reworked.

But, you know, I can't speak officially on NQF's behalf but I know that they are very seriously looking at just the workload involved. And I have a feeling that changing the codes any more frequently would work for them. I also had some comments about the other timelines but I'm not sure if you wanted them – to take them one at a time or if you wanted them...

Pat Brooks: Please go ahead.

Nelly Leon-Chisen: OK. The other thing is that not everyone that's involved with codes and code updates is sitting in this room, so I hope that in the proposed rule in the Federal Register this year that you do make mention of the intent or ask for comments for a code-free so that everybody else has an idea where you're headed.

The only date that I would really, really have problems with is having, even a very limited update, the day that we're supposed to implement the new system. And so I'm not sure what it will take because I realize that there are provisions that you have to make for new technology and perhaps there could be an exception where it's kind of like what we do for April 1st updates where you allow the public to provide comments whether there is a need to have an April update for a particular proposal, that you follow that process, because I think it would just be total, total disaster to have everybody get ready, and then the day that we're supposed to go live, who knows, who knows, there's so many possibilities of things that could go wrong.

And just one or two codes that are changed, it would mean a lot of system changes, I mean, not so much for the education part but more for all those automated processes that payers and providers and everyone else has. And it would mean – just like when people were talking about updating their systems to accommodate the year 2000 where every calendar date had to be looked at, someone would have to go through and figure out where those, you know, even limited number of updates would need to be made. And I'm not sure that the field would have enough people available to incorporate all those changes because I have a feeling some of them are going to be scrambling just to meet that date for rolling out ICD-10.

Pat Brooks: So you're suggesting that this committee would help assist with those as we get closer, maybe tighten up the criteria even more?

Nelly Leon-Chisen: Yes.

Pat Brooks: Is that your suggestion?

Nelly Leon-Chisen: Yes.

Pat Brooks: OK.

Nelly Leon-Chisen: Yes, tighten it to the point where maybe we just don't do it. I mean, I think that would be my preference.

Pat Brooks: OK. And also some of you perhaps, maybe by announcing these dates in advance, perhaps we can move up some of those changes so that we don't have, if this might be possible, that we don't have a request for that year if people knew, perhaps. Any more comments? OK. Then, Operator, (Melissa), shall we open up the phone lines and allow them to have some comments?

Operator: Again, if you would like to make a comment, please press star-one on your telephone keypad. There are no comments at this time.

Pat Brooks: Well, great. So after this meeting, you're all going to give this some more thought and then you'll comment to us. And we do intend to make known to the public through several vehicles that we're considering this so that we get a great deal of comment in all this.

And we would like your comments back on if you think that we ought to have a firm decision made by the September meeting so that we can all discuss how we implement whatever we've decided to do.

OK. Next thing we're going to do is we're going to move to the ICD-10-PCS updates. And I will tell you basically that – some of you have seen in our website, we have a place called What's New on our ICD-10-PCS from CMS and on Donna's ICD-10-CM website. And we do have duplicates of the ICD-10-CM files on CMS' website.

Those of you who want to know what changes each year, we won't go through all of those now but I'll just tell you, that website's there. You can look through that and see what has changed. Many of those changes were because we had a new ICD-9 code.

The other changes were because people identified issues that needed streamlining or improving. So I would ask you to look at that. We will now have – turn it over to Rhonda Butler who's going to talk to us about the ICD-10-PCS updates we're considering for 2011. Rhonda?

Rhonda Butler: Thank you, Pat, and hello, everybody in this room and on the phone. I have a few slides for those of you on the phone but they follow very closely the two pages that are in your handouts.

And for those of you who are regular attenders at the public meeting, this is the first time we've done anything like this. This is kind of a dry run at the process of the PCS update becoming a public participatory thing. The announcement Pat just made about the changes that were made for last year, we get public input, we get internal input from CMS and we make those changes and we announce them.

And as you know, we've never talked about what we think we're going to do from year to year in PCS until now. So this is a quickie take on what we're experimenting with for the future. We're all going to have to negotiate this process together, learn how to update it together, learn how to ask for changes and learn how to discuss what that would mean.

And the three changes that I'm going to outline for you here are essentially the kinds of things any of you who are involved in this process, certainly the team at CMS and the team at CDC who implement the change – the annual changes to ICD-9-CM know that the day after you've implemented the changes, you're already compiling the short list of changes for next year. And so this is what you're seeing, things that came in that were too late to make the deadline for the next year.

The first is a proposed change to capture the information that is clinically relevant to ultrasound procedures that are done via the esophagus. Clinically, typically, it's called the TEE in the chart or transesophageal ultrasound. So you're going down through the throat and you're doing an ultrasound of the heart.

PCS currently does not specify that that mode of reaching the heart was performed, so you can't tell whether it's internal or external to the body, whether they were using a probe or whether they were just doing a typical extracorporeal ultrasound.

So the proposal is to add this new qualifier. It will be in the table, in the imaging section for the heart body part. And so that would – when it's added to that table, that would result in – if you do the math and multiply the amount and look at them as separate code description, that would result in eight new codes. And there's the table. And the proposed addition is to add as a qualifier this value that says transesophageal and so then you would have that information captured in the code. So that's how it's done.

The next two are additional codes that we feel are pertinent to the new root operation supplement that was added, not just last year but the year before, I do believe. I'm losing track here. But adding a new root operation to a code system was a very big deal. We haven't done that since it was first – since PCS was first introduced in 1998.

So adding a new root operation was a big process, of figuring out which values, you know, what rule-based criteria we are going to look at for adding, for populating all those tables. And so, in subsequent update cycles, we've been tweaking that, we've been looking at places we missed or places where we overdid it.

So here is one area. The body system J, skin and subcutaneous or subcutaneous tissue and fascia needs to be able to capture this, the type of information that's described by root operation supplement procedures. So soft tissue body parts, the pelvic region is an example of that.

So the proposal is to add this – create a new table, root operation supplement for the body system J, and it would look like this. Now, notice I've, in the slide on – here in the room, I've just copied the slide that's available in your handout and just to save space, I didn't put the entire table on there. There are 12 other body parts that specify the subcutaneous tissues and fascia, of parts of the extremities, upper arm, lower arm and so forth, left and right.

So that's what's being proposed and if you multiply all those values out, you end up with the creation of 132 codes. Hopefully, we'll wean the public of freaking out over the number of codes. Computers handle big numbers now and so you're not memorizing all 132 of these; it's OK.

All right. The third proposed change is a very specific change to one of the tables for root operation supplement that already exists, and this was in response to a public request for – actually, it was a question, you know, how would I code these procedures for scleral buckle where they're putting this plastic deal around the outside of the eyeball to kind of reshape it and treat glaucoma. That is what scleral buckle procedures do, isn't it?

Oh, that's right, retinal tears. Yes. So we're adding specifically the body part of the eye generally to this table. So, a body part that said, just says eye left or right because currently, in the root operation supplement, as you'll see in the table, you have very specific codes for the various anatomical structures that make up the eye, but we needed that eye body part to say that you're putting this scleral buckle on the eye generally.

And so that just adds – several more codes to that table but we're not creating a whole new table in this case. And that is the three general areas where we're proposing changes to PCS so far, and I'd be happy to take any questions. And here's Linda Holtzman. Go ahead, Linda.

Linda Holtzman: You're shocked, shocked, right? Can you go back to the second one? It was about supplements for soft tissue or – yes.

Rhonda Butler: Yes.

Linda Holtzman: I might have missed it, but what – can you give me an example of what would be a subcutaneous tissue or fascia supplement as opposed to a replacement?

Rhonda Butler: How about a cystocele or rectocele repair when they're in the pelvic region body part, they're using mesh to shore up and basically tighten up that subcutaneous tissue and fascia. You're not repairing the female reproductive structures per se but you're in the area around it.

Linda Holtzman: OK. I just want to be sure I could differentiate it because I know – well, I think I know. Like a graft would be replacement.

Rhonda Butler: Exactly.

Linda Holtzman: Oh.

Rhonda Butler: But sometimes, yes, and sometimes graft – remember, the key differentiator between supplements and replacements is that supplement – replacement is replacing a body part.

Linda Holtzman: Right.

Rhonda Butler: It's doing what it's saying. So the old one isn't there in some ways. It's either eroded, it's been burned off, or it has been taken off. This one, you're not taking anything out or nothing has been lost in the original anatomy. It's all still technically there but it needs some help.

Linda Holtzman: OK. So, this would be something like putting in some kind of a mesh?

Rhonda Butler: Right.

Linda Holtzman: OK. And I'm just hesitating on that because sometimes in the documentation, the surgeons tend to use mesh and graft interchangeably, but that's not your issue. OK.

Rhonda Butler: Yes. Well, that's the quandary of the ages, what did they mean when they said what they said.

Nelly Leon-Chisen: Nelly Leon-Chisen, American Hospital Association. This brings to mind a couple of things to consider as we – not specific to this proposal but as we consider what criteria would be used for determining what would be a limited number of updates. And hopefully, we'll uncover all the root operations that we can think of now.

But I think one of the criteria could possibly be, don't create any root operations, no matter what it is, and I don't know, you know, how you'd do that because, I mean, as we can see, even with a little bitty proposal like the

second one, you've come up with 132 codes and that's just by adding one, you know, root operation that was already new and now we're adding a body part and that kind of thing. And you can imagine if we have something like that. Even like the year before, we're supposed to implement ICD-10 and all of a sudden, we got one proposal but it could be a whole new root operation and would create hundreds of new codes.

I mean that's just sort of like the worst case scenario to think about; but it's not just the matter of sort of adding 132 codes into the system. It would be figuring out where those types of procedures were in the application, whether it was an adjudication, you know, medical necessity guidelines, quality measure, you name it. But figuring out what was the code that was used to report that before, where that code is, take those out and swap them in with the new codes.

So it's a lot of work. And so I don't have a specific recommendation for these proposals today, but just sort of having us all think about what would it mean if we would still be able to do major updates. And, you know, limited, major, comprehensive, minor, that sometimes is in the eye of the beholder. So it's just something to think about in terms of, you know, what are we going to call limited.

Pat Brooks: I think that's a good point. We'll make note of that for that separate issue. And additional comments like that this (inaudible), that you want to jot down, that would be really good to discuss in September when we talk about, you know, how we're proceeding forward.

Does any have any other comments on these three particular issues? If not, Operator, why don't we open the phone lines?

Operator: At this time, I would like to remind everyone in order to ask a question, press star then the number one on your telephone keypad. There are no further questions at this time.

Pat Brooks: Thank you, Rhonda. OK, we'll get Donna up here to do her – oh, we have one more comment from the floor.

(Melinda Segment): Hi, (Melinda Segment) from Ingenix. Rhonda, can I ask you one question about something on the 2010 update?

Rhonda Butler: Sure.

(Melinda Segment): We noticed that in body systems R and S which are upper joints in medical-surgical procedures that for the root operation fusion, that we got a new device character and the character value is three which is inter-body internal fixation device. And what we noticed when we were updating the books is that within that same body system or those two body systems, device value three is infusion device elsewhere within the same body system.

And we were just kind of wondering about it because it didn't seem like there were duplication of values within a body system elsewhere in the classification. And so we're kind of wondering about that.

Rhonda Butler: Right. That's – and that was intentional. That's not an error. The fact that devices are not stable within or I shouldn't say stable, but are not consistent with body – within body systems. We should expect that, you should prepare for it in your systems and not have something come up flagged as an error because that is our future.

A body system, a device and a qualifier can be root operation-dependent. It can be body part dependent. It can be approach-dependent. It could be any of those things. That's one of the characteristics of the system is that any of those 31 values in a defined portion of a table can mean what it means.

Now, when the thing was – when PCS was first introduced in 1998, it was basically the rough tables, the basic armamentarium of what you would consider PCS.

And as we get these very specific requests based on ICD-9-CM code updates or specific areas where a value is of use but it won't be used anywhere else, for example, trans-esophageal qualifier on an imaging system, we can't just tuck that value away and say we can't use it anywhere else. That limits our ability to add new values.

Pat Brooks: You know, you make a good point, because we're working on the PCS guidelines, maybe this would be a good PCS guideline that we could work on so that people would just fess up that this is our approach, that we have to reuse these numbers and just be aware and it's because, you know, we need to do it.

Female: Yes.

Pat Brooks: So it's a very good point.

Female: They should be aware of it because it's the first time that we saw when we were putting together the appendixes that show what characters are valid for each body system and it was just the first time that we had to put, well, it could be infusion device or it could be this inter-body internal fixation device, but only for this root operation.

Pat Brooks: That's an excellent point.

Female: Yes and...

Pat Brooks: So we'll look at that for the 2011 guidelines.

Female: So people have to be aware of that for reporting instances also. If they're just looking back at their procedures done on those two body systems that if they looked at that device character, you know, they need to also take into account the root operations for that to really make sure that they understand what 3 really represents, right?

Pat Brooks: OK. We'll take one more comment here before we'll go to phones. Oh, we've already done the phones, OK. Yes, Linda?

Linda Holtzman: Since you raised the issue of the PCS guidelines, I would like to make a suggestion.

Pat Brooks: OK.

Linda Holtzman: I think one of the things that would be very helpful to myself and hopefully other people would be if you had a section in the guidelines that talked about

or gave examples of each of the device characters. You know, when I look at autologous tissue substitute and synthetic substitute and non-autologous tissue substitute, and then I'm actually looking at the chart and I think which one of those is it? And, sometimes, it's not at all clear.

I know that I was looking at infusion characters and I said, "Well, OK, so this is a reservoir and this is a pump. What does character X mean?" I don't know. So, I think it would really be helpful to have a separate section in the guidelines that lists every single device character and gives at least one or two examples of what each of those characters mean, so that you have a better sense for which one of those device characters to choose. Thank you.

Pat Brooks: Thank you for those comments. And perhaps what we'll start doing is adding onto one of our future coordination (events) in this committee as get a little caught up, some discussion, quick discussions of the guidelines as they change. But that's very helpful for us to consider.

OK, now, I think we need to get Donna up here to go through the ICD-10-CM updates. And while she's coming, let me just make one announcement for those of you who haven't seen it.

Those of you were asking us every year, where do – who's doing ICD-10 software books, whatever, encoders, two organizations have agreed to serve as clearing houses to post up information for vendors who will have ICD-10 products available. It doesn't mean necessarily that they endorse them but they're trying to list things in one place.

And one of those is WEDI. You can go to www.wedi.org, Wedi.org. They are listing ICD-10 products. And also HIMSS, the Health Information and Management System Society, www.himss.org/icd9 – I'm sorry, ICD-10. And I'll put both of these in the summary report. But if you're looking for a product, or if you're a vendor here, you've got a product, you may just want to have that listed there so people know where to go look. And now we'll let Donna talk about ICD-10-CM.

Donna Pickett: OK, just a few brief updates. And for those of you who haven't visited the NCHS website – but I have a feeling many of you already have – you know,

we posted the 2010 update to ICD-10-CM and that included changes to the tabular list, the alphabetic index, the coding guidelines, of course, the equivalence maps. We also reposted updated table of drugs and chemicals, table of neoplasms and the index to the external cause of injury chapter.

Now, by way of background, because many of you may not be aware how the changes flow through into ICD-10-CM, not only are we dealing with the ICD-9-CM annual update flowing into ICD-10-CM, but we are also having to deal with the updates that WHO does to ICD-10 itself. It used to be years ago when we were still in an ICD-9 environment, WHO did not make any changes annually to the classification.

However, with the implementation of ICD-10, there is an update process. The meetings are held annually and updates are posted on the WHO website. So we're also having again to deal with the actual WHO changes. And for the first time with the 2008 that we incorporated into ICD-10-CM, it also included codes that were deleted from ICD-10. That actually was a first and that had to do with changes made by WHO to the neoplasm chapter, Changes Related to Leukemia and Lymphoma.

As you can see on this slide – apologies to those on the phone but we will be posting the slides so you'll have this information available following the meeting – the 2008 approvals, there were actually 42 pages of changes to the tabular list and another 52 pages of changes to the alphabetic index. So as you can see, you know, the staff were peddling quite fast because there's a lot of information that's flowing through and the update cycle is separate from our update cycle.

So, staff is actually having to deal with two sets of updates when we are updating ICD-10-CM. And, again, the 2000 update not only included the 9-CM update which was, for two years, the October 2008 and the October 2009 but also the WHO updates.

Addenda, yes, many of you have called; you kept wondering where that addenda was. I see all the heads nodding. We weren't ignoring you, trust me. We were having some issues trying to put together addenda documents that

you kind of know and love, you know, and you're familiar with through the ICD-9-CM process, but also being able to post something on our website that is compliant and that everyone who needs to access it can actually view it in a way that they need to view it.

So, what we have done, our IT people are working with us to get something posted but as an interim measure, I hate saying this, but you can call us. And we do have an addenda that we can distribute to you. Again, we just can't post it on the website at this point but if you want to see the addenda – and, again, it's a change-only agenda – you can contact us and we can make that document available to you.

Two screenshots, one just to show you how the new addenda will look, and again, it still has pretty much the look and feel of what you're familiar with from the ICD-9-CM addenda. The major difference with the tabular addenda is that in the left margin, you won't see revise, add, or delete. There is a legend, however, at the bottom of the page which will give you an indication of what has changed.

And for the alphabetic index for ICD-10 CM, again, this looks like what you normally would see as part of your ICD-9 CM addenda changes.

So, again you know how to contact us, our information is on the Web, it's in the topic package and you can contact us to release the information. And a big thank you to the NCHS staff that worked on this. I know there are some who have seen earlier version of the addenda and it kept being refined until we could get to something that everyone thought was more useful in terms of understanding where the changes were for ICD-10 CM.

I mentioned the WHO update. This is a screen shot of the ICD-10 webpage for WHO. They do have the cumulative changes that began, I believe, in 1996, and that's not shown in this slide, but there's a document that has cumulative changes and it is also the individual year changes that are posted on the website.

When I made this screen shot I had noted to WHO that they had not added yet the 2008 update, but they will be releasing that information and probably

adding the 2009 update, those things that were just approved this past October, shortly.

For the 2011 update, again, the process will be very similar. We will be looking at corrections that people have suggested to us and going through those to see, you know, where there is concurrence and what needs to be changed and as necessary those changes will be made.

We are going to be dealing with the WHO updates once again. At this point we have a draft that has 24 pages of changes to the tabular list and another 25 pages of changes to the alphabetic index. So, again, as you can see, this starts to get to be a rather interesting process because we're having to maintain things side by side.

And also we would be looking to include in 10 CM any of the 9 CM things that will be approved for this October that are not already represented in ICD-10 CM.

Another issue that has come up that I don't have on the slide is, we are beginning to receive requests from people that are interested in providing proposals to update ICD-10 CM that specifically affect ICD-10 CM, they're not something that's flowing through the ICD-9 CM process. And I guess it would be interesting to hear from people, how we should be processing those. In the past, many of those proposals would come directly to us and we would just incorporate them into ICD-10 CM without necessarily bringing them forward to the (C&M) process. And I think we really would like to hear some feedback from all of you as to whether some of those proposals actually should come through (C&M) for discussion, particularly as we talk about things in relation to a freeze. But also just to see for some new, entirely new concepts whether those things actually need a fuller discussion.

And so, if anybody would like to share those thoughts with us, I'd be pleased to have people step to the microphone and provide input for us as we consider how to move forward with some of these proposals.

Sue Bowman: I actually think that that would be a good idea, particularly for a new concept or major changes to be able to get the fuller input. And also it would provide

a better industry understanding as to the rationale of maybe where the changes come from, what the reason behind them is, that kind of thing.

Donna Pickett: OK. Thank you Sue. Any other comments? Operator, could you see if there are questions on the phone line?

Operator: I would like to remind everyone, in order to make a comment press star, then the number on your telephone keypad. There are no comments at this time.

Donna Pickett: OK. Thank you operator. Having nothing else, if there are any questions anyone would like to ask regarding the 10 CM updates, we'd be pleased to try to entertain them or get back to you if we don't have an immediate answer.

OK. I thank you all and let's – we can proceed with the meeting.

Pat Brooks: Thank you, Donna. We'll now move to our ICD-9 CM procedure topics. This is the second topic on your agenda where we will be discussing central venous catheter placement using intra-arterial electrocardiographic guidance.

And we have here today to do the clinical presentation, Dr. Peter Rothenberg, President of PacerView Technologies.

Peter Rothenberg: Well, good morning. I would like to make a correction right off, this is not intra-atrial. This is not intra-atrial, this is an intravascular procedure, principally, an intravenous procedure. Oh, I am Dr. Peter Rothenberg, I'm from PacerView Technologies.

I'm here on behalf of Bard Access Systems and I'm here to request the new ICD-9 code that incorporates magnetic and ECG guidance, placement and confirmation of centro-venous access catheters.

Centro-venous catheters or CVCs are catheters that access large intrathoracic veins that return blood to the heart. Most commonly they target the superior vena cava. The superior vena cava is created by a merger of the right and left brachiocephalic veins. It terminates by merging with the right atrium. This termination point, the caval-atrial junction, will be referred to numerous times during this presentation.

A peripherally inserted central catheter, or PICC line, is a central catheter where the point of insertion is an arm vein, rather than on a more central insertions site such as the subclavian or the internal jugular. As typically performed, a large arm vein is located with ultrasound; a measurement is then taken from the point of insertion to a surface landmark, (the ones that) overlie the distal end of the superior vena cava, usually the third right intercostal space.

The catheter is then inserted to this length and a chest x-ray performed to document the final PICC location. Navigational technologies like the Bard-Sherlock, the (Biosys) Navigator were developed to remove much of the uncertainty of blindly traversing central vessels.

As currently embodied, a stylet inserted into the catheter and a companion component on the chest wall allow a small magnetic field to be detected and tracked. The same surface landmark is targeted. ECG guidance utilizes the display of a continuous intravascular cardiogram and following characteristic changes in the wave forms, the operator may determine the catheter position in the distal superior vena cava relative to the caval-atrial junction.

This technique permits fine-tuning of positioning and is complementary to a navigational system. If this is your patient, PICC lines the way they are traditionally performed, you identify a vein in the arm with ultrasound. You then take a measurement from this point of insertion to a surface landmark thought to overlie in the distal end of the superior vena cava, usually the third right intercostal space. You then insert the PICC line to that length, take a chest x-ray to document your final PICC position.

With the advent of navigational technologies, you now take a stylet with a small amount of magnetic substance at the tip. You insert the stylet into the PICC catheter, the tip of the stylet and the tip of the catheter are aligned, and you then insert the two of them together up the arm in the area of that surface landmark. That magnetic substance can be detected in the case of the Bard-Sherlock, by the sensor on the chest, and the position of that magnetic substance can be detected on a bedside monitor.

In the case of the ECG guidance, you are now acquiring a continuous cardiogram from the tip of the catheter's stylet. That continuous cardiogram is also displayed on a bedside monitor. The operator – the operator will follow these characteristic wave forms and then make the appropriate changes in his catheter position. Catheter tip location is so important because the incidence of catheter malfunction and complications is dependant on the distance from the caval-atrial junction. This relationship applies whether the catheter is placed too short or too long.

If the catheter is too short, the risk of catheter malfunction increases with the distance from the cavoatrial junction to greater than 80 percent, and the risk of catheter-related complications increases almost twenty-fold. If the catheter is too long and the catheter enters the atrium, there's a risk of atrial perforation and catheter-related thrombi.

Current guidelines are to place the tip of the central catheter in the distal third of the superior vena cava up to and including the cavoatrial junction. Chest x-ray is the current community standard for documenting cavoatrial junction placement. Paradoxically, chest x-rays are incapable of visualizing the cavoatrial junction.

The superior vena cava would appear to terminate where the shadows of the mediastinum and the right heart (border) meet. In actuality, the cavoatrial junction lies one to three sono-meters below that junction point and it's hidden within the cardiac silhouette. Furthermore, patients who were ill enough to acquire a PICC line commonly don't have such sharply demarcated borders.

Radiologists also don't do very well at interpretation. One study looked at 212 central catheters. When the catheters were placed, they then did chest x-ray and they also did transesophageal echocardiography or TEE to actually document the true location. Then they showed the x-rays to a senior radiologist with more than 10 years experience and two fifth-year radiology residents.

And what they found was, when the catheter tip was actually in the atrium, three out of five were missed by the senior radiologist. When the radiologist

told you the catheter was in the atrium, he was wrong 86 percent of the time. They also showed that interpretive accuracy was highly dependent on the experience of the radiologist.

So that when the catheter tip was within the atrial silhouette on chest x-ray, but shown to be outside of the heart by transesophageal echo, a senior radiologist was able to use his experience, other radiologic markers to correctly conclude 94 percent of the time that the catheter indeed was outside the heart whereas radiology residents were accurate only 52 percent of the time.

Navigational technologies are particularly useful in detecting aberrant catheter course during placement; however, for final tip location, they rely on surface landmarks. ECG guidance rather than using shadows of anatomic structures on film or inferring internal anatomy from surface anatomy detects a biologic structure and has been shown to be comparably accurate to transesophageal echo.

Numerous studies have documented the accuracy of the ECG guidance. One study took 60 patients in need of central catheters; 30 head catheters placed with ECG guidance, 30 head catheters placed using standard surface landmarks. Once all catheters were thought to be correctly positioned according to their respective techniques, transesophageal echo was performed to document tip location.

Satisfactory placement was defined as within one sono-meter of the cavoatrial junction and what they found was a 100 percent concordance between ECG guidance and transesophageal echo whereas surface landmarks were only 53 percent accurate.

So what is the rationale for ECG guidance? The heart is a muscle. And like any muscle, it's innervated by an electrical impulse. Although almost any of the heart muscle fibers could initiate the impulse, under normal circumstances, it originates in the SA or the sinoatrial node which is a specialized cluster of cells that lies at the cavoatrial junction.

This is your superior vena cava. The front of the atrium is opened up like a door. This is the atrium here. This is the orifice of the SVC where the SVC enters the right atrium and your SA node sits right at that junction. Once the impulse is created in the SA node, it travels down through the atrial tissue into the ventricles to stimulate the heart to contract.

These impulses repetitively travel along a well-defined and orderly path and it is this travel that is mapped by an electrocardiograph. So when the impulse leaves the SA node, it starts to depolarize the atrial tissue, creating a P-wave on your cardiogram. When it depolarizes your ventricular muscle, it creates a QRS on your cardiogram.

Here's your cardiogram. The impulse leaves the SA node and shortly thereafter as your atrial tissue depolarizes, your P-wave is created. When it reaches your ventricles and your ventricular muscle is depolarizing, it creates your QRS. This electrical impulse can be detected by electrodes either on the surface of the body or from internal electrodes within the body, usually in a heart chamber or a blood vessel.

Since the impulse moves from one point to another – we use pairs of electrode to look from one point to another. Bipolar leads look from one point to another and they are the basis of ECG guidance. Standard bipolar leads are created by pairing together two of three standard surface electrodes. You may be familiar with these if you go to your doctor and you get a cardiogram.

Lead one looks from the left arm to the right, lead two from the left leg to the right arm, lead three from the left leg to the left arm. The lead one is looking – the electrode one is looking from is considered the positive. The electrode one is looking toward is the negative.

The Bard product, the Sherlock 3CG TPS system uses a modified lead two bipolar system, looking upwards from the left leg towards the tip of the stylet. The left leg serves as your positive. The tip of the stylet serves as your negative.

Since the SA node sits at the entrance of the right atrium, this chamber really has a built-in tip location system. Now, ECG guidance only works in patients

with an SA nodal rhythm. It does not work in patients with atrial fibrillation. It does not work in patients who are pacemaker-dependent. It does work in patients who have a pacemaker, but are not dependent on it for their rhythm.

So if you take a catheter and you advance it through the superior vena cava toward the SA node, multiple data points for the size and shape of a P-wave are required. As the tip passes the mid superior vena cava, the U shape of the P-wave becomes spiked and dramatically increases its voltage. This is the proximal superior vena cava. You have a U-shaped P-wave about three tenths of a millivolt.

As you pass the mid-superior vena cava, it begins to elongate and becomes frankly spike-like and reaches its maximum negative deflection opposite the SA node at the cavoatrial junction. This is a continuous trip that takes us from the proximal superior vena cava through the right atrium into the right ventricle. Here you are in the proximal superior vena cava, U-shaped P-wave.

As you get into the second quarter of the superior vena cava, it begins to increase its voltage some. Passing the mid superior vena cava, it becomes obviously spike-like and reaches its maximum negative deflection opposite the SA node. This here is atrial entry and this is right ventricular entry.

So imagine that you're sitting at the bedside and you're advancing your catheter. You are acquiring a continuous electrocardiogram from the tip of your catheter. This is what you see. Here's your P-wave. As you enter the second quarter of the SVC, your P-wave starts to increase its voltage a little bit. Passing the mid SVC, it becomes obviously spike-like and it reaches its maximum negative deflection opposite the SA node.

This little nubbin here tells you that you're now entering the right atrium. Current ICD-9 codes do not address the component procedures of this technique. There is no ICD-9 code that refers to use of a magnetic navigational system for central catheter placement. There is no code that refers to the acquisition of a continuous intravascular cardiogram.

Code 8952 does refer to a continuous cardiogram, but appears to refer only to a surface-derived cardiogram, not intravascular. There's no ICD-9 code that

refers to monitoring P wave morphology from a continuous intravascular cardiogram for the purposes of central catheter placement in the distal SVC or the cavoatrial junction. So, therefore, the following ICD-9 code is requested: magnet and ECG guidance of central venous access catheter placement and confirmation.

So, in summary, today's current practice is to place a PICC line by accessing a peripheral vein and then threading the catheter. In lieu of a navigational or ECG guidance system, distance to the superior vena cava and the cavoatrial junction is estimated by taking measurements from a point of insertion to a surface landmark.

Navigational systems generally guide the user to the same surface landmark. And because of this, their accuracy may be as low as 50 to 60 percent. ECG guidance improves this to 90 to 100 percent. Compared to the current community standard of chest x-ray, no radiation is involved. ECG guidance is objectively definable and is not subject to patient habitus, variable chest x-ray quality, or a radiologist's interpretation.

ECG and magnetic guidance each give placement information immediately and in real time rather than waiting for a chest x-ray to be developed. ECG and magnetic guidance technique saves x-ray technologist's time in taking the image, the radiologist's time in interpreting the image, transcription time in typing the report, information technology in storing the image, and so on.

ECG magnetic guidance may help to avoid many types of (inaudible) placements in real time. So, finally, there is no ICD-9 code currently available that describes either the individual components of this procedure or combination of these components of this central catheter procedure. Thank you.

Pat Brooks: We'll go through the coding options and then we'll provide people a chance to ask questions, clinical and coding. I'll mention, first of all, that if we have no new technology application for this, and that the procedure is FDA-approved. Now, we'll look at the current coding. Currently, the codes you would use to

capture this procedure would be two codes, 3893 for the venous catheterization, and 3852 for the electrocardiogram.

We've developed two options for you to consider. One option would be not to create a new code and to continue assigning codes 3893 and 8952 to capture this procedure. Option two would be to create a new code, and we show you new code 3897 with the code title, electrocardiogram-guided central venous catheter placement, and that's different than the one the doctor mentioned.

Our recommendation would be to go with option two and to create new code 3897. And in the interim, you would continue to assign codes 3893 and 8952 to capture this procedure. Now, I'll open up the microphone to those here who would like to either ask a clinical question or who would like to comment on this proposal, if you would just please come to the microphone.

John Shaw: Hi, John Shaw from Next Wave. I had a question on the presentation. You indicated that proper placement can reduce complications by 20 times or something to that effect. Which complications are in that?

Peter Rothenberg: The risk of complications has been shown dependent on the distance from the cavoatrial junction. It's principally venous thrombosis so that as your catheter is more proximal than 6 centimeters from the cavoatrial junction, meaning that if your right atrium cavoatrial junction is here and you are now up here higher in the chest, if you are more – if that distance is more than 6 centimeters, the risk of venous thrombosis in that subclavian vein can exceed 28-plus percent.

John Shaw: Thank you.

Pat Brooks: Do we have any more comments or does anyone support any of these options? If you do, could you come to the mike?

Tien Langlee: Tien Langlee from the University of Maryland. I have a question. Is this always done by this PICC line or is support also done because we have two types of codes? We have – one is for the port vascular access v-line; the other one is for central v-line. If these particular procedures only done by central

venous line, do we use 3897 for new code or there is not a code out for the port placement?

Peter Rothenberg: That's a trick question. ECG guidance has been used with all different kinds of central catheters including port central catheters and PICC lines. Magnetic technologies have been used with PICC lines. To my knowledge, they're not used with other types of implantives or others.

Tien Langlee: So, if you're going to update this code 3897, what if my doctors decide to do the port for this – I think it's EGC...

Peter Rothenberg: ECG.

Tien Langlee: ECG, so how are we going to report that?

Peter Rothenberg: Yes. Well, the bigger problem will be how he'll perform that. If you don't use the Bard technology which will be a combined magnetic-ECG guidance system, it's difficult in this country to do ECG guidance. In Europe, they're using ECG guidance with a proprietary catheter, but that's ECG guidance alone. That technology is not available in this country.

Tien Langlee: Thank you.

Pat Brooks: OK. We have no other comments right now, so why don't we open the phone lines for questions and comments? Operator?

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad. There are no comments at this time.

Pat Brooks: OK. Then I will look forward to receiving comments, after you think about this, in writing. And so please do write to us by April 2nd. Thank you very much. We will now turn the podium over to Ann Fagan who has several procedure code topics to begin.

Ann Fagan: Well, good morning. If you printed out your handout paper, we're going to talk about page 17, the closed chest intracardiac mitral valve repair. And

basically – now, those of you who’ve been with us awhile know that this is not the first time we have touched on this. Hopefully, it will be the last.

OK. Basically, what we’re talking about here is that the procedure provides a minimally invasive closed chest repair of mitral valve in order to reduce mitral valve regurgitation. This is a catheter-based approach and a unique code for mitral valve identification is being requested. This is not new technology. The Food and Drug Administration pre-market approval is planned for the end of the first quarter of 2010. So, actually, the timing is right in terms of code creation.

It is expected that the technology for this particular device named MitraClip and marketed by – well, never mind that part – will be reviewed by FDA in the Circulatory Systems Advisory Panel in mid-2010, and the PMA approval is expected in the first half of 2011.

All right. It is my pleasure to introduce Dr. Scott Lim, Virginia Children’s Hospital Center at the University of Virginia Medical Center, and he is an associate professor of pediatric cardiology.

Scott Lim:

Good morning. It’s my pleasure to be here. And as Ann said, I’m going to share with you from a clinical standpoint my experience in closed chest intracardiac mitral valve repair with a MitraClip system, and our experiences as we have worked with this technology.

So what we’re talking about when we say this is a disease of mitral regurgitation. The mitral valve is a valve on the left side of the heart right here. And regurgitation means leakage of that valve, and that can be either due to the muscle of the heart is weak and doesn’t have the strength to properly close that valve or that valve is fundamentally abnormal and because of it, it leaks.

So with each heartbeat, some of the blood, rather than being ejected out of the heart, leaks backwards to the lungs, causing symptoms of shortness of breath. Traditionally, we found that medical management with medicines is not effective for this condition as the disease is progressive, unfortunately.

Surgery, open heart surgery is definitive but invasive, and due to its invasive nature, oftentimes is delayed or not offered particularly in the high risk elderly patients, resulting in decreased survival for these patients and repeated hospitalizations for heart failure.

So, mitral regurgitation or MR is shown here, what ends happening, the increased amount of mitral regurgitation causes more blood to leak backwards and less to be ejected forward. The heart trying to compensate for that remodels, and unfortunately, remodels in a poor way, becoming dilated, decreasing the amount of blood being ejected forward, decreasing the cardiac output.

The patient then has increased symptoms or NYHA functional class, and decreased quality of life with increased hospitalizations. Medicines try to address this. However, as we just said, medicines are essentially just band-aids for this and don't halt the progression of the disease, leading to a significant cost to our healthcare system.

Surgery on the other hand will address this, decreasing the MR and in turn causing the heart to remodel in a beneficial fashion, improving the quality of life and symptoms for the patient. However, as we said, because of its highly invasive nature, surgery, while it might be optimal for a relatively young person, for the elderly and many other patients that constitute a significant part of this population, is not offered to all of them.

So the mitral clip, as I'll show you in a moment, because it's less invasive, it goes through a catheter, a small incision on the leg, tries to do the same thing that surgery does to repair that valve as a less invasive alternative.

Now, how we do this? This is an example of the mitral clip where this part here is the clip that's inserted on the leaking part of this mitral valve. The clip is at the end of the catheter. However, to get that there, to the appropriate place is a very labor-intensive procedure.

And so, this is how I do it in my hospital for my patients. We use general anesthesia with continuous monitoring throughout the case. We also use

continuous TEE or ultrasound guidance to place that clip in the exact right place.

This is all done in real time or the heart is beating. To do that, we do a standard catheterization and then a non-standard transseptal puncture, which I'll show you in a moment, to gain access through a wall of the heart, to the left side of the heart.

We then use that ultrasound to guide the mitral clip to the appropriate place in the valve, to place it on the valve and to assess the efficacy of its placement before then deploying it in recovering the patients.

To do all this, we have number of physicians involved. Those are – they're actually scrub (inaudible), the cardiac anesthesiologist, and as I've mentioned, a cardiologist specializing in the ultrasound to do that, as well as all of our nurses and other staff in the cath lab. It's actually done in many places more and more in what's called the hybrid room which is a combination of part cath lab, part operating room.

So, this is an example from just one patient we did that one long ago. And she was 88 years old. She was seen by both myself and one of our cardiac surgeons. And we were both concerned. She was quite symptomatic and quite frail, but she was not a good candidate for the standard open heart surgery. So, this is a picture of an echocardiogram. The color is leakage, significant leakage from her mitral valve.

The MitraClip procedure involves four-key steps and I'll go to them one by one. And a hallmark of all of them is that they are guided, unlike any other procedure we do just about, by ultrasound during the procedure. It can even be compared to an open heart surgery where we do ultrasound before and after. This involved – these pictures all the way through it. This is the heart. This is the left atrium. And this right here is the mitral valve. And when we add on the color, it shows us exactly where, beat by beat, the valve is leaking.

And then, we can work to go ahead and place the mitral clip just on that point of leakage there. As you can see, these are two-dimensional images and we used multiple two- dimensional images in our brains to put forth a three

dimensional image of where we need to place that clip. And the first step is to gain access to the left side of the heart. There's a wall in this plane, and we're doing what's called the transseptal puncture where we have a catheter with a needle at the end, and we're puncturing to place our clip in the left side of the heart.

We have to do that in a very precise position to allow this mechanical system controlling the clip to work properly. So, we're using the ultrasound to visualize. This is the transseptal puncture needle coming across. And we want to make sure the right position relative to that mitral valve, which is where we want to place the clip.

In order for this mechanical system to function appropriately, it has to be lined up just so, it has to be at certain height above that valve. And that's what they're doing right here is they're measuring that distance. And as I said, not only in the procedure, they have the MR physicians, myself, with hands on the catheter controlling the clip, we've got a physician doing – who's solely dedicated just to doing these measurements and helping us with ultrasound to guide the procedure.

Once we're in the right position, we can go ahead and advance that transseptal puncture catheter across to the left side of the heart. Then, in order to place the mitral clip, we have to put out a stiff wire, which is what you're seeing here. We dilate up that wall, the hole that we just created. So, therefore, then place a very stiff wire all the way across in our – on that stiff wire, we place this 8 millimeter diameter steerable guide catheter to the left side of the heart.

And through that, we can then safely, carefully introduce the mitral clip. This is an ultrasound picture watching as we do that and we place that steerable guide catheter in that position above the mitral valve.

The next step is to steer and navigate the mitral clip to the origin of the mitral regurgitation. And these are images showing us introducing this black catheter with the mitral clip at the very end of it and it's locking into place in this mechanical system. We have all these other knobs to help control the direction of that catheter. And this is an ultrasound picture of us, you know,

introducing out the catheter with the mitral clip into the left side of the heart above that mitral valve.

As you can see, traditionally, we use a lot of fluoroscopy in the cath lab, which doesn't show us the structures. So, this procedure is complicated by using much more ultrasound there. And then we can angulate the catheter as shown by this model here. So that we're trying to place the mitral clip right on the point of leakage and make sure that it's parallel to the leaflets in the mitral valve so it grabs appropriately and securely onto the mitral valve.

Compared to many of the more standard procedures we do in the catheterization laboratory, this is by far a much more complicated and labor-intensive procedure in order to do something like this which is really unique.

So at this point here, we're angulating that catheter a bit more so it will now be paralleled to – well, the valve and to – we use ultrasound to show where the leakage of that valve is. Once we have it parallel with it, we could then advance the whole system farther in to the patient, as you can see right there. So that is now positioned appropriately above the valve and above the leakage.

The next step here is to go ahead and open up the mitral clip. It has two arms for grabbing the two leaflets of the mitral valve. Once those arms are opened up with the next step, which I'll show you here, is to orient them so each arm is positioned appropriately to grab both leaflets. And we do that, again, by ultrasound guidance right here. You can see it. It's fully open. Those arms are positioned above each leaflet to grab it.

The next step is to say, all right, are we angulated or are we – we look at the leaflets in a different view by ultrasound to make sure that, again, we are lined up appropriately. And then, it can – if we're not lined up appropriately, adjust the catheter which is controlling that mitral clip on the end so that each arm is above the leaflet appropriately as seen here in this model, in here in that same patient.

Once we like it, we can then advance the MitraClip across the leaflets. We change the angle of those two arms. And the next step is to go ahead and

grasp the leaflets at the point of leakage. Then we do that by pulling back on that handle and adjusting that the arms in the mechanism of that mitral clip.

And here's a fluoroscopic view showing the exact same thing happening right there. And then we used the ultrasound to say, are – did we grab it in the right place? And as you can see here, did we reduce or eliminate the leakage from that mitral valve? Which in this case, we did. And if we like it, great; if we don't, we can adjust and move the mitral clip a millimeter one way, a millimeter the other way.

And the final step is once we're happy with its position, is to go ahead and deploy the mitral clip device which goes through a series of unlocking steps to release the shaft of the catheter from that mitral clip, making – leaving it as a permanent implant for that patient. Here, we're unscrewing the shaft to the catheter from that clip.

And we'll show you what that looks like in this model here, and then show what it looks like actually in the real patient once we release that and that becomes a permanent implant there. Then we reassess again, did we do this adequately, do we have any residual leakage in this particular patient's case? And the answer is no. What we've done now is clip the central part of the valve leaflets right here together so that there's no more leakage there. And these are the before and the after pictures in that same patient.

So, there has been a growing body of clinical evidence as we've used the MitraClip in a series of research trials, from the very first feasibility trials to a randomized trial to a separate registry for high-risk patients in (continued) access. There is now been over 1,100 MitraClips procedures performed to date.

The initial data that came out from the feasibility trials, we've now had published in peer review journals looking at its safety and found very encouraging – more than 90 percent freedom from major adverse events. And this is also encouraging because this is a very novel procedure with a lot of learning going on.

The patient, how they're benefited, and this is a chart showing their symptom class. Meaning, this is a baseline before the patients got their MitraClip procedure, and more than half of them were severely symptomatic from heart failure. Then following these patients out 12 months, over 90 percent of them were minimally or not symptomatic at all, meaning, that they sustained a significant clinical benefit from that MitraClip procedure.

We also created a separate high-risk registry for those patients that were felt to be so high risk that they were not good candidates for the regular open heart surgery. And what we found when we looked at those patients is that they were so high risk that for every patient we calculate, what would be the risk of mortality, of not surviving having a regular open heart surgery and that was in a group of the high-risk registry, over 18 percent.

We also looked and compared to our control group, medically treated, and their actual mortality following the MitraClip procedure was significantly less, less than eight percent. And comparing them to a medically treated control group, following them out a year, we found that they did better in terms of survival at a year than those patients who just got the traditional treatment of medicines alone.

Also, following these patients for the 12 months after their procedure, we found that we had a significantly decreased rate of repeat hospitalizations for heart failure. So all this data was, from a physician's standpoint, it was very encouraging for this difficult-to-treat group of patients.

So what we found, to date is that the MitraClip therapy offers safe and reproducible results even and especially in a very high risk population of patients from this very novel procedure. Those patients benefited in a number of different ways, and it worked for both patients with functional as well as degenerative valve disease (of the) mitral valve.

Our surgeons too are – we do this together with our surgical colleagues, and one of the things that's very gratifying too is we feel that this isn't burning any bridges for those patients in terms of future surgical option.

So with that, I'd like to conclude this and thank CMS for considering a new code to better reflect this very novel procedure that I think is benefiting all of our patients.

Ann Fagan: OK. Not unfortunately, but when this company came in to present to CMS, I – that's the unfortunate part, I wasn't here. But I have a question. So once the clip is in, it stays in; there's no removal?

Scott Lim: That's correct. This is designed to be a permanent implant for the patient. So, if this goes in and works well, it's stays there for the rest of your life.

Ann Fagan: I'm anticipating your request for removal codes, OK? OK. Let's talk about, yes, let's talk about the current coding. So, obviously, we don't have one for a closed – catheter-based closed chest repair of the mitral valves, specifically, mitral valve. Therefore, code 3596, Percutaneous Valvuloplasty, is recommended, which is consistent with instruction that is published in Coding Clinic for ICD-9-CM, third quarter of 2004, page 10.

So, the coding options, you know, we always do – coding option number one is not to do anything. So, basically, that's option one; don't do anything; don't create a new code, instead, use the available code.

OK. So, option two is to create a new code to describe the procedure making it very specific to the mitral valve because that's what we have today. Will there be other valves that can be repaired in the catheter-based technique?

Scott Lim: There certainly will be other ways to repair valves and other technologies coming down the line. Yes.

Female: OK. Coming down the line, which is why we're only going to do mitral valve today. OK. So, the recommendation then is at Category 35.9, "Other Operations on Valves and Septum of Heart," is to create a new code at 3597 for endovascular mitral valvuloplasty.

Glancing up one line, you can see that we would take – an excludes term to code 3596, excluding it from that code, and our recommendation is to create a new code as described in option two with corresponding changes to Code

3596. But then, of course, in the interim, we have to use 3596, Percutaneous Valvuloplasty; and so we create the new code if we do so. So, do we have any comments, either for myself or for Dr. Lim?

Female: I actually have a question of – what’s wrong with 3596? Is it mainly that it doesn’t specify which valve? I mean, it’s still a percutaneous procedure, right?

Scott Lim: 3596 is for a percutaneous procedure for a different disease process, and you’re doing an entirely different procedure. It’s done at my institution on an outpatient basis. It’s done for rheumatic heart disease; it is mainly affecting the mitral valve as the most common indication. And this is something we don’t really see anymore in the United States. So...

Female: But you could pick up the diagnosis off of the diagnosis codes, we typically don’t make new procedure codes for different diagnosis. And, I guess, the question then is, if we’re going to split it out on the basis of the valve just like we do on the open procedures, why not have codes for aortic valve, pulmonary valve, or are you saying that all the other valves then would remain at 3596?

Scott Lim: No. Those are different – entirely different procedures. So, with a balloon mitral valvuloplasty...

Female: Well, the balloon is not – it’s an inclusion term under 3596, but it’s not required for 3596. I guess that’s why I’m saying, is it’s just a percutaneous valvuloplasty. So, I guess, you know, it’s not necessarily that you have to have a balloon (inaudible) 3596.

Scott Lim: As a physician in the United States doing that procedure, that’s the only way it is done. There is no other option in the United States. And it’s done – from my standpoint, it’s entirely different. This code, in my understanding, is trying to look for how do we describe what is now a novel and entirely different procedure? And that’s why I think 3596 does an injustice for describing what’s just been done for my patients.

Female: OK. And I guess as a coder, I'm sorry if this sounds a little bit too basic, but what makes this procedure novel? The fact that there is no balloon and it's on the mitral valve? Or...?

Scott Lim: No. This is novel because it's for a different disease process.

Female: Right. Then let's take out the disease process because I – you know, as a coder, I sort of see it as being a diagnosis code.

Scott Lim: It involves a permanent implant of a device into the patient...

Female: And the other ones are not permanent?

Scott Lim: Currently, yes, there's nothing – the balloon goes in for about – and I inflate it for about five seconds and I take it right back out.

Female: So they don't leave anything behind?

Scott Lim: Correct. And we don't use general anesthesia, we don't use all these other things that we normally use, and it's a much quicker outpatient procedure.

Female: OK. I think also if this goes through, the excludes note under 3596 should stay excludes; and the vascular mitral valvuloplasty, because there is another code for open mitral valvuloplasty.

Scott Lim: Yes. Yes. Thank you. I should've – I forgot to point out something or say something being I don't have any equity or stock in the companies involved in this. I'm simply here as a physician who thinks that this is a great idea for something – a new code for this for my patients.

Keith Allen: My name is Keith Allen. I'm a practicing cardiovascular and thoracic surgeon in the Mid America Heart Institute in Kansas, Missouri. As a disclosure, I'm a clinical advisor (with) the (Abbott). I'm also a principal investigator in the Edwards Percutaneous Aortic Valve Trial, otherwise known as the (Partner) Trial.

I come here really to applaud CMS for addressing this issue head on. As we've gotten more knowledgeable over the last decade about valvular heart

disease, the way we manage this process has become more complex. Unfortunately, our patients have gotten sicker and older and more challenging to take care of and more expensive.

You're going to see in the coming years new technology that is less invasive that will allow us to treat a larger population of patients that would otherwise be denied therapy. And the current codes don't accurately reflect that treatment.

These codes are based on technology and practices that surgeons implemented decades ago. And so, the fast pace of change that we're seeing in this percutaneous endovascular technology, it's really crucial that CMS, as they are doing, recognize that the current codes are inadequate, and I just simply want to applaud you for being proactive on that measure.

Ann Fagan: Thank you, Dr. Allen. Linda?

Linda Holtzman: Linda Holtzman, Clarity Coding. I'd also like to just mention before I say anything else that I sometimes do consulting for Medtronic including their cardiovascular division which does make devices for valves.

I have to say that I really like the idea of creating a new code for this procedure. And I like putting it at 3597, but I hate that description. There's two parts of it I hate. I hate the part that says endovascular...

Ann Fagan: Can I interrupt? You know we're generic...

Linda Holtzman: Yes, I do. Yes. I don't like the word "endovascular" and I don't like the word "valvuloplasty." Other than that, mitral is great. The reason that I don't like "endovascular" is because I don't think there's enough of a clinical distinction between percutaneous and endovascular. I think – even the gentleman before me who was a physician himself used the term "percutaneous" to refer to this procedure. And the procedure reports that I read for this procedure, I see "endovascular" and I also see "percutaneous." And my understanding of the distinction between "percutaneous" and "endovascular" really has to do with how are you accessing the vessel.

If you just do a puncture and everything goes in through that puncture, people tend to say, “That’s percutaneous.” If you have to do a great, big hunking cut down so that you can get some fat catheter in there and, you know, a delivery device or a delivery system for a large device, then people tend to refer to that as endovascular. But it’s not consistent, just, you know, as we just saw.

Also, there’s like an evolution too, many procedures, many of these vascular procedures, at least in my observation, they start out as endovascular, and the catheters are fairly large. And then over time, these catheters get smaller and smaller and smaller and they become what you would consider a percutaneous procedure.

So, to me, to make the distinction here between percutaneous and endovascular really is a false distinction and one that won’t serve us well within a year or two years. So I don’t quite know yet like how I’d word it but I don’t believe endovascular is the way to go.

My other concern is with the word “valvuloplasty.” And I take Nelly’s point that you are doing a repair on a valve. And I know the coding clinic that says, “You know, we’re currently using 3596 for valvuloplasty for this.” But I really do feel there’s a huge difference in these procedures. One is using a balloon, and the other implants a permanent device, and those are usually different techniques.

And if we use the term “valvuloplasty” to refer to – in other words, valvuloplasty to me is too big, too broad a term here. It creates too big a bucket. You can start putting any kind of valve repair into valvuloplasty. If it doesn’t have another code, just put it in valvuloplasty. It degrades the data because you won’t be able to make distinctions between these very different types of devices.

I also think that it’s worth – I’m almost done here. I also think it is worth noting what’s coming down the pike because there are many endovascular percutaneous valve procedures including valve replacements that are being done endovascular, percutaneous techniques, and you’d hate to see all that get mashed into this as well.

So I'm kind of thinking maybe something along the lines of – well, first, I would like to see 3596 revised to really be specific to balloon valvuloplasty, and then to create a new code, 3597, something like, you know, percutaneous insertion of valve repair device or something like that which would make a much clearer distinction between what these two codes are. And I think I'm done.

Scott Lim: Thank you. I think those are very excellent points. As a physician doing these procedures, I wholeheartedly agree with everything you said.

Linda Holtzman: You're the first one (to wholeheartedly say that).

Ann Fagan: OK. We'll take one more question from the floor.

Carlos Ruiz: My name is Carlos Ruiz. I'm a pediatric cardiologist from NYU, and I'd like to, first, make a follow-up comment to the previous comment. Perhaps we should use the word "transcatheter" because it really doesn't make any difference whether you put a catheter through the chest or through the groin and whether the incision is one millimeter or two millimeters. So I would probably perhaps suggest using a different word that explains that.

But I really applaud CMS for taking the steps into getting a new code. And I see – first of all, I have no disclosures pertaining to any company so I just want to make clear to that. And it's important in today's age where the cost of medicine is escalating to an incredible pace.

We are doing a lot of things that we don't know really if they are worthwhile doing or not. And my point is that we need to follow and track outcomes. And if we want to track outcomes in a longitudinal way, we must know in detail what that procedure entails and we need a code to really specify what was done so that we can track whether that procedure was worth or not. And I applaud CMS for doing that because I think it's the only way that we will achieve that. Thank you very much.

Ann Fagan: Thank you for your remarks, Dr. Ruiz. Now, we do have some time constraints today. We have a lot of topics to get to and we have to go, you know, back and forth through the phone. So I'm afraid I'm going to have to

cut off the comments on this section. But if you will please look at the website.

There are the addresses that you can e-mail your comments to all of us, any of us. Start with Pat. She'll distribute them as appropriate, and we can go from there. Operator, can you open the phone lines for any questions or comments?

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad. There is a comment from Gorav Ailawadi. Your line is open.

Gorav Ailawadi: Yes. This is Gorav Ailawadi. I'm one of the surgeons that works with Dr. Lim from the University of Virginia. And I wanted to reiterate what he said. I do think this is a much different procedure, much more complex than a balloon valvuloplasty. It requires a fair amount of expertise and then, certainly, leaving the device in is a distinguishing factor.

We have seen quite a bit of benefit especially in the high-risk group of patients that really we don't have any good surgical option or if we do put those patients with a standard open surgical approach, they have a high mortality.

Ann Fagan: Are there any more questions on the phone line? Comments? OK, thank you very much.

OK. Since I'm up here, we'll just go the next topic which is the thoracoscopic cardiac ablation procedure often known as maze. And we know, we've seen this one before, too. So, it is my pleasure to introduce Dr. Andrew Wechsler. He holds the Stanley K. Brockman chair at the Department of Cardiology – I'm sorry, Cardiothoracic Surgery, Drexel University, College of Medicine.

Now, the issue here, the maze procedure can be performed by open thoracoscopic or endovascular approaches. The question is, should a new ICD-9 procedure code be established to distinctly identify the thoracoscopic maze procedure differentiating between the three of them? Is it new technology? No. Is Food and Drug approval required? No. No, that's not applicable.

So, I will give this to Dr. Wechsler, and he'll tell you all about thoracoscopic maze.

Andrew Wechsler: Hello, good morning. As the slide says, my name is Andrew Wechsler and I'm a practicing heart surgeon in Philadelphia. And I'm a person who actually does these procedures, and I've been doing them for about 10 years. And I'd like to describe a little bit about the maze procedure to you. I thought so. So, as you can see, this is a review of the normal sequence of activation of the heartbeat. And in the lower, your lower left side, it demonstrates the normal activation of the heart.

The heartbeat begins with some cells in the atrium as you heard in earlier presentations. That begins with a depolarization or electrical impulse in the upper part of the heart that rapidly spreads to the other atrium, and then down through the conducting pathway system into the ventricles. And this coordinated activity of the heart is very important for optimizing cardiac performance.

In atrial fibrillation, as you probably heard in the past, the initiation of the cardiac electrical impulse becomes completely chaotic and disorganized, and originates from multiple foci within the atrium. And it's fortunate that this node, through which electrical impulse have to pass in order to get to the squeezing part of the ventricles, acts like a tunnel or a gate, or else you would be capable of having heart rates in excess of 300 per minute. But the filtering capacity of the atrial ventricular node reduces the traffic that can go through it. There are people with atrial fibrillation who, in fact, do develop very, very rapid heart rates, so much so that they can barely retain consciousness.

They are the risks of atrial fibrillation. One of the problems with this chaotic activation of the atria is that there is not a coordinated contraction, and blood tends to stagnate in the atria and can form clots, particularly in the atrial appendages or ears on the atrium. Those clots can then drop into the contractile part of the left ventricle, and embolize out into the systemic circulation.

People that have atrial fibrillation, and I'm sure there are people in the room that probably have atrial fibrillation, are at an increased risk of – for having a stroke as a consequence of these blood clots being present. That risk is seven to nine times the normal population. Moreover, because atrial fibrillation commonly occurs in people who have impaired heart function, the absence of a coordinated contraction of the upper part of the heart followed by the lower part of the heart results in less effective cardiac performance.

And when patients who have atrial fibrillation have strokes, their prognosis, their outcome is less favorable than patients who have strokes from other causes, and atrial fibrillation increases almost linearly as you get older. So that by the time you get to be 80 years old the occurrence rate of atrial fibrillation may be as high as 10 or 15 percent in the general population.

Because of this, there are a number of treatments that are available. The first of these is medication, which is designed either to cure the abnormal heart rhythm, or when that can't be done, to slow up the rate at which the electrical impulses are transmitted to the ventricle and reduce the heart rate.

When the episode of atrial fibrillation is a relatively sudden onset and medication is not effective in reversing it or if somebody becomes very symptomatic, they can be subjected to an electrical shock, which depolarizes the entire heart in the hope that the normal conducting pathway will take over the cardiac rhythm.

In patients who typically conduct very rapidly through their atrial-ventricular node and medication cannot control this or produces its own complications, it's possible to electrically ablate or get rid of that node completely, so there's no conduction between the upper and lower part of the heart. In other words, you create heart block. And then, a pacemaker is implanted that at least gives the patient a reproducible heart rhythm.

Or, alternatively, in patients who have atrial fibrillation and it's very problematic and who generally do not respond to medications, the atrial fibrillation will be treated through a catheter placed in their leg just like a cardiac catheterization, or alternatively, they might undergo a surgical

procedure called a maze procedure. And we'll talk about each of this in a little bit more detail now.

The maze procedure works by creating a set of lesions or scars in the upper part of the heart, both in the right atrium and in the left atrium. As these lesions, which can be created in a variety of ways, heal, they produce an electrical block and they isolate small segments of the atrium, which interferes with the maintenance of the atrial fibrillation. You have to have a certain mass of atrial tissue in order to have atrial fibrillation persist.

The original way that these lesions were created or scars was by a surgical incision. So, you actually cut the atrium wherever you wanted to, sewed it back together again, that produced the scar across which electricity could not be conducted. Now, it is a very invasive procedure. It has the obvious complication of bleeding because there are multiple, multiple incisions that are made.

And as an alternative a variety of energy sources have been applied that can replicate exactly the lesions that are done by what was called the cut-and-sew technique. Four of these techniques, radiotherapy, ultrasound, laser, and microwave work by heating the tissue to the point of causing death of the tissue. One does the exact opposite which is cryotherapy. It cools the tissue to such a low temperature that it kills the tissue.

But regardless of the technique, it produces a scar across which atrial activity – electrical activity is not transmitted. It can be done using penlight devices or probes, or a clamp, which is shown here, crossing – blocking the pulmonary veins from entering the left atrium, because it's known that some of the atrial fibrillation signals originate in those pulmonary veins. So, if you can create a radio frequency or cold block here, you could block those impulses from getting to the heart.

And there are basically three approaches to this, and I'm going to present them in historic order rather than in order of complexity or likeness. So, the first of these the open approach is the oldest approach. This was developed in

1987 by a surgeon named Jim Cox, and it is the most invasive of the approaches.

The second approach is an endovascular or percutaneous approach, which is done in the cardiac catheterization laboratory. And the third approach is an attempt to minimize the tissue damage done in the course of a large median sternotomy or thoracotomy by using a thoracoscopic approach wherein instruments and visualization is introduced through much smaller incisions.

So, in the open approach, usually a median sternotomy or a full large thoracotomy is performed. The cardiopulmonary bypass is generally used although it's possible to do it without of it using the devices that I mentioned. And the lesions are placed on the direct vision either of the epicardium or of the endocardium.

And you can see here is an example of the lesion sets, here, isolating each of the pulmonary veins, which drains into the left atrium. So, it could be done using the classic maze, which is a cut-and-sew maze, or it could be done today using a probe, or a clamp using one of the energy sources that I mentioned.

And the endovascular approach is completely different. The endovascular approach uses a technique in the cardiac catheterization lab or a catheter is introduced by a stick in the femoral vein. The catheter is passed up the venous system into the right atrium across the interatrial septum, and then using several different techniques employing different energy sources.

An attempt is made, either to specifically ablate the source of the atrial fibrillation or to internally replicate the maze procedure by creating multiple incision lines. This did not come along until about 13 to 14 years after the open technique was established, because the catheters and the techniques are a very great complexity, and it was not possible, the technology just did not permit this until recently.

The procedure is done blindly in the sense that the operator cannot really visualize the heart, so it's done under fluoroscopic control. And you can see the catheter. There are magnetic techniques and a variety of maneuvers that can be used to guarantee the position of the catheter when the lesions are

created. But it is an entirely closed procedure. It leaves the patients with two puncture wounds or one puncture wound in their leg, and is oftentimes done as an – as a one day overnight procedure.

Now, with the thoracoscopic approach, there are two aspects of the thoracoscopic approach and they really don't differ that greatly one from the other. The concept is that you can minimize the trauma to the patient by working either through very small incisions on one side or both sides depending on the operator's choice, that you can guide the instruments by using a video camera that's inserted through a hole made into the chest wall or operating port.

On the other hand, once the instruments are introduced into the chest, the maneuvers are essentially identical to those of the open procedure. You have to dissect past the lung tissue. You have to open the pericardium or the heart sack, and the various structures. You have to dissect tissues that lie around the aorta, and the pulmonary artery, and the pulmonary veins, large important structures in the chest. You have much greater risks of bleeding.

And then, the procedure is done with external visualization for the most part through the videoscope. And there are two ways of doing this. You can make a small incision in the chest as is shown here and introduce the visualization through a port – the video camera through a port, but do all of the surgical manipulations through the small incision, or you could do this totally thoracoscopically in which the manipulation of the surgical instruments is done by introducing them through ports and having an additional port which is used for visualization of the cardiac structures. And that would be referred to then as a totally thoracoscopic approach.

This is a much newer approach. Very few surgeons in this country actually do this today. And more commonly, this would be done at as a thoracoscopically assisted approach. Excuse me.

This is a little summary chart showing the differences in the approaches. The primary difference is that in the percutaneous or endovascular approach, it's done in a cath lab by an electrophysiologist. There is no incision made in the

chest anywhere, there is no pericardial incision, there is no tissue dissection, and the lesions are all made on the inner surface of the atrium under fluoroscopic or echocardiographic visualization.

Completely different from the other two approaches which are variants of surgical approaches to the heart. In one, a median sternotomy is performed; or a large thoracotomy. It's done in the operating room, tissue dissection is required. Only a trained cardiac surgeon can do this procedure, and it requires all of the instrumentation necessary for an open-heart operation.

A thoracoscopic approach is just another way of doing the same thing, but it's a very important difference, because the guidance and the instrumentation work is all done through ports and tiny incisions. But the same dissection is required, the same pericardial incision is required, the same tissue dissection is required, and the same risks exist to injuring major structures within the chest. And when such an event occurs, the need to be able to convert this immediately to a larger operation exists.

These procedures are easy to distinguish one from the other. The endovascular approach is done in a cath lab by an electrophysiologist and involves the use of catheters.

The open procedure is documented because the surgeon uses either a thoracotomy or a median sternotomy, more often a median sternotomy than a thoracotomy.

The thoracoscopic procedure, whether it's thoracoscopic assisted or totally thoracoscopic, may involve a mini-thoracotomy but always will involve the creation of ports and the use of instruments and be defined as a thoracoscopic procedure.

There may be some – as we move forward, need to differentiate between a totally thoracoscopic and a thoracoscopic-assisted procedure. But clearly, thoracoscopic procedures are widely different from endovascular procedures.

Now the current coding structure doesn't uniquely identify the thoracoscopic approach. There was a recently proposed revision to ICD-9-CM-3733 and

3734, which would not allow for a procedural difference between the thoracoscopic, that is a surgical approach, and the endovascular approach, whereas the two procedures are vastly different one from the other.

So, a review of the encoded data is enabled; if you have unique codes for each approach, it's possible to measure utilization when you identify properly a code that really describes the procedure that was done. And also for outcome analysis in administrative databases, this will be greatly facilitated.

It's very important to point out that we do not yet know the optimal therapy for atrial fibrillation. And only by retrospective review of databases are we going to determine whether an endovascular approach is most appropriate, a large incision is most appropriate, or whether a thoracoscopic-based procedure can achieve the same outcomes as either a large incision or catheter lab based approach. And we're only going to be able to do that if we code things properly and clearly define one procedure from the other.

So, I'm happy to answer any questions if there are some.

Ann Fagan: I think we're going to do the decoding part first. Excuse me a minute. We're going to do the coding part first, and then we'll take both clinical and coding questions.

Andrew Wechsler: Stay up here?

Ann Fagan: Yes.

Andrew Wechsler: OK.

Ann Fagan: That would fine – thank you very much. OK. All right, we know the background. In the interest of timing I'm going to speed along a little bit – we know we have two codes; 3733 and 3734. Jumping down to this bullet when 3733 and 34 were last revised in 2003, the thoracoscopic approach was not yet available so we didn't address that. But we chose 3733 for transthoracoscopic approaches.

OK. So, most recently, in September 2009, we sort of hit on this again and then it turned into lots and lots of comments and needed much more investigation and data before we leap into making some major boo-boo and confusing the nation and, as well as ourselves. So, we said, "OK. Let's table this little rascal."

So, basically what we got here is, obviously, coding option one, make no changes. Just continue to go to 3733. Option two would be to revise 3733 as proposed in the agenda and would move the thoracoscopic approach out of 33 and into 34. People didn't like that a lot. A lot of doctors didn't like that. They said, "No, we can't follow these trend data. It just won't work. We won't do this."

So, basically, here's option three. Create a new code for thoracoscopic maze procedure with accompanying revisions to the existing code, which will allow tracking and identification.

OK. So, basically, what we would do is what you see here for 3733 – this was really a challenge to move these things around. And every time we move things, we cut and paste, and put them into the PowerPoint, sizes were changed, things were changed.

So, what you see here is not – I mean, the proposal is real but don't look at the spacing. So, basically, what we thought, we would include the 3733 ablation or incision of heart tissue including all those things and adding ultrasound as well to open chest approach.

We would delete the inclusion term of modified mass procedure.

Transthoracic approach we'd add inclusion notes and term that by median sternotomy so that the coders would be able to find it, you know, if they had the operative report.

Add inclusion term that by thoracotomy without the use of thoracoscope. Revision at the excursion terms would be to add a new code for – by thoracoscopic approach at 3737.

All right, now, the 3734 existing code, we would delete others and add endovascular. And then, we would revise the inclusion term to take out resection and add ultrasound. And you can see that the one is lined through and the other one is underlined so that's how we identify what we're changing. Then, we would revise the inclusion term to take out endovascular and add percutaneous, add the exclusion term, excludes ablation, excision or destruction of lesion or tissue of heart open approach 3733 or the new code transthoracoscopic approach 3737. All right and again, these are on the website.

So, you don't have to write furiously. You can print it when you get home. OK. With any luck you can read this, but it's very tiny. This would be the new code, 3737, entitled, excision or destruction of other lesion or tissue of heart thoracoscopic approach and then, it includes all those other things because we do them, you know, in many different approaches.

It would be modified maze procedure thoracoscopic approach that via thoracoscopically assisted, you can see we've combined the two, thoracoscopic and thoracoscopically assisted in the one new code. With thoracotomy, with sub-xiphoid incision with port access, (inaudible) 3733 and 3734. Now, our recommendation is to create a new code at option three and obviously, change notes to 3734 and 3733 as well.

But in the meantime, we've got to put them somewhere, so, we would put them in 3733. Should the new code be created, 3733 is what we would use until then. So, there you have it. Now, we can take clinical questions or coding questions from the CMS auditorium.

Nelly Leon-Chisen: I'll make this quick. We've seen this procedure change over time. So, I think these are very distinct procedures, and thank you Dr. Wechsler for making it very clear where our coder could understand what kind of documentation we would need. So, I would speak in support of option three.

Andrew Wechsler: Thank you, Nelly.

Kathryn Barry: Hi. I'm Kathryn Barry from Medical Education Training Associates. Thank you so much Dr. Wechsler for providing that comparison chart and as you

know, we submitted a comment asking that the transthoracic may not be combined with the endovascular approach and so, we thank you for making this a clinical presentation and distinguishing what the clinical characteristics are. They are quite different and support option three. Thank you very much.

Andrew Wechsler: Thank you Kathryn. I appreciate your support. Are there any comments here in the room?

John Shaw: A quick question came to mind in terms of trying to fit this into the future limited coding, how many of each of the three kinds of procedures are there per year that give us a scope issue and how different might be levels of complications be in each of the three?

Andrew Wechsler: Terrific question. Right now, the majority of the procedures are performed using a catheter-based or endovascular technique. The complication rate in large studies, both randomized and registries, are actually comparable between these surgical techniques including all of them and the transcatheter techniques.

The reason that you're seeing the evolution of these novel approaches to treating atrial fibrillation is that for patients who have longstanding atrial fibrillation without getting into all of the terminology, the results with catheter-based are rarely successful on the first go round. They require two to three attempts, sometimes even more, and they're lengthy procedures, they require anesthesia for most of the procedure to avoid the pain of the procedure.

The thoracoscopic approaches are actually quicker in most instances than are the catheter based procedures and they produce a very definable set of lesions. And, so many people believe that the future of atrial fibrillation surgery may end up being a thoracoscopically-based approach followed up with a catheter approach that might identify one or two residual points in the atrium that could be treated. So, what you are seeing right now is the vast majority procedures being done in an endovascular fashion with more and more places beginning to switch to a combined approach because of the frustration with the catheter-based approach.

John Shaw: With the catheter-based approaches, if you have to go in multiple times, are they during the same session or would they be re-hospitalization or...

Andrew Wechsler: They are actually usually spaced apart and require different hospitalizations because the success of the procedure is generally not measured within the first short period of time after the procedure is done.

John Shaw: So, in terms of complications, they are equivalent but in terms of redo's, it sounds like there is a difference and therefore, it makes sense to have the separate procedures to capture that.

Andrew Wechsler: Yes sir. Exactly.

Tien Langlee: I'm just a little worried about the 37 because of the confusion for us. We have two codes, same (3733) is very simpler to open procedures. Can we just keep code the procedure at 3733 and put in an add-on code? Which is 1745 for (thoracic) computer (system) something and use that instead of creating a brand new code...

Andrew Weschler: (Inaudible).

Tien Langlee: ...1745, this code was 1745 which is the thoracoscopy (inaudible). It's not a (inaudible).

Ann Fagan: Well, that's an interesting concept and we'll take it under advisement. I wrote that down. Thank you.

Tien Langlee: OK.

Ann Fagan: Can we have any phone comments, please?

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the one on your telephone keypad. There are no comments at this time.

Andrew Wechsler: OK. Thank you very much, that concludes my presentation.

Ann Fagan: And here comes Pat.

Pat Brooks: We'll move on quickly. If I can remind, to the extent possible, if our clinical presenters can keep their presentations between 15 to 20 minutes, so we can maximize the time for the Q&As. So, to the extent possible, you can get close to the 15, that'll be great and Amy Gruber will do the next topic now.

Amy Gruber: The next topic is fat grafting for reconstructive surgery and the issue is ICD-9-CM does not have specific codes for harvesting or placing fat grafts used in reconstructive surgery. Should new procedure codes will be established to distinctly identify these procedures? We have here today, Dr. Steven Cohen, who's a clinical professor at the University of California, San Diego to provide us with a clinical presentation of these techniques. Dr.Cohen?

Dr. Steven Cohen: Well, by way of disclosure, I'm also a consultant for a company called (Saitori) that is involved in cell enriched fat grafting. There are basically several different means of fat grafting and this has undergone a resurgence over the last three to five years.

Especially, as we've determined that fat has, in addition to all of the negative connotations, has some very exciting progenator cells and stem cells that can be harvested and used in cell enriched fat grafting. Hence, we think that there maybe a need for new coding as these fields continue to develop. So, correction of soft defects or soft tissue defects by taking fat from one area of the body and moving it to another has been used in medicine for years and years and years, hundreds of years.

When we do liposuction to obtain fat, we inject a fluid called tumescent fluid and this is composed of a local an, another medication, epinephrine, to reduce bleeding and to also lead to a more comfortable harvest. So, fat, typically, when we're using it for grafting is harvested via liposuction first. Now, in traditional fat grafting techniques, there are a variety of ways of preparing the fat for re-injection.

But probably, the most sophisticated presently is to use a centrifuge to condense the fat and to eliminate the extra fluid, the free lipids and the tumescent fluid that has been injected for the harvest. And this gives us a

more pure graft that can then be injected in small (aliquots) into the patient for a variety of applications. So, these micro-droplets of fat are tehre-injected.

So, for instance, in a woman who might have had lumpectomy and radiation to the breast in treatment of breast cancer may present with a lesion that is a defect that could range from silver dollar size to, you know, a small, you know, a small can size, if you will. And one of the terrific treatments is just being able to simply harvest her fat and inject this. So, typically, there are one or two insertion points and we use the fanning pattern and we build these grafts not by just kind of filling up a cup but by injecting threads of graft material into the tissue much like you place rebar into concrete, so these grafts can then achieve a blood supply.

Many women now qualify for lumpectomy versus complete mastectomy and as breast cancer treatment has become less invasive, unfortunately, there are no currently accepted reconstructive options and yet quite a bit of disfigurement can be left by removing, you know, anywhere from a quarter of the breast to potentially a third of the breast with these treatments.

Furthermore, the skin can be damaged by the radiation that is used to often control local recurrence that might take place down the line. So, this creates a situation where you now have a radiated bed and surgeons are hesitant to use grafting techniques in these areas. Hence, again, more complicated techniques are often required.

Nevertheless, fat grafting results in very short outpatient surgery, very quick recovery, and again, no visible scars, and as we progress toward more cell enriched technologies, we think that this will also continue to become a more and more popular way of treating these patients. So, fat for many reasons is an ideal soft tissue filler. It's taken from the same individual that it's replaced in, nobody leaves the operating room.

A fancy, more complex flap bringing in new blood supply is not necessary. But the problems with fat grafting alone is the variability the graft take. So, these can vary quite a bit and lead to unpredictable outcomes and disappointment for the patients.

Now, why is this variability occurring? There could be slews of different reasons, but the main thing we know is that graft persistence is highly depending on maintaining graft viability, long enough to get a new blood supply, so, that this tissue becomes living material. Well, why fat or why cell enriched fat grafting?

Well, by enriching fat grafts, we are able to increase angiogenesis, hence, improve graft survival. In these cases, we are able to reverse or improve the skin damage that has occurred by radiation therapy, so that the skin becomes less red, it's softer, less painful and more accommodating to the fat grafts that now go on to survive. We also know that with better fat graft survival, there are less chance for lipid cysts and calcifications that can cause some confusion on follow-up mammographic studies and MRI studies.

So, here would be kind of a traditional graft and really the enriched graft is simply material that comes out of the traditional graft, recombined with the traditional graft and this increased concentration pre-clinically and from clinical trials across Asia and Europe indicate that the graft survived to a greater degree.

So, here is just a really brief scenario for the enriched grafting procedure. The tumescent fluid, again, is injected, fat is harvested, the same conventional way. Half the fat is then digested to liberate these regenerative cells and adipocyte-derived or fat-derived stem cells which will then concentrate it and then these regenerative cells which range anywhere from 50 up to even a 100 million cells (or) recombine with the other half of the fat to create an enriched graft.

And the enriched graft is then placed as I showed you back into the patient's graft a variety of soft tissue defects that can be quite large, 500 milliliter defects and can be quite small. Here are some examples, this happens to be out of the study in Japan. You can see the lumpectomy preoperatively and you can see the correction postoperatively.

So, right now, how is fat grafting documented? Not very well. First of all, a fat graft could be a teeny little fat graft. The fat graft could be a (container) of

fat grafts. A teeny little fat graft can take one second to harvest and another second to put back in. Large volumes may require a considerable amount of time and cell-enriched grafting requires a process that ultimately takes an additional hour and a half and will add to surgery time initially.

So, the other issues that relate to this are especially as we start to consider treatment of patients with breast cancer, it's critical that these be tracked right from the outset and the present coding system does not really provide specific codes for both fat grafting or cell-enriched grafting that makes this data collection and analysis possible. So, I will be brief and if there are any questions, I'm happy to answer them. Thank you very much for your time.

Amy Gruber: OK, we will move on to the coding options. There are two – there are two on page 25. Option one is to continue to assign code 85.99 of the operations on the breast for fat grafting to the breast. If grafting is performed with the total reconstruction of the breast, continue to assign codes for the total reconstruction to breast, that is category 85.70 through 85.79. For liposuction harvest, the fat graft, continue to assign code 86.83, size reduction plastic operation.

The second option would be to create new codes for fat graft of the breast, fat grafts of other subcutaneous sites and harvesting fat for grafting for a total of five new codes. The first new code would be 85.55, fat graft to the breast without use of enriched graft. Another new code would be add 85.86 fat graft to breast with use of enriched graft.

Another new code would be 86.87 fat graft without use of enriched graft, 86.88 fat graft with use of enriched graft as well 86.90, the extraction of fat for graft or banking. CMS' recommendation at this time is option one but we welcome public comment. So, I will open it up for discussion. Any comments here in the audience?

Linda Holtzman: Linda Holtzman, Clarity Coding, first let me note that I worked with Dr. Cohen in developing this proposal. One of the reasons that I got interested in this is because I've coded fat grafting to breast, I don't know, 6 to 7,000 times in the last few years.

And it's – you know, for many years, I was a surgical oncology coder and I was dealing with these reconstructions constantly. And it was very frustrating to not have a way to identify fat grafting. But fat grafting is real grafting.

You're taking tissue from elsewhere in the body and putting it in another place in the body. You know, it's being drawn out by a liposuction catheter but it's still real grafting and we have codes for all other types of graft to the breast and elsewhere. I like the notion of being able to identify fat grafting distinctly as well, particularly to be able to follow the outcome.

The other issue for me is every time I put down 8683 for harvesting, I just hated doing that, and I realized, that's not a reason to create this code because I hated it. But I knew that everyone of these was going to kick out at the payer and somebody would – forgive me.

I know I shouldn't get into the C word but coverage. But when you use the code for size reduction plastic operation to represent harvesting graft material for reconstruction, it just doesn't go. It really degrades what's happening here. It doesn't represent it well.

Also, if we just leave things as they are, there is no – as far as I can tell, there's really no way to identify fat grafting to other sites of body and certainly that takes place when you're trying to repair damage elsewhere in the subcutaneous tissue, so, on the arms and legs, that kind of thing. So, I like it. I hope you'll reconsider it.

Amy Gruber: You like option one? OK. Any other comments?

Linda Holtzman: No, no. I like option two, re-, creating new...

Amy Gruber: Excuse me, option two.

Sue Bowman: I like the idea of having separate for the fat grafting. I'm just concerned about the differentiation between without and with enriched graft and how well that's documented, that the coder will be able to pick that an enriched graft was involved?

Amy Gruber: Thank you. Anyone else here in the audience? If not, operator, can you please open up the phone line for any comments.

Operator: This time, I would like to remind everyone in order to make a comment, press star than the number one on your telephone keypad. The first comment comes from (Susan Taylor Proctor), you're line is open.

(Susan Taylor Proctor): I – I'd like to say that I agree with Linda Holtzman on this and I'll be submitting a written comment as well. Thank you.

Operator: There are no further comments at this time.

Pat Brooks: Thank you. Please send your comments. Our next topic is on number six on the agenda, Sternal Fixation with Rigid Plates. And I would like to introduce Dr. Arthur Martella from the University of Pennsylvania and he's going to be assisting with this. And while he's coming up, I'll tell you that the issue is that currently there is not a unique ICD-9 procedure code to capture the internal fixation of the sternum using rigid plates.

We currently use a more generic code 78.51 internal fixation of the bone without fracture reduction, scapula, clavicle, thorax and to include ribs and sternum. This is rather vague. It doesn't really show the thing we're trying to capture, which is, this particular fixation device. And that the issue has been raised because it may prove to help prevent sternal dehiscence and deep sternal wound infection.

There is not a new tech application and it hasn't been cleared by the FDA. So, I'll introduce Dr. Martella who will explain this procedure to us.

Arthur Martella: Thank you. Good morning. I think it's been interesting that you've already heard two talks today on non-sternotomy approaches to things that were traditionally done with a sternotomy incision. But I think both of those speakers would agree that the vast majority of heart surgery is still for the foreseeable future going to be done with the sternotomy approach. And just a sort of an idea of what numbers we're talking in the United States is close to 700,000 procedures, open heart procedures done with the sternotomy approach.

And that includes a hundred thousand or so valve replacements, as well as probably 400 plus – a hundred thousand plus coronary revascularization procedures. The sternotomy is the ideal approach for heart surgery in many ways. And that is because it really gives us full exposure not only to the procedure that is planned but also to any potential problems or issues that may occur.

So it is clearly the surgeons' choice for most operations done on the heart. The problem, however, is that although it is a great operation for the surgeon, it's not necessarily the best operation for the patient. Breathing, unfortunately, as you all know, is a dynamic process. Our chests are continuously moving in and out, up and down.

Coughing and deep breathing is one of our biggest problems as heart surgeons post-operatively; getting our patients to deep-breathe and cough is a major issue. A lot of that is related to the pain that they have and just an inability to want to take a deep breath because of the stiffness and tightness of the chest. But when they do cough, unfortunately it puts a tremendous amount of pressure on the incision itself. In addition to that, we frequently, or almost all of heart surgeons I would say in the United States, limit the use of our patients' arms for a minimum of six weeks.

Usually it's about eight weeks and with a gradual increase at that point. And that's simply because our pec muscles, or – these – our pec muscle attachments are to the sternum itself and to the costal cartilages off to the sides, and when you use your arms, you're pulling your sternum apart in effect. So, we really try to limit our patients' use of arms to the extent that we really teach our patients how to get out of chairs without their arms early on after surgery. Sternal problems are two basically.

Sternal dehiscence and a – and what may lead to deep sternal wound infections, and those are the two main issues. Basically, sternal dehiscence is when the two portions of the sternum, which are hopefully divided down the middle, don't heal completely. And you can have partial dehiscence and you can have a complete dehiscence.

And part of the problem is that as you – you just saw on the previous slide, those sternal halves, they're fairly – can be fairly thin and in the traditional approach, we place wires around that sternum. And those wires if the patient is breathing, coughing, can gradually cut through those sternal edges and lead to basically, again, a sternal dehiscence but a complicated problem they try to fix. In addition to that, the sternal dehiscence – if it is not addressed surgically, meaning going back to the operating room to repair, will lead to a chronic pain problem for that patient. There are a number of risk factors for sternal dehiscence, and ultimately, risk factors for sternal wound infections. But the number one risk factor is clearly obesity.

There are other contributing factors including diabetes, emphysema or COPD, renal failure, steroid use and as part of the emphysema picture tobacco using – current tobacco smokers. And that's particularly because they have secretion problems that – or manifest after surgery and have difficulty clearing their secretions and that also leads to a more exaggerated coughing response and risk for dehiscing of sternum basically. Post-operative sternal dehiscence in obese patients has been looked at in a number of fairly large studies.

There's one – there's a few – two studies that I'm actually going to show right now and one of them shows that basically obesity has been identified as the single most identifiable factor in who goes on to having sternal wound complications. And you can see in the slide here that there's basically a plateau here where patients with BMIs between 35 and 45 have an increase in sternal wound infections but not horrible. But when they get to 45 or so, which is a large patient and a relatively small number of our patients in general, the risk of sternal wound problems jumps up considerably.

And again, another review, 15 year review of a large number of patients, again, you see that there's this area here between BMI of 30 and 45, where it is somewhat of a plateau. But then again, again, as we saw before, at 45, 40 to 45, there's a significant jump in sternal wound problems. In – these days when we approach coronary surgery, we have that – and I use this as an example, we have a number of options for how we approach the patient, their disease and their contributing factors.

We can do them on pump, we can use all arteries, we can use bilateral mammaries or radio arteries. We can use techniques that do not touch the aorta and we have a number of technologies there for that. We can even use the robot these days.

We can use a complete revascularization or as even somebody mentioned earlier, we can use the (hybrid suite) to do these procedures. And I could spend half a day talking about how we would graft the right coronary artery. But when it comes to closing out patients, we still use general wires for all our patients.

Every patient is closed the same way, whether they're weighing 400 pounds with a BMI of 45 or they're a very small 85-old patient with BMI of 15. Rigid plate fixation is not something new. It's been utilized for fractures for virtually every bone in the body for a number of years by the orthopedic surgeons.

The orthopedic surgeons have been, well, over 30 years and the plastic surgeons have embraced this technology over 20 years ago and the neurosurgeon, even in the last 10 years have started using plates. Cardiac surgeons actually are the only group currently who really continue to provide bone fixation with wires. What we're suggesting is that in the very high risk patient group, BMIs 45 and above that we will consider plate fixation for this group of patients.

These patients are at high risk for returning to the or staying in the intensive care unit, remaining on the ventilator, and having postoperative problems weeks to months down the road. We also think that there's another group of patients with a BMI in the 30 to 45 range who have other associated risk factors also, meaning, severe COPD, diabetes, steroid use, or chronic renal failure who may also benefit from this approach. There is, interestingly, some studies that also suggest, unrelated to BMI, patients with severe COPD who are active smokers and on steroids have the same risk as this group also.

So, in conclusion, I think we can identify a certain group of patients who are high risk for having sternal wound problems and sternal – specifically, sternal

dehiscence which ultimately leads to deep sternal wound infections, and they would be the morbidly obese patients and the secondary associated risk factors with a sort of slightly less BMI.

We think rigid plate fixation can reduce the risk of sternal dehiscence and deep sternal wound infections and may also contribute to reducing the risk of pulmonary complications and potentially prolong mechanical ventilation and ICU stay. Thank you.

Pat Brooks: Thank you. If you can just wait over here. I'll go through the coding proposal first and then you can ask your questions and make your comments. While we're pulling that up, it's – I mentioned to you earlier the current code is code 78.51 for this condition. And so an option one would be not to create a new code, just to continue using that code should one want to do so.

An option two that you see here is to create a new code and that new code would be 8494, Insertion of Sternal Fixation Device with Rigid Plates. And then, clearly, we would have to exclude that under 78.5. And CMS recommends option two that we do create this new code so that we can track it to see how – provide information on how well it works. And we would like to hear questions and comments at the microphone.

I see people nodding their heads because they like it. But if someone would like to come up here and say they support it or not, that would be great. OK. So, people are nodding their heads; they like this. And, Operator, shall we open the phone lines to see if anyone else has something to say?

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad. There are no comments at this time.

Pat Brooks: OK, thank you very much then. And we'll look forward to your written comments. Now, we're going to move out of order a little bit, and Mady here will introduce our next topic which is going to be number nine.

Mady Hue: If you're following along, we're going to turn to page 36 in your handouts. I'd like to go over the issue. Currently, there's no specific ICD-9 procedure

code that describes a minimally invasive interlaminar lumbar decompression laminotomy with epidurography and image guidance. We currently have code 03.09, Other Exploration Decompression of Spinal Canal, which is used to identify lumbar decompression.

So at this time, I'd like to introduce Dr. Lora Lee Brown from Coastal Orthopedics and Pain Management out of Bradenton, Florida to give a clinical presentation.

Lora Lee Brown: First, I'd like to thank you for the opportunity to present to you. And just a quick slide about myself, I am a practicing pain management physician. My background is in anesthesia, and I've dedicated my career to taking care of patients that suffer from intractable chronic pain.

I want to talk to you about this particular procedure because I think it's so important for a segment of the population that I treat as well as many other physicians around the country. We're going to quickly talk about the technology itself, the clinical benefits; I'm going to emphasize that it has been cleared by FDA and that is being utilized by physicians in hospitals around the country today. This is a unique approach that allows us to decompress or debulk the spinal canal using an interlaminar approach.

The interlaminar space is the space between the lamina and the center of the spine that allows us to access the epidural space. This is very minimally invasive and less traumatic than traditional surgical approaches. And the clinical findings to date have demonstrated this to be an extremely safe procedure.

Now, you have to understand spinal stenosis to understand the application of this particular procedure. First, spinal stenosis is a disease process where the spinal canal, the center of the bony canal, is restricted, and the neural structures that bypass that level of the spine are impinged.

This usually manifests as pain; many times pain in the back, sometimes pain in the back and legs that's provoked with prolonged standing and walking and improves when one sits and that force or that pressure is relieved. There are,

according to the literature, about 1.2 million people in the country that suffer with symptomatic spinal stenosis.

There are probably a lot more people that suffer with symptomatic spinal stenosis that aren't being treated for or being cared for because the treatment options are not robust at this time. Of those people, about 250,000 undergo open surgery, that's a laminectomy or laminotomy or discectomy, for treatment of this. This particular treatment focuses on a subsection of that 250,000 people, a subsection of people that suffer from spinal stenosis primarily related to enlargement of the ligamentum flavum. And we're going to talk a little bit about that.

What I want you guys to understand is right now in the current treatment algorithm, we have conservative therapy at the bottom which includes things like physical therapy and over-the-counter medications and such, and when patients' disease process progresses beyond this point, we have epidural steroid injections that are used to treat spinal stenosis. And, traditionally, that's pretty much all we've had before those patients progress on to open surgery. What this particular treatment does is that it allows us a treatment alternative to fill this gap, to give folks a non-surgical treatment choice to alleviate their pain, their suffering, and their inability to function and live a fulfilling life.

Now, how this procedure works is, again, I've talked to you about ligamentum flavum, and I'm going to show you a picture of what the ligamentum flavum is in just a moment. But in some folks with spinal stenosis, they have enlarged ligamentum flavum.

This procedure actually allows us to debulk or remove that enlarged or hypertrophic tissue which relieve a tension band that occurs at that level; a dynamic buckling effect, if you will, of the ligament that causes pressure on the neural structures.

This is a great picture and a great example to illustrate enlarged ligamentum flavum. You see it right here. This is a slice through the spine, the lumbar spine specifically. This is the tail bone, this L5, L4, L3, L2, and L1 vertebral

bodies. The disc or the black things in between the vertebral bodies, this white area here is the spinal canal. You'll see that there are gray strings coming through; those are the nerves.

And you'll see in this particular patient, there is an impingement here, an hourglass deformity, and that is what we call spinal stenosis. And in this patient, spinal stenosis is predominantly related to a very large ligamentum flavum. If you look at the levels below and the levels above, you will see that you don't have that hypertrophy or that enlargement of the ligamentum flavum.

Now, one of the things that's intrinsic to this particular procedure is something called an epidurogram. As a practicing pain management physician, I use epidurograms all the time, and that's where we actually inject contrast into the epidural space. I use that prior to injecting any kind of corticosteroid to ensure that I'm in the correct anatomical space.

In this procedure, we also use an epidurogram. That epidurogram provides us a road map. That is our safety zone. That tells us where we are anatomically; hence, the need for fluoroscopy in this procedure.

Now, here's a cadaver sample – sample here that's been sliced through and, again, you see the bone here of the vertebral bodies, above and below a disc, the spinal canal that we saw in the last picture. This is the bony lamina of the – or the spinous process, that's the bone you feel when you rub your finger down the back of your spine. And here, this white tissue, is the enlarged ligamentum flavum.

When we are performing this procedure, we access this space through a very small skin incision or nick, if you will, and we place a trocar or a working cannula down to the level of the lamina. And then through that cannula, we actually insert a couple of instruments that we work with that were specifically designed for this procedure.

One of the instruments is a bone-cutting instrument that allows us to remove a very small amount of bone from the inferior and the superior lamina allowing us to create a small lamina on the defect so that we may utilize the tissue

resecting device that allows us to actually debulk the ligamentum flavum. And that's the ligamentum flavum in an animated format to show you. This is the tissue that we removed.

And when we removed that tissue, we actually leave intact the healthy anterior border here of the ligamentum flavum. So that anterior border is left intact and we're simply removing the enlarged cartilus – cartilaginous hypertrophied tissue.

When we approach a patient, we map everything out utilizing the x-ray machine or the fluoroscope and this illustrates that mapping process. When we actually enter – if we are treating this level here, we would enter from the level below and we use a trajectory that's on a slight angle that allows us to access this interlaminar space. And again, we use the epidurogram that you see here as our safety border, if you will.

The spinal structures and the neural structures are anterior to the epidurogram over here. When we work in this space we never bypass the epidurogram making this a very, very safe procedure. The tissue sculptor is a device that was designed specifically for this procedure. It has factors or characteristics built into it that also improve the safety of the procedure overall, but that is utilized through the working port and tissue is resected.

Now, how do you know when you're done? Well, typically, that epidurogram comes into play again and you'll see an improvement in the epidurogram. You'll see a wider contrast flow, a more complete contrast flow where you did not see that previously.

There have been some significant researches being completed recently. This is a remarkable study that was published recently by Dr. Tim Deer and Leo Kapural. Leo Kapural is a professor at the Cleveland Clinic and a good friend of mine. Ninety consecutive patients underwent this treatment. Of those 90 patients, there were zero reported complications or adverse effects.

When we look at this procedure and we compare it to the surgical literature, over here the (support trial) which was published not long ago that looked at the outcomes of open spine surgery, we find that in the IRB mild one study

that looked at consecutive 75 patients at 14 centers, there were zero dural tears, zero blood transfusions, zero adverse effects or events. When we look at Dr. Deer and Dr. Kapural's study, we looked at 90 patients, zero dural tears, zero blood transfusions, zero adverse events.

When we compare that to the literature looking at open spine surgery, we are eliminating this on average 9 percent occurrence of dural tear and 14.3 percent occurrence of blood transfusions or need for transfusions; intraoperative complications at almost 10 percent and postoperative complications at 12 percent.

When we look at the outcome of this procedure – and this is looking at the 75 patients in the ERB mild one study – we see that the outcome, when measured by pain using a visual analog scale, improved by more than two points. We see a 66.7 percent success rate. And when we look at function or mobility, we actually see improvement as well of over 50 percent in these patients.

Now, mind you, I want you guys to realize, spinal stenosis is a degenerative disease associated with an aging spine. It is a progressive disease and many of these folks are older and have other pre-morbidities as well, necessitating many times the need for this procedure to be done in a hospital as it's currently being done. This device's approach in procedure is FDA cleared; it was FDA cleared in December 19th of 2000.

And what I'm here today to ask of you is to consider a new procedural code for this procedure. And the procedure in itself is unique compared to existing codes. Existing code 03.09 is other exploration, decompression of spinal canal, which is utilized most times for laminectomy and laminotomy procedures which are open surgical cases.

There is not a code in existence today that specifically defines decompression of the posterior part of the spine for treatment of spinal stenosis utilizing epidurography and fluoroscopic guidance. What's nice about this is this procedure is less invasive, it's safe and the outcomes are significant and it's a great treatment option for so many patients that suffer with spinal stenosis. The other thing that's really important is that we do need to measure the

outcomes of our patients that undergo this procedure, and in doing so, we need to be able to track those outcomes via a new code.

Also, I want to just kind of emphasize that the diagnosis code is very established, it's going to be spinal stenosis which is 724.02. So, again, I want to emphasize why this is important to me as a practicing physician. I've seen many patients that come into my office that can't stand or walk longer than 10 minutes, and after having decompression procedures like this done, their walking and standing tolerance has improved dramatically.

They can go back to the golf course. They can go to Disney with their kids – their grandkids rather. Their quality of life improves dramatically. And what's important to me is that we make sure that those patients have access to this kind of new technology. And I think that the establishment of this code is going to be critical to them. Thank you. I'll take any questions.

Mady Hue: OK. We'll go ahead and review the coding options and then we'll take any clinical and coding questions or comments. On page 37 – I'm just trying to get to the right slide – OK. All right. So you can see it on screen two.

OK. So, for coding option one, we have do not create a new code. Continue to use the existing code 0309 and also a code from subcategory 87.2 for x-ray of spine to describe the procedure with epidurography and image guidance. Option two would be to create a new code to describe the intralaminar lumbar decompression with epidurography and image guidance.

We're proposing new codes 03.03 with the title as such, and also revising existing code 03.09 for other and open exploration, decompression of spinal canal with the exclusion (inaudible). CMS is recommending option two and at this time, we'll take any comments from the floor.

Female: No, maybe. I have one question for you, Dr. Brown. Do you have some reference to the – you talked about the dural tears with the other procedure. You also spoke about the bone sculptor which is a device you're using. How frequently is this done in the country? Is it done pretty frequently since 2006 when it first came out?

Dr. Brown: This particular procedure?

Female: Yes. Yes.

Dr. Brown: There've been over 600 cases done in the United States to date.

Female: Six hundred?

Dr. Brown: Yes.

Female: OK. So...

Dr. Brown: However, I think that the – you know – again, when I talked – when I spoke earlier about the treatment algorithm and the definition of spinal stenosis and the demographics of spinal stenosis. Of the 1.2 million people diagnosed with spinal stenosis or the 250,000 cases – open surgical cases that are done for treatment of spinal stenosis – the segment of patients that would be considered candidates for this is much smaller than that.

Female: I see.

Dr. Brown: I would say, probably, 20 percent of those patients.

Female: OK. All right. And I support the new code because it's more specific to what you're actually doing. I was just curious how frequently it's done because I'm not sure if CPT addressed it for a new code as far as CPT, do you know if you have a...

Dr. Brown: Not at this time.

Female: All right, thanks.

Linda Holtzman: I'm Linda Holtzman from Clarity Coding. I have a clinical question and then I want to follow-up with a coding point.

Dr. Brown: Sure.

Linda Holtzman: Also, before I ask, I should note that I sometimes do consulting for Medtronic including their – soft organic division which handles spine instruments and devices.

Dr. Brown: Yes. Sure.

Linda Holtzman: Although, I have no particular axe to grind on this particular issue. My clinical question is if I was following your presentation correctly – usually, when I see a decompression, they're actually taking out the lamina as a therapeutic step.

Dr. Brown: Yes.

Linda Holtzman: But it appears here that you're do – performing a laminotomy primarily for access to the ligaments and flavum. And then, the therapeutic portion of the procedure is to I guess de-bulk the ligaments. Is that correct?

Dr. Brown: In most cases, in most cases. There are some times when you can have osteocytes develop on the lamina that the bone sculpture can actually assist you in removing but, by and large, most of the times the de-bulking process that there is a laminotomy usually performed or almost always performed as well.

Linda Holtzman: Right, but the laminotomy would be primarily for access to the ligaments and flavum. The reason I asked you is because – I have no objection to a new code.

Dr. Brown: Yes.

Linda Holtzman: I think it's a good idea to describe this distinct technique. But, I'm not sure about the wording here and also about how (inaudible) existing coding conventions. You know, 0309, the current code, we don't use that code – we don't code laminotomy or laminectomy if it sees as an operative approach. And I don't mean to like weigh you down with all the coding, techy stuff, but – so I'll look at Mady while I say this – we don't code the laminotomy and laminectomy if it's an operative approach, so I have kind of an issue with laminotomy being in the title of the code.

I think we might be better here to describe exactly what's happening by saying something like, final decompression via de-bulking of ligamentum flavum or something like that, that's more specific to exactly what's taking place here. And then, you can have an inclusion note that says something like, includes that via laminotomy, and that would make it more clear what the distinction would be between 0303 and 0309 because they are (inaudible) primarily a bony procedure.

Dr. Brown: Can I comment from a clinical standpoint?

Linda Holtzman: Sure.

Dr. Brown: There are – as I said earlier – there are situations where the bone resection is actually critical to the outcome of the case, and I suspect that future development in this direction is going to include more technology to allow us to remove more bone. So, in keeping with the direction of the technology, that might not be a good idea.

Linda Holtzman: The notion of not putting laminotomy as an operative approach is 30 years old. So it's kind of hard to step away from that at this point. Maybe there could be a situation where you could use both codes if you have a therapeutic laminectomy in addition to this proce – the ligamentum flavum procedure.

The other thing I wanted to mention is I'd like to get away from the term intralaminar decompression, because I have to tell you, I have seen that terminology in other spine procedures that have nothing to do with this. I've seen physicians refer to intralaminar decompression when they're putting devices in between the lamina to hold it apart or even to fuse it.

And, so, if we – because that terminology, at least in my own experience is used for other types of procedures that have nothing to do with this, and in fact, are the exact opposite of this, I would really be reluctant to use that terminology here and would prefer to use something that's more specific to the procedure taking place on the ligamentum flavum.

Mady Hue: OK. So you'd like to see the title revised, but you're supporting a new code?

Linda Holtzman: Yes, it could make sense. I mean, it is different from the current laminotomy. The 0309 typically is in a bony type procedure and it sounds more like the soft tissue procedure via a bony access. But, I really have an issue with using intralaminar decompression just because I think that would be very confusing for myself and other coders because I see that terminology used for other kinds of procedures.

Mady Hue: All right. Thank you, Linda. Are there any other comments on the floor? OK. Operator, could we check the phone lines, see if there's any clinical or coding questions?

Operator: At this time, I would remind everyone in order to make a comment, press star then the number one on your telephone keypad. You have a comment from Tamar Thompson. Your line is open.

Mady Hue: Is there somebody there?

Tamar Thompson: Hello, this is Tamar Thompson with Kimbell and Associates. I am a certified coder and I would like to support CMS's recommendation for this particular procedure and will be following up with comments as well.

Mady Hue: Thank you.

Operator: There are no further comments at this time.

Mady Hue: OK. Thank you very much. Thank you. Are you ready for lunch? Oh, OK. Oh, OK, it's not lunch time yet. I don't have a watch, sorry. All right, we are going to – we're going to backtrack and go to page 30 and there is no speaker – clinical speaker, anyway, it's just me. We're going to talk about laparoscopic hernia repair without graft or prosthesis.

The issue is that a couple of years ago, we created a bunch of codes for laparoscopic hernia repair with a graft or prosthesis and now it's being performed without graft or prosthesis, even though we asked at that meeting if it would happen and they told us, no. But the frequency from what we've been told from the requestor is extremely low, less than 10 cases. However,

we are going to go ahead and propose some options here. Now, I got to backtrack. OK, let me get my slide for those of you here. OK, we're good, Charlie.

OK. So, for coding options; option one is, you know, do not create a new code to describe laparoscopic incisional, inguinal or ventral hernia repairs without a graft or prosthesis, continue to use the following codes that are available. And subcategories 53.5, it identifies repair of other hernia of the anterior abdominal wall without graft or prosthesis. Even though these codes do not describe a laparoscopic approach, as it says, they do indicate that a graft or prosthesis was not used. We could also explore adding an inclusion term at 5359 to identify that a laparoscopic hernia repair was performed.

OK. Option two would be to go ahead and create new codes to describe laparoscopic repairs at the various sites without a graft or prosthesis and we would place the exclusion notes where they belong. So, following in line with all the recent revisions that (Pat) had proposed and were approved at 17.1 for unilateral repair of inguinal hernia, 17.2 for the bilateral repair, we would propose to add those new codes as you see to identify that they're being done without the graft or prosthesis.

And also, at subcategory of 53.5, we could add a new code 53.52 for laparoscopic incisional hernia repair and new code 53.57 for laparoscopic repair of other hernia of the anterior abdominal wall. And then, we would revise existing codes 5351 and 5359. Now, our recommendation at this time is not to create the new codes because of the volume issue but, as usual, we would also like to hear input on this recommendation. So, if you'd like to come to the floor. We have one?

Nelly Leon-Chisen: Yes. Actually, this was a question that came to us at the AHA central office and we were kind of surprised when we were looking to see, you know, why that wasn't a code created. But I think given that there's only 10 cases, I hate to be creating all these codes. I mean, you know? I mean, as (Sue) said it's almost like one code per person. And so I would say, at least, if there's a way to fit those procedures under existing codes, I mean, you know, it just – let's just leave it alone for now.

Mady Hue: OK. Yes. You support no codes.

Nelly Leon-Chisen: Right.

Mady Hue: OK. Thank you, Nelly. Any other comments from the audience? All right. So, can we check their lines for any comments?

Operator: This time, I would like to remind everyone, in order to make a comment, press star and the number one on your telephone keypad. There are no comments at this time.

Mady Hue: OK. Thank you. So it looks like we have support not to create new codes, for interim coding advice, continue to code 53.59 to describe the laparoscopic hernia repairs without a graft or prosthesis. OK, I'm going to turn it back over to Pat – to Ann.

Ann Fagan: Well, we're just hopping all over the agenda here. This particular case is – number 10, biopsy of soft tissue mass and – we find the little rascal. And you see that I have no physician support actually in the room but I worked on this with Dr. Kelly, so I have his stamp of approval.

All right. This actually came to us from the outside. A coder wrote in and said, "You know, I was in a hospital and I had to do this biopsy – code this biopsy and it just, it just didn't seem to go well. It just had to go to an open procedure and I didn't think that was quite right." So, she sent me an op report and documentation and supports the idea of not using an open code and creating a new one. So, basically, what we're talking about here is this isn't – obviously, isn't new tech.

The current coding – there's a lot of diagnostic biopsy procedures including percutaneous and needle which exists in several chapters across the classification including adrenal glands, lungs, spleen, breasts, et cetera. So, we said, "Well, gee. How come it's not there where we need it?" So, option one, of course, is not to create a new code. The index directs coders to use soft tissue, NEC 8321, to describe this procedure. This code is located in subcategory (832), diagnostic procedure on muscle (tension), (fascia) and

(bursa) including that of hand, and there's an excludes note directing coders to 8611, for biopsy of skin and sub-Q.

So that's one option; option two then creates a new code in subcategory 83.2 to match the other closed diagnostic procedure codes, and then add conforming language to 8611. So, at 86 – I'm sorry, 83.2, diagnostic procedure on muscle, we would revise the title to call it open biopsy of soft tissue, and then at 8322, we would add a new code, a closed or percutaneous, or needle biopsy of soft tissue, excluding 8611; and at 8611 we would revise that to read that it was a closed percutaneous or needle biopsy of skin and sub-cue.

OK. So what we've said was that we recommend – we create a new code and in the interim, of course, you would use 8321 because that's what we have. Are there any comments here in the CMS auditorium? You guys are hungry. You're ready to go lunch.

OK. You think there's some need to create a new code? Oh, you guys are asleep. I'm not seeing head nods and nothing here. Oh, done.

John Shaw: I think more a question, do we know – do we know how many of these there are?

Ann Fagan: No.

John Shaw: OK. That would be – at least be a question. No.

Ann Fagan: Oh, OK. Well, because we have no code to describe it, they're all under open. Linda?

Linda Holtzman: My question is about the revision to the skin biopsy code. It sounds like a dumb question but is there a difference between an open and closed biopsy to the skin? I mean, I don't think you can have a percutaneous biopsy of the skin because percutaneous means through the skin, right?

I mean, if you do a punch biopsy of the skin, or you cut a little bit of the – with the blade away, how would you code that?

Ann Fagan: Well, that's a good question, I'm not a clinician.

Linda Holtzman: I mean, now it's easy because you only have one code. Throw it all under 8611.

Ann Fagan: Yes.

Linda Holtzman: But if we change that to be closed percutaneous needle, how would you code it they cut? I don't know.

Ann Fagan: Are you suggesting we use 8611 alone then?

Linda Holtzman: Yes actually. I guess I am, because...

Ann Fagan: Yes.

Linda Holtzman: ...skin biopsy – well, in the first place you don't see a lot on the inpatient side, but also, I think that one code would be fine to describe all the techniques for obtaining skin.

Ann Fagan: Yes. OK, that's a good comment, thank you. Any other comments here? OK, can we hear from the phone audience?

Operator: At this time I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad.

And there are no comments at this time.

Ann Fagan: Thank you very much, I appreciate this.

Pat Brooks: Well, thank you to everyone, we've had a very productive morning, so now, I'm going to let you go to lunch. Please be back promptly at 1:30, we will start 1:30 here this afternoon. And I think most people know where the cafeteria is. Go down the hall, to the big open area, and it's down one floor, the cafeteria. Thank you.

Pat Brooks: We're ready to get started, if everybody would join us, and operator if you'd bring the other callers back on line?

Operator: Everyone is back.

Pat Brooks: And we'll be starting the afternoon sessions of the ICD-9 coordination and maintenance committee, and Amy Gruber is going to be the – doing the first of the three topics this afternoon, and I'll just turn it over to Amy for introduction.

Amy Gruber: The first topic is the cranial implantation of a neurostimulator, and it's on page 32 of your handout. The issue, there are procedure codes to identify the implantation replacement of neurostimulator pulse generators that are subcutaneously implanted. There is a new procedure in which the leads of a neurostimulator pulse generator are implanted in the cranium.

Should new procedure codes be created to identify the neurostimulator pulse generators that are cranially implanted – for fiscal year 2011, there were no new (tech) application, and FDA approval for this procedure is anticipated in early 2011.

Here today, we have the dynamic duo of Doctor Martha Morrell, chief medical officer at NeuroPace, inc. and Doctor Robert Worth is a professor of neurological surgery, Indiana University. They will provide us with a clinical presentation. Docs?

Dr. Martha Morrell: Thank you very much. I love being called dynamic even before I show you that I am. I am the chief medical officer at NeuroPace. I'm an employee at NeuroPace, also a professor of neurology at Stanford, and Doctor Worth is one of our investigators and very experienced in our technology.

NeuroPace is a development stage medical device company located in Mountainview, and NeuroPace is sponsoring the RNS system clinical investigations. What is RNS system? It is a – the first ever cranially implanted responsive neurostimulator system, and it was designed for the treatment of medically intractable localization-related epilepsy, otherwise known as focal or partial epilepsy.

Doctor Worth and I will give you a very high level overview of epilepsy and our technology; present the highlights of our clinical trial results to date.

Doctor Worth will discuss the surgical procedure, and then we will present our coding request.

Epilepsy is a disturbingly common disease affecting upwards of one percent of adults and children, and the hallmark are seizures which arise when there is abnormal electrical activity in the brain. People can get injured during seizures, and perhaps even more concerningly, repeated seizures cause cognitive disability, mood – adverse mood effects and, altogether, these individuals have a very poor quality of life.

Antiepileptic drugs are the mainstay of therapy, and there have been really encouraging advances. Nevertheless, 30 to 40 percent of people with epilepsy continue to have seizures despite best medical treatment, and those individuals may now consider two other options; the biggest, neurostimulator, which is approved for treatment of epilepsy, and also resective brain surgery.

The RNS system hopes to be another option, and this would be targeted towards adults with medically resistant epilepsy of partial origin. The RNS system is unique in several ways. There is a neurostimulator that contains technology that allows it to both detect abnormal brain electrical activity and to provide stimulation in response to that activity. And it does so through implanted leads containing electrodes.

The physician communicates with the device via a programmer, and the physician is the one who decides how to program the device, both what to detect and what electrographic signals to stimulate.

The illustration you see there is of a patient using a remote monitor. The patient is able to pull information off of the device and to send that through the Web to a secure data repository, and the physician is then able to access that and review exactly what has been happening both in terms of detections and stimulations at his or her leisure.

The currently available brain neurostimulators are placed in the subpectoral or subcutaneous space and are connected to leads that are tunneled through the neck, and then the end part of the leads are placed in the brain. The RNS system is quite different in that the leads are implanted in the area of brain from which the seizures arise, and so it is different from patient to patient.

The neurostimulator is also distinguished because it is placed in the cranium. There are several reasons why it is so designed. The first is that in order to perform the sensing function, we need to eliminate the electrical noise of the outside, and so the cranial implant does that. It also reduces the risk of lead migration and breakage; the breakage usually occurring in the neck in commercially available neurostimulators, and we believe it may reduce the risk of infection since most of the infections are from the subcutaneous space.

We have conducted or are conducting three clinical trials. The first was a feasibility trial to demonstrate safety and show preliminary information for efficacy, and that is complete. We have also completed the double-blinded portion of our pivotal trial. This is a randomized, double-blind trial in which patients are randomized one-to-one to receive active stimulation or to receive sham stimulation. The trial has involved 191 subjects who have been implanted with the RNS system across 31 centers in the United States.

After the two-year-long feasibility and pivotal trial, subjects are then strongly encouraged to enroll in the long-term treatment trial that will go on an additional five years and allow us to collect a total of seven years of safety and efficacy data.

And as Amy mentioned, we are planning to submit our pre-market approval application to FDA very soon.

The trial results to date are very gratifying. We matched our primary efficacy endpoint as agreed upon with FDA, and that was to demonstrate a statistically significant reduction in the mean frequency of seizures in the group that were receiving stimulation versus the group who were implanted with the device but were not receiving stimulation.

We also met our primary safety endpoint and that was to demonstrate that our safety profile was equivalent to or not worse than for comparable procedures. Also, with the accumulating experience, we have in subjects implanted with our device, we have been able to demonstrate that the safety over the long-term is sustained and that the efficacy, in fact, improves over time.

And so, at this point, I'm turning the podium over to Dr. Worth to describe the implantation procedure.

Dr. Robert Worth: Thanks, Martha. I will disclose that I did participate in the pivotal trial, but I have no other disclosures to make. So, this is an overview of the surgical procedure. The implant procedure is performed as an inpatient under general anesthesia, typically, and involves implantation of the lead and also of the neurostimulator device.

And then once the patient has gone home and recovered from that, then they return and have the neurostimulator programming carried out as an outpatient by the patient's neurological clinician.

This is a cartoon to just illustrate the overall parts of the device. And here, we see two types of electrodes. These electrodes are implanted actually either within the brain with this is a depth electrode, or on the surface of the brain, so under the dura but on the surface of the brain subdurally.

And these are actually implanted in the areas that have been identified as the focal generators for the patient's seizures. Then these leads come out through the skull and are attached to this RNS device, the generator which is actually implanted into the skull. And we'll talk more about that in a minute.

I want to use this slide to highlight the significant difference between the RNS device and the Deep Brain Stimulator or the DBS system, which has been in use for treatment of Parkinson's disease and essential tremors and some other movement disorders since 1997.

If you focus on this picture here on your left for a minute, what you'll notice is that the generator is mounted under the skin on the chest, and it's then

connected to the brain electrodes with this wire which is technically called a lead extender.

So what that means is that once the brain electrodes are implanted by standard neurosurgical technique, then the rest of the work, implanting the generator and tunneling the leads, is primarily soft tissue work. And this has led to a natural bifurcation in this surgical procedure where surgeons will typically implant the brain electrodes and then the patients will come back at a second surgery to have the soft tissue work and the generator implanted.

In contrast, the RNS device is all implanted in the same area. And as we said earlier, the electrodes are implanted within the skull, on the brain or in the brain, and the RNS device, the generator, is actually implanted in the skull itself. So, it's much more natural to do this as a single procedure.

So now, I want to drill down on specifically what's done with these various procedures, in case any of you want to try this at home. So with the DB – again, with the DBS system on the left, what's done is an incision is made on the chest, there's a subcutaneous pocket created for seating the generator, and then a device is used to tunnel from the skull down to the chest to pass these lead extender wires, one for each electrode, and the lead extenders will then attach to the neurostimulator and the device is tacked to the fascia, and the wounds are closed.

For the RNS device, what's done is that the incision again is on the skull. There is a template that's furnished that allows one to outline on the skull, on the cranium, an area the exact size of the tray that inserts in the skull. Technically, the tray is called a (ferrell). And then standard cranial instruments, a craniotome and a cranial saw is used to do a craniotomy. It actually removes a piece of the skull, and then the (ferrell) tray sets into that craniotomy site and is attached to the skull with bone screws. And then the leads that have – are brought out through the skull, the leads from the electrodes are attached to the RNS generator device, and the generator device slides in to the (ferrell) tray and is held in place with the said screw.

And here you can see a picture of that, an illustration where that has been done. This is the RNS device. You can see the bone screw is holding the (inaudible) tray in place. And then, these are the wires, the leads coming out through the skull and attaching to the RNS device. One thing that is important to know is that this mounts flush with the skull so it is not sticking up under the skin. It just becomes part of the skull and mounts flush.

And this is another illustration that shows the RNS device in the skull, and in this case, two depth electrodes in the hippocampi bilateral. And again, on this scan we see the two depth electrodes in the hippocampi. And then this is the RNS device and you can – it shows nicely how it just becomes part of the, of the skull itself.

Finally, it is – the device runs on batteries. And so it is necessary periodically to change those batteries. And what's done is that when we design the skull incision for implanting the RNS device, we design it in such a way that we can open just a portion of it, typically about a third and have access to that RNS device.

We pop the old generator out of the tray, disconnect the leads, reconnect the new leads to a new generator and pop it back in place and close everything up. And that can typically be done as an outpatient under local anesthesia in about an hour.

Infrequently, it might be necessary to have to remove the RNS stimulator permanently and that would be a similar type of procedure although it would require additional incisions to remove the electrodes.

And so finally, just to highlight again the differences between these procedures. With the DBS device, it is all subcutaneous and the tissues that are involved are skin and subcutaneous tissue; with the RNS device, the tissues that are involved are things that the neurosurgeons would deal with, the scalp, skull and the dura.

The instruments reflect these differences, soft tissue instruments for the DBS generator and cranial instruments for the RNS generator. And the expertise for the implanting of the DBS device is that would – that would be –

possessed by a general surgeon although mostly these are done by neurosurgeons, but for the RNS device the expertise required is neurosurgical.

Dr. Morrell: Thank you.

Dr. Morrell: The current coding is listed here for lead implantation replacement 2.93 and implant to replacement of the neurostimulator pulse generator 86.95 and you'll see the codes for the removal procedure for the leads and the neurostimulator.

The issue is that the – although the lead codes worked quite well for our device, the neurostimulator do not because they are typically used for subcutaneous placement and fall within skin and soft tissue.

The – what we have found is since the RNS neurostimulator is placed in the cranium and not under the skin or in the subcutaneous tissue that in our clinical trials there has been a great deal of confusion on the part of the coders who look in the subcutaneous and skin section to find a code for a neurostimulator.

There has, therefore, been a great deal of variability in the coding in our trial. And we feel that, it – where they look for it, and it is understandable, is to look in the section on the skull, brain and cerebral meninges. The other issue is that the current coding does not allow us to collect data specific to cranially implanted neurostimulators.

So our recommendation and our request is that two new codes be created in the section for skull and brain that would cover the implantation or replacement of the neurostimulator and also removal of the (neurostimulator) pulse generator.

We see several advantages to this. First of all, it is the right organ system and it differentiates between the cranial and, what is common now, the subcutaneous neurostimulator procedure; it will also allow for accurate data collection on outcomes for cranial implanted neurostimulators which is a novel, a brand new therapy. And it puts the code in the proper body part and this will facilitate the coder's efforts.

Thank you very much and we would love to take any questions.

Dr. Morrell: Would you like to – oh, I’m sorry.

Amy Gruber: OK, why don’t we move on to the coding options? There are two coding options beginning on page 34. That’s it, OK. Actually, it’s one back. OK.

Two coding options, option 1 would be to continue the assigned code 02.93 implantation and replacement of intracranial neurostimulator lead and code 86.95 insertion of a replacement dual array neurostimulator pulse generator not specified as rechargeable for the cranial implantation or replacement of the neurostimulator. Continue to assign code 86.05 incision with removal of foreign body or device from skin and subcutaneous tissue for the removal of the pulse generator.

Option 2 would be to create two new codes for the cranial implantation or replacement of the neurostimulator pulse generator and removal of the pulse generator in the category 01.2 craniotomy and craniectomy. There will be revisions to the code, also known under code 02.93 and exclusion terms under the neurostimulator pulse generator codes.

They would look like this. Two – The two new codes would be 01.20 cranial implantation or replacement of neurostimulator pulse generator with the code on or the code on the lead implantation, as well as 01.29 cranial removal of neurostimulator pulse generator.

The CMS at this time recommends option 2. We are entrusted in your comments or any clinical questions for the two doctors. Any comment?

Sue Bowman: Well, I support the new code. One question I have though is the interim coding, given that 86.95 is in operations on the skin and subcutaneous tissue, that doesn’t seem appropriate even in the interim. And I was wondering if it should just be in the, you know, other craniotomy or other operations on the skull or, you know, something in that section of the classification.

Amy Gruber: OK, we’ll take that under advisement, thank you.

Lisa Taylor: Hello, I'm Lisa Taylor from Resolution Health. We're a developer of quality and performance measures and I would like to ask for a consideration of codes. When devices are implanted and inserted, they have an analogous V code so that we know of the status.

Amy Gruber: OK, National Center is in the audience and I'm sure they are taking careful notes about that.

Nelly Leon-Chisen: I would suggest a code also known as 01.2, at 02.93 and to (code) also the insertion of the cranial stimulator pulse generator, similar to what you have with the current codes.

Amy Gruber: OK. Thank you.

Linda Holtzman: I also think it's a good idea to have a new code. I should actually say thank you when you said that the lead code 0293, our (future needs are fine) because I'm one of those that wrote the proposal for the current description of 0293.

I mentioned that because I consult with Medtronic and they are the people behind the deep brain stimulation technology. I just wanted to ask a clinical question and I have a coding follow up.

I really appreciated the picture that you showed of how it fixed right into the defect in the craniectomy because I couldn't quite understand. Where is it? Is it inside the skull or is it sitting on the brain? So that helps a lot.

So my clinical question is there is still, or at least because I'm perceiving it, there is still some kind of subcutaneous tunneling going on the lead because the lead is being brought up through the burrow hole and then is going across the existing skull to be attached and then it's under the scalp. Is that correct or am I not understanding it?

Dr. Worth: No, that's correct.

Linda Holtzman: Oh, OK.

Dr. Worth: The lead passes through the subgaleal space just the same way that a DBS lead passes through the subgaleal space. So, it's but – but as you know it's a very small...

Linda Holtzman: Right, it's a much shorter track then, but there is still at least a small area – so, I just want to make sure I understood it. I know that with the deep brain it's going – the subcutaneous track is going right down the neck and all that stuff. OK. I guess my coding question then is, why not, why not put this in the 029 category? Why did you go to the 012?

Amy Gruber: Because that was the craniotomy, craniectomy section and we're able to find two new codes in that area.

Linda Holtzman: You know, if I were looking for this, first, I also would not look under skin, so I appreciate the issues that you're having with that. But if I were looking for this and I was coding the lead as 0293, then I might look down at like 0297 or 0298 to put the generator itself as opposed to the 012.

Just a thought that it might be easier to find if you have it, you know, in the same category as the lead. And then to follow up on Nelly's comment, you have the code also, note under 0293...

Amy Gruber: Yes.

Linda Holtzman: And it's code also insertion of neurostimulator pulse generator. Obviously, you'll need to have to add the word subcutaneous to that and then have another code also note that says, code also, intracranial, so that the coders can make that distinction very clear that some of the generator codes are subcutaneous and others are intracranial. And I think that will help them very much in making the distinction between the two types of the devices and knowing which category to go to.

Amy Gruber: OK, thank you. Any other comments in the audience? No? OK, at this time, operator, can you please open up the phone lines?

Operator: At this time, I would like to remind everyone in order to make a comment, press star, then the number one on your telephone keypad. There are no comments at this time.

Amy Gruber: Thank you.

Amy Gruber: Thank you.

Amy Gruber: The next topic we're going to discuss is continuous glucose monitoring and that's on page 40 in your handout. The issue is there are multiple codes for monitoring various physiologic parameters and metabolic levels such as continuous intra-arterial blood gas monitoring, intravascular pressure measurement and intracranial oxygen and temperature monitoring.

Currently, coders do not assign any codes to capture blood tests such as continuous monitoring of glucose levels. Furthermore, there are no codes to capture a variety of laboratory tests. Glycemic control has become an important standard in hospital care.

The question before you is should new procedure codes be established to identify in patient techniques for continuous glucose monitoring. Here to provide us with clinical background is Dr. Steven Wittlin, who is the Associate Professor of Medicine at University of Rochester Medical Center. Dr. Wittlin.

Dr. Wittlin: Hi.

Amy Gruber: Hi.

Dr. Wittlin: I'd like to thank CMS for the opportunity to present. My only disclaimer is that I receive a consulting honorarium from Edwards Lifesty – Lifescience and Medtronics Diabetes. And my other disclaimer is whereas I'm supposed to know a bit about diabetes, I know virtually nothing about coding. So, forgive me.

OK, so, glucose monitoring measures the concentration of sugar in the blood to identify episodes and trends in hypo and hyperglycemia. There are two populations that essentially we address. The outpatient population and –

currently there exists continuous glucose monitoring that can either be read, blinded to the patient in the physician's office or patients can wear a continuous glucose monitor which gives them continuous feedback throughout the day on their blood sugars, and those allow the patients to see changes in their blood sugars every five minutes.

This addresses patients with diabetes. A second population which is currently not addressed are inpatients. And inpatients either come in to the hospital with diabetes, but we find that many patients develop hyperglycemia while in the hospital and that this hyperglycemia is an important prognostic marker. Patients who are hyperglycemic do less well both in terms of morbidity and mortality. And it turns out that hyperglycemia is especially common in acutely ill patients, especially those treated in intensive care units.

And initially, the increased morbidity and mortality was shown in patients who underwent cardiothoracic surgery, but it has been extended to critically ill patients and increased morbidity has been seen in patients in medical ICU's. And to safely target normoglycemia has been a problem, such that a study that I will show you in a slide or two demonstrated clearly in a randomized study that patients who had intensive blood sugar control had improved prognosis in an intensive care unit.

Subsequent multi-center studies have had problems in that hypoglycemia has limited the ability of people to control blood sugars aggressively while in the hospital and that has been a problem that we think is maybe addressed by continuous glucose monitoring. So, this is a study by (Van den Berghe) that was published nearly a decade ago. And this looked at intensive insulin therapy in critically ill surgical patients and you can see that mortality was – is this the pointer? Oh, well.

Mortality was reduced by 34 percent, sepsis by 46 percent, dialysis by 41 percent, blood transfusions by 50 percent and ICU polyneuropathy was reduced by 44 percent. This was rather striking and, as I'll discuss in a few minutes, has led to major recommendations on the part of many institutions that monitor hospital quality of care as the importance of controlling blood sugar. The problem is to do it.

The standard blood sugar monitoring that currently occurs in hospitals is intermittent by point of care testing finger sticks. Conventional monitoring is generally performed by an ICU nurse.

There's an insulin infusion in the ICU and they get periodic blood sugar measurements every hour or three. The gold standard for measuring plasma glucose in the hospital remains the central laboratory. And for practical reasons, finger sticks are used simply because by the time you get the result from the laboratory the blood sugar has changed.

This is not the appropriate forum for me to go into the many vicissitudes in the measuring of finger stick blood sugars, but it is fraught with problems in terms of obtaining a proper drop, interference of substances – hematocrit affects many measures that are used to measure finger sticks and the like. They are generally performed on an intermittent basis, as I mentioned. This sampling is labor intensive, they can be inaccurate, as I've mentioned and it only is a snapshot view.

It's the difference between us looking at my presentation, taking a photo right now versus seeing the whole thing on a video. Continuous glucose monitoring takes – and it displays glucose measurements on an ongoing automated basis every few minutes. For example, one continuous glucose monitor samples interstitial fluid every 10 seconds and averages those numbers every five minutes and gives you a reading.

Not only does it do that, but potential benefits are that it can show you the vector, the direction in which the blood sugar is going. So, when I discuss this with audiences, I always give the thought question. If I told you – and you had diabetes – that your sugar was 90, what would you do?

Or if I told you your sugar was 90 and it's falling at the rate of 50 milligrams per deciliter every 20 minutes what would you do? And the answers may be very different. So, that's one thing that continuous glucose monitoring can do. It shows the direction and speed of change.

One can also, and one has both high and low glucose alerts that can be personalized to the given patient and that can protect against what is really the rate limiting step in aggressively managing blood sugar, which is the fear of hypoglycemia.

It also can make graphs available on a periodic basis, either short term or 24 hours to look at the trends in the blood sugar. So, you get a more complete picture of the trends and an early recognition of needs for intervention in the critical care unit.

Parenthetically, and this is anecdotal, but our chief of Critical Care in the Intensive Care Unit has said this to me, and I've mentioned this to colleagues across the country and they've concurred and that is oft-times and I don't know what percentage oft-times is. When our guy looked at it, it was about 25 to 30 percent.

Nurses in the Critical Care Unit will actually go off protocol because they're afraid of making the patient hypoglycemic. So, an alarm for hypoglycemia is extremely important. This is the Clarke Error Grid Analysis, which is a standard analysis of accuracy of a meter. And in this case, if you want everything in the A or B range and 95 percent are in the A range in this continuous glucose monitoring. Moreover, because of the benefits of the trend analysis that you get, Clarke has actually devised a second way of looking at these analyses because the trend information is so important to understanding what's going on because it's dynamic feedback rather than a single point in time.

So, they're really currently available or currently being studied are two modes of measuring continuous glucose monitoring. One is in-blood glucose monitoring, where the sensor is placed in a peripheral line in an established vascular catheter and directly measures blood glucose levels.

The alternative is interstitial or quote, unquote "tissue fluid glucose monitoring" where a sensor is placed in the subcutaneous tissues, for example, on the abdomen, and measures the glucose levels in the interstitial fluid. So,

the blood-continuous glucose monitoring, a 72-hour glucose oxidized sensor is placed in a peripheral catheter.

A sample is drawn into the catheter and covers the sensor and it measures the blood glucose concentration, and it can compare it to historical blood glucoses. And the result and the trend are – then – it's hard with the lights on but here is blood – here are the blood glucoses, the green is the target area. And you could see that if there were an alarm at some point here, it would alarm and let the nurse know that the blood sugar is above the target blood glucose level. So, this is kind of what the set-up looks like. This is using blood. It calibrates itself every seven and a half minutes.

The interstitial continuous glucose monitoring, this is, again, it's a 72-hour sensor but it is in the subcutaneous tissues. It is already being used clinically in outpatients as I mentioned. The sensor is calibrated against the blood glucose reading so that the numbers that you see correlate with what the blood glucose would be reading. And an interstitial glucose concentration is measured and the value and a graph are displayed, again, on a bedside monitor. For both of these, the cycle repeats every few minutes and the important thing here is an alarm will sound.

So, if, for example, you say, "I don't want the blood glucose to fall below 80," and you set an appropriate target, if the continuous glucose monitor registers below 80, an alarm will sound. And that should prevent severe hypoglycemia. The key documentation for the continuous glucose monitoring is the glucose readout printout in the medical record, which will also specify whether it is in-blood B.G. or interstitial I.G. glucose.

You can see kind of from this tracing although it's cartoonish, the concept I'm trying to convey. This blood sugar, right here, looks absolutely normal, but you would be missing a blood sugar that's very high doing it on an intermittent basis whereas the continuous monitor picks it up quite readily.

OK. The first inpatient – the first inpatient device received its C.E. mark in October of 2009. A major multi-sensor clinical trial is underway and enrollment is expected to be completed in February or March, and they

anticipate FDA submission late this year. The indication for use that's proposed is for automatic real-time monitoring and trending of blood glucose concentrations and critically ill adults over the age of 18 in the hospital.

OK. It turns out, based on the data that I gave you earlier and other data, that there is a great impetus for looking at glucose as a quality measure in recent years. And this will have implications in the future for reporting and for payment.

So, the AHRQ, the Agency for Healthcare Research in Quality, sees it as a quality indicator and as a patient safety indicator. It is viewed under CMS IPPS rule that this is a hospital – hyperglycemia is a hospital-acquired condition. And for annual payments from the RHQDAPU, you need to report quality data for an annual payment update in the future. And all of these are regarding – are around glucose, this is a technique for improving that.

So, the ARHQ QI PSI designation, by the way, this is alphabet soup, I had to review. Post-op physiologic metabolic derangement is an adverse effect and it's considered potentially preventable and it's for public reporting such as Hospital Compare, U.S. News and World Report rankings, et cetera. And clearly, this would address that issue.

The HAC designation – and certain manifestations of “poor blood sugar controls.” Quote, unquote. Well, this was listed at a reasonable preventable condition when not present on admission, and that includes diabetic ketoacidosis, nonketotic hyperosmolar coma, secondary diabetes with hyperosmolarity, secondary diabetes with ketoacidosis and hypoglycemic coma, this addresses all of those issues.

Again, next alphabet, the RHQDAPU quality measure, the program requires hospitals to report on specific quality measures to receive a full annual update to Medicare rates. And, by the way, this is the only reason that I know anything about this, is because our hospital's participating. Cardiac surgery patients with controlled 6:00 a.m. post op blood glucose is a criteria, and so, certainly, it is an important issue here in terms of cardiac surgery.

It is a quality measure under the Surgical Care Improvement Project. In fact, in the number of cardiac surgery patients with levels less than 200 on post op dates one and two is criteria. And in terms of the post-op physiologic metabolic derangement, it's being considered as an additional measure for the RHQDAPU Program for fiscal year 2012

OK. So the rationale. Why do we need new codes? The absence of a coding – and clearly, this is – this is the only part of coding that I know anything about because I've asked people who know something. There is no code that resembles this really, that reflects the CGMS. And the lack of that code inhibits the ability to do data review.

So, will this actually do what we want it to do, which is reduce hospital complications in terms of hyperglycemia and hypoglycemic complications, reduce morbidity and mortality, the only way to know that is to be able to track it, and the only way to track it is to have a code.

Outcome measures are hindered by an inability to identify when it has been used. And furthermore, they will – if we have this thing in codes, that will facilitates data development so that we can assess the value of this in the (text) of a value based purchasing initiative, as well as quality measures centered on the controlled glycemic levels.

So, that really is my presentation and I thank you for having given me the opportunity to do this.

Amy Gruber: There are two coding options there before you. Option one is to continuing unto code for continuous glucose monitoring as there is no code. Option two would be to create two new codes for continuous glucose monitoring under categories 00.9 of the procedures and interventions, one for blood and one for interstitial. Same as with recommendation at this time there's option one but we welcome public comment. Any comments in the audience?

Nelly Leon-Chisen: It's more of a question rather than a comment. We've been creating several monitoring codes over the last few years and I'm wondering if you've seen those codes show up in the data because as you mentioned in the

introductory paragraph of this agenda item, currently, coders don't assign codes for blood tests at least on the inpatient setting.

And so while I don't doubt the clinical benefits of doing continuous blood glucose monitoring, I'm just wondering if we would be creating a code, if this goes through, we would be creating a code that would never be used even though there would be use of the device and there is an interesting controlling blood glucose. But between monitoring and actually doing something about those levels to control the blood sugar, there may still be a disconnect because these measures are really looking at maintaining glucose control as opposed to saying you need to monitor continuously.

So I guess there's a couple of questions in there. Are the monitoring codes being used? And, you know, you may not have that data right now. You probably don't because I don't. So that might be one of the things to sort of take a look at before we create a proliferation of monitoring everything. Thank you.

Jean Yoder: Jean Yoder, the Military Health System. OK, we don't code. Our coders, our institutional coders don't code most of the laboratory stuff because the lab codes it itself and, therefore, we have all of the CPT codes from the lab so we don't need these separate institutional codes in volume three. But we do need codes like I've asked for before for seclusion or for restraints, those kinds of things because JCAHO tracks those and we need to find all of those patients because we need to do this.

So when I'm speaking of trying to track something like this and to see if there are good results, then it makes it very difficult. And I know it's an anomaly of our system but we only use line three. We don't use CPT codes for things that nurses and techs would be doing in the hospital and this is a nurse/tech thing as opposed to a physician doing the procedure. I mean, the physician – well, OK, who inserts the probe?

Dr. Wittlin: Presumably, an intravenous line would be put in by either a physician or a tech.

Jean Yoder: OK.

Dr. Wittlin : The sub-Q does not require a physician.

Jean Yoder: OK. Well, because the thing is, if it's something that a physician does then we're looking at a CPT code. And based on my personal experience, those may not be as easy to get a disease, OK. So it's just that if I'm trying to monitor and see if the patients are getting better or if I want to code restraints or seclusion or any of those kinds of things, then I either have to look at the V codes for the status or I have to look at a procedure code. So I kind of like having the option of – it's an option of coding this if I need it to collect my data.

Dr. Wittlin: Should I respond to that or...

Female: You don't have to.

Amy Gruber: OK. So, you support option two? OK.

Linda Holtzman: But to comment also, which I'm sure shocks you – but I should mention first that I actually work with Dr. Wittlin in developing this proposal. And it's true that ICD-9-CM, you know, right at this time, coders, I think, feel like they can't skip over some of these things but we have – first, this is not a lab test per se, although, interestingly, ICD-9-CM does actually have some codes for lab tests.

It's categories 90 and 91, which nobody knows that they are because we don't use them, right? But there are codes and it can be coded. Now, this is not a lab test in the sense that you won't have a CPT code for this. It's not like you're sending down the blood, you know, every three hours or eight hours or whatever it is. That's what this will replace. This is continuous monitoring. And we do have plenty of codes for monitoring.

And in the past, I think, we might have felt, you know, as Nelly mentioned that, you know, maybe we don't need to use those codes, you know. So, what's the reason to have them? But there are more and more initiative now that rely on this kind of thing. And, I mean, there are so many of these new initiatives and I don't even know what half of those alphabet soups are myself.

But the point is that as these initiatives evolve, and it all relies on the encoded data, we may need to take another look at our role in this as coders.

And one of the best examples for that is if you look at ICD-10-PCS, there's a whole section on measurement and monitoring. It's section four. And I was very happy to see it. I mean, so many of these new initiatives rely in being able to collect data, collect and analyze data that shows we're doing this kind of monitoring.

And maybe it's time for us to really rethink our need to do that. There's clear documentation in the medical record. It's relatively easy to find. It's one sheet. It says right on the top and it will tell you which type it is. It's a kind of thing I think we need to think about for the future going forward.

Amy Gruber: Thank you. John?

John Shaw: This one I'm very conflicted on. On the one hand, this is an important issue between obesity and diabetes in this country. It's a huge issue.

Amy Gruber: Yes.

John Shaw: As the presentation went through, many outcome measures are in place and starting to find their way into the payment system and the quality measurement system to try to address it. What's great about this is this is one of the things you do about it. It's not just, "Here's the flag." But, "Here's a flag and this is what we tried to do about it to catch it in time so it didn't become an indicator in a quality outcome that we don't like." So, from that perspective, I really like this because it's not only giving us additional data but giving us additional data that highlights action that we can take to actually improve healthcare or the concept.

On the other side, our coders are going to code it...

Amy Gruber: Yes.

John Shaw: ... and if they do code it, is MEDPAR still going to throw it away because it's beyond the number of physicians that they're currently keeping? So, I'm not

sure, as a user of all these data, whether I would be comfortable actually using it for a couple of years until at least we get all the physicians. Because if this does get coded, it's not going to be up at the top.

Amy Gruber: Thank you. Yes.

Sharon Whitmore: Hi. Sharon Whitmore. I just would like to know who's going to document this. How is it going to be documented? Because, currently, if coders – if a physician isn't doing the procedure and it's going to be monitored by your ICU nurses, most of us don't necessarily code from nursing documentation – we're not supposed to – so unless we get physicians on board to document that this is being done and it's being monitored and that they're taking an active role looking at it, which it sounds like you are but we're still talking about the documentation, we as coders still wouldn't take it up.

Dr. Wittlin: Can I make a comment?

Amy Gruber: Sure.

Dr. Wittlin: I had thought a bit about that point. And the areas that we are initially suggesting this for cardiothoracic surgery, post-op, perhaps coronary care units, intensive care units, there is a very – there would be a very high incidence of use because of the very high incidence of hyperglycemia.

So for example, if half of the people in an Intensive Care Unit were hyperglycemic and required this particular form of monitoring, it would be fairly simple, I would think, to be able to identify those as high risk areas. It would be in the doctor order's entry and would be something that should/ought to be readily picked up.

I understand that if you would say across the hospital initially that that would be problematic, but these are very high-intensity areas for this use.

Sue Bowman: Well, I just like to comment that, you know, I agree with the presenter and all of the people who have spoken about the importance of collecting this kind of information. But I guess my vision of the future is a little bit different where I don't really see this kind of thing which is an aspect of clinical practice and

there are many things to go on everyday in clinical practice that we don't capture in ICD-9 or ICD-10, but this would be the sort of thing that will be captured by clinical terminologies and electronic health record systems.

Many of the day-to-day aspects of clinical practice that tie in to quality indicators and other aspects of care, I think, is the wave of the future for this kind of reporting and not a coder sitting there looking up and assigning a code on a claim for this kind of aspect.

Amy Gruber: Thank you. Any other comments in the audience? No? Operator, can you please open up the lines for comments.

Operator: At this time, I would like to remind everyone in order to make a comment, press star then the number one on your telephone keypad. There are no comments at this time. Thank you.

Amy Gruber: Thank you. Moving on, next on page 42, the topic is circulating tumor cell enumeration test. Circulating tumor cells in purple blood have emerged as an accurate and valuable message to monitor patient to response to treatment in a variety of cancer populations. Should a new procedure code be created to identify the testing for the enumeration of circulating tumor cells. Here to provide us with the clinical background is Dr. Ralph Boccia who is the medical director of the Center for Cancer and Blood Disorders in Bethesda, Maryland.

Dr. Ralph Boccia: Well, thank you to everyone and good afternoon. You know, I think I probably couldn't have had this poised at a better time having just finished this last discussion that you folks all had about quality indicators and collecting data and monitoring things. Because this is really the basis by which this ICD-9 coding request is being made

I think everyone's aware and it was pointed out again and by some of you at the audience that electronic health records and the big push by the government to get electronic health records into all systems, both the community as well as the hospital, as well as the academic center is a very big push right now. Very important push because of quality indicators that you need to distinguish

between levels of quality of care, the government's push to reimburse based on levels of quality of care.

And then, of course, based on guidelines that we impose on ourselves as clinicians, the need for us to monitor our own outcomes individually as well as a group mentality to monitor outcomes with the notion that whatever we're doing now, we want to be able to improve on and find the areas that we might be weak on.

So having said that, this technology is a technology whereby we can actually capture, identify and quantify the number of circulating carcinoma cells in a patient with advanced malignancies and I'll be showing you this data in just a second, which is in fact predictive of outcome.

So, the high points that we're going to hit today is, first of all, I'm going to describe to you what by definition is a circulating tumor cell; show you its clinical utility as we use it in the clinic both – in the community as well as academic centers and just go over the timelines for its FDA approval, and then, suggest to you that this ICD-9 Code that we are requesting for it will actually help us in our collection of data, our retrospective look backs in our huge database that we have with electronic health records will help us identify weaknesses, strengths and between looking at quality indices and helping us with research we'll do or we are already doing, promote better patient care which is our obviously our goal.

So, the CellSearch Technology is again identifying what is called a circulating tumor cell. And it's based on this technology of using antibodies and electronic iron beads and magnets to actually not just to identify them but to isolate them so that we can count them. We have identified cut-offs above which and below which the prognosis for patients change, so this helps us tell how well a patient will do both at what we call baseline which is the beginning where they are diagnosed and then, helps us monitor them serially going down the line. And it allows for all of those things to be put into the patient record and for us to be able to not only look prospectively but retrospectively as well.

Now, this cartoon here illustrates the difference between a circulating tumor cell and a white blood cell which happens to co-migrate in the system. So that, we can actually distinguish the circulating tumor cells from the white cells in a very easy way, technicians as well as physicians including pathologists.

So, the first of these is in fact what is called the (feral) fluid. It hooks on to this antibody, the EpCAM antibody here. So, what we're doing is we're looking at two markers or receptors on this cancer cell surface that we can develop an antibody which, which in this case brings the magnetic beads to the cell itself and it allows them to be attached to the cell.

We then have another antibody that is developed inside a keratin antibody, which also can be attached to the cell and brings a fluorescence to it which you can see here, which makes it very easy to – for the observer to identify. This is distinguished between these other co-migrating cells by a different antibody which has been made against a very different surface receptor on the white cell in order to distinguish these two cells apart.

And then of course, they're both stained to show the cells in fact are intact. And that they have a nucleus that identifies them as being intact, and this technology's very different than the other technology. And here it is, this FDA-approved system, we collect in a tube called the cell-save tube, which has a preservative that allows it to in fact remain intact and be accessible for 96 hours.

These are the reagents when mixed together in the AutoPrep System allows these cells to come together with the reagent, these antibodies, the feral fluid and the fluorescent antibodies.

It's then put into a device called a (Mag Vest). Now, remember I said that it brought magnetic beads. This is essentially the magnet, so that the magnet can now actually separate these cells which are surrounded by these magnetic beads.

So that they can be put into the autoanalyzer which is basically a camera, allowing the cells now to be identified, quantified, captured, and quantified, and photographed.

So, its intended use as per its FDA approval is to enumerate the circulating tumor cells by identifying those markers as we've just mentioned. The presence – I guess I think I have it here – the presence right now of these circulating tumor cells for its FDA indication is for patients with advanced prostate cancer, breast cancer, and colon cancer. The enumeration of it in this in fact is predictive of outcome, what we call progression free survival which is the beginning of the treatment until the patients' disease gets worst.

And we're talking about advanced patients so that we know that it eventually will, and also, overall survival which is our main indicator of outcome with regard to therapy effectiveness. So at this point, the CellSearch is again FDA approved to predict prognosis, thus, progression free and overall survival in patients. Initially the FDA approval was in metastatic breast cancer patients both at baseline and first follow-up.

Then, expanded later on in December of 2006 to aid in the monitoring of patients with breast cancer, so not just the baseline prognosis in the first follow-up but serial follow-ups during their therapy. And then, on '07 to include metastatic colorectal cancer and a no-aid prostate cancer. So these are its three indications, again, baseline prognosis and follow-up predictability with serial monitoring.

So, the testing, what is its clinical value? And I want to now and show you in fact how it has helped us monitor these patients. Remember that in general when we have a patient with cancer the way we monitor them is either with physical examinations, follow-up x-rays. And we have these things called tumor markers. Many of which I know you know, CEA, CA 27-29, PSAs and things like that.

So, this is now testing – has been conducted looking at circulating tumor cells proving that it is in fact a reliable prognostic indicator for those three diseases. It may, in fact, be and I'll show you the data at least as predictive and maybe

even more predictive than the current standards that we have. Most of which are again these tumor markers in the blood and x-rays that we use in certain instances.

And there is evidence in fact that it can help in clinical decision making which is important; meaning, we start patients on this very aggressive and often toxic therapies. And in fact, if they're not working, it's nice to know that earlier than it is later. And that's when this assay in fact appears to have a role.

So here is a busy-looking slide that's – again, this is metastatic breast cancer, metastatic colorectal cancer, metastatic prostate cancer. I said that it has a cutoff above which and below which we can predict. It turns out that it's five circulating tumor cells for breast and prostate cancer, and three for colorectal cancer based on the original data in development.

So that, in fact, you can imagine that more cells you have, probably the worse you do. So patients end up with worse prognosis if they have more than five circulating tumor cells if they have breast or prostate cancer, more than three if they colorectal cancer.

And our primary comparators are now this CTC imaging in the studies done with breast cancer, CTCs plus imaging in the studies we did with colorectal cancer. And because we don't have good imaging for prostate cancer, the bone scans which is the predominant area that men get metastases in prostate cancer, it's very difficult to follow, the comparator is, in fact, the PSA.

This is the data now. These are what we call Kaplan-Meier survival curves. So, what this show is over time how well patients do. And so, the curves go, this is a 100 percent alive and then obviously down here, unfortunately, would be none alive. This is time and months. So the higher and the longer you stay up, the better you do. And so, what this looks at now is in metastatic breast cancer patients, if you had fewer than five circulating tumor cells, so you had a smaller burden comparing that to more than five circulating tumor cells.

At all these time points when it is measured, it shows you the patients with low numbers do much better than those with high numbers. And you can see that, in fact, it's predictive of a – at baseline now because we're talking about

baseline – of a doubling of survival if you have the low number or you can say the corollary which is a halving of the expected survival at baseline if you have the high number.

And then it holds true for the breast cancer, the prostate cancer, and the colorectal cancer group. You could just – but it's essentially if you have the high number, it's a halving of survival. It is predictive in all of three of these tumor types.

This now looks at looking at it serially over time, does it continue to provide that. And the answer is yes. So what you can see here is that if your burden is high with metastatic breast cancer, colorectal cancer, or prostate cancer, these numbers are in months of expected survival.

You can see that these bars are very short and have very small numbers, opposed to if you have small numbers of circulating tumor cells all the time, it falls below that threshold or cut-off, you could see that you have a very good prognosis at least comparably.

And here are numbers that either start low and go high or start high and go low, and it's intermediate. But what it shows you is that you can start high. And if you come down, your expected outcome will improve.

This is now a look at concordance between the results of circulating tumor cells and the typical comparator which is x-ray for breast cancer or for colorectal cancer and the PSA for prostate cancer. And bottom line here is that it shows that if you have an x-ray that shows improvement and a low CTC, you're going to do very well. You would expect that.

And on the other hand, if you have a high CTC and an x-ray that looks like it's getting worse, you're going to do very poorly. The question becomes, what if there's discordance.

Bottom line here is if there's discordance, the CTC looks in fact better. What that shows us is, in fact, there may be certain radiologic correlates which are difficult to follow besides the difference between inter-observer variation where this is a simple count, one, two, three, four, five, et cetera.

So, one of the benefits now of counting these cells, well, as I just in fact mentioned, inter-reader variability is a classic description, which is one of the reasons in fact in clinical trials you often have central review.

You have so many different people reading x-rays, you get different results. And in fact, if you provide the same x-ray to the same radiologist, you will often get a different reading because it can be that variable. So this is one potential advantage is that it's a simple kind of cells, not a well-it-looks-like-to-me kind of thing.

Also, we see although these two more markers we use and have for many years, there are artificial spikes. We occasionally see some of these markers go up before they go down. So, if you start somebody on therapy and it goes up which is the wrong direction, you're saying to yourself, "Oh my God, is it time to switch because these are progressing?"

And so, those two more markers are not a perfect system where this one looks much more predictive and so that helps you in that regard. Other non-cancer related issues that patients face in fact can falsely elevate those classic examples of CA-125 for ovary cancer.

If you have some sort of pelvic inflammation, that will artificially spike up. That's the gold standard, what we follow ladies with ovarian cancer with.

And the PSAs in fact look like it takes many months to treat before hormone therapies actually kick in and you see their PSA drop. And it averages about four months where this assay in fact will predict it at just one month.

Oops, let me go back here. So it provides evidence for prognostic information as I've just shown you. More insights compared to standard dosing – standard imaging and it is still indicated with standard imaging by the way.

Convenient serial monitoring – it's a simple blood test. We do them typically and often, like we do with the clinical trials, once per cycle. And that's simple blood test, just a tube of blood.

So, we feel that this substantial amount of data published with this immunomagnetic-based CTC enumeration shows efficacy. It is a quantitative test that's just a simple count. The data is published for these cutoffs in these three tumor types which is the FDA indication.

Comparing that to the other technology that's out there, a polymerase chain reaction or PCR, this is the only one done in Taq cells. You know exactly what you're dealing with when you look at the screen which is essentially that machine I showed you in the right which is basically a microscope photographing them for us to be counted.

This is the dilemma that we face right now. And this is the multitude of different ICD-9 codes that face the diagnostic codes. We're talking about the laboratory codes where the code right now is for microscopic evaluation of blood.

Well, there's a lot of different microscopic evaluations of blood. And so the dilemma that we face is we have no way to categorize those people. We have no way to monitor the results of these things, taking our new and very – I can tell you personally – very expensive electronic health record systems and be able to track these people, look back at them without this test having its own ICD-9 code.

So both we individually in the community as well as our hospitals could benefit by this code so that we can order it, track it, and report back to bodies such as yourself how it works. A new more precise code will identify those patients individually and a more precise code will, as I said, help us track these patients both for outcomes in the clinical setting as well as the research setting. And there is none right now.

So, this is at least the verbiage that is suggested. Obviously, this is something that can be discussed. And whatever the ICD-9 code will be, it's for circulating tumor cell enumeration immunomagnetic.

So with that, I will turn it back over to our moderator. I'll be happy to take any of the questions that she directs.

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad. At this time, there are no comments in the queue.

Amy Gruber: Thank you. There are two coding options there before you. The first coding option is to continue to code 9359 microscopic examination of blood, other microscopic examination for this testing; or option two, create a new code for the circulating tumor cell enumeration immunomagnetic, and the new code would be at 00.97.

CMS (has recommended) this time option one but we welcome public comment. Amy?

Amy Blum: Hi. I actually had a couple of questions. I think this is very interesting and I like this. I have no preference as far as the procedure coding but from a diagnostic standpoint, number one, how is that going to be used for staging? Is this going to be part of the new staging criteria?

Dr. Boccia: Not yet but, you know, the technology, as it evolves, and more clinical information and data is being generated, all those things will be looked at.

Amy Blum: OK. So, from a diagnostic perspective, do you think that at the point of diagnosis, would the number of cells – could that piece of information be added to the diagnostic code to give you an idea of severity, similar to how we code metastatic sites and such?

Dr. Boccia: I suppose it certainly could be. Certainly nothing I had ever thought of, but you know, it is certainly a severity indicator, is it not, based on the data that I showed you.

Amy Blum: Well, I'm just thinking about (Ken). I have a little ability there to make some code, third thing and this is an extremely – I know – ridiculous question. If we can attract the cells with a magnet, why can't we then suck those cells up with a magnet and suck them out of the body?

Dr. Boccia: We're going to send you into the lab, OK?

Amy Blum: OK.

Dr. Boccia: Obviously, you know, sadly, the tumor burden is more than just the cell that breaks off from the original primary site or even the metastatic deposits. So, great idea, but unfortunately, it would only be a small fraction of the total body burden of cancer cells.

Amy Blum: Great, thank you.

Lisa Taylor: Hello, Lisa Taylor from Resolution Health. We're a quality and performance steward measure developer. My first question to you is, is this a test that's going to be performed routinely on outpatients? Or is this something that will be done on the inpatient side when there is the first diagnosis of cancer?

Dr. Boccia: I'm going to say that probably the majority of the testing, like in monitoring, like is done with the other modalities, meaning imaging and tumor markers, will be outpatient. But you can imagine instances where you would want that – that evaluation as an inpatient as well.

Let's just say you have a patient who has been doing fairly well and all of a sudden just crashes, ends up in the hospital. So, the first thing, of course, as an oncologist, we do, is their cancer progressing? So, often, we'll do some tests, whether it's an imaging modality or not, to evaluate that patient to see if it's cancer-related or not.

And so, in the hospital that would be a test we might order, much like we might order a follow-up PSA on a patient who came in who had prostate cancer or a, you know, a CT scan. So, both inpatient and outpatient services would benefit from this, but probably the majority of it will be in fact, be outpatient.

Lisa Taylor: OK. Well...

Dr. Boccia: Since – I'm sorry – since most patients are treated outpatient.

Lisa Taylor: Right. And coders typically, on the inpatient side are coding – would not be coding from this section of the procedure codebook in ICD-9. That kind of

test would be captured via the Chargemaster and rolled up versus, in summary charges. From a quality measure developer side, we typically look for – to monitor to see if that is done based on outpatient claims.

And that would be picked up with – via CPT Codes. We typically exclude a patient from our measure if they'd been an inpatient because a lab test would be rolled up into summary charges and we would never see lab tests, so that's typically how it's handled in quality measures. And so, you do not see these tests, and we are working towards being able to abstract them straight out of an EHR versus the enriched – the administrative data. So, so...

Dr. Boccia: So, if you had a...

Lisa Taylor: So, developing...

Dr. Boccia: ... an ICD bank, could you be able to do that?

Lisa Taylor: Right. But as we've all – the coding people have commented, we don't code from that section of the codebook for procedures. And if we started doing that, the list of procedure codes would be so long and the abstracting process would be extremely burdensome. And at this point, those codes – what's the number of codes that go in on a claim at this point? Six or?

Female: Yes.

Lisa Taylor: So, we wouldn't be seeing all of these codes in the claims data. So, even if they coded them, it's not in the data flow, it would just be data in the hospital.

Dr. Boccia: So, I would just finalize that by saying again, the vast majority of these will be outpatient not inpatient. Without – with a CPT Code, we're lost. We cannot retrieve data in that respect and match it with our diagnoses and so, in order for us to be able to use this effectively we need some way to access our medical records and be able to retrieve this data, whether it's an inpatient or outpatient. You know, EHR is still going to be an EHR.

Lisa Taylor: But outpatient claims are not coded with ICD-9 procedure codes, so you're still not going to get it on the outpatient side. You'd have to – you would see

it using a CPT Code. If you're going to be analyzing claims data for outcomes research, or for quality measures, you would be picking it up with a CPT code. Thank you.

Amy Gruber: Thank you, any other comments? Thank you. Please submit it in writing if you think about it, if you have any more thoughts. At this time, I'm going to turn it over to Mady.

Mady Hue: OK, we're on page 44 of the handout. We're going to discuss intra-operative angiography and coronary artery bypass surgery. The issue is that currently, there is not a unique ICD-9 code to identify intra-operative coronary angiography versus those that are not performed intra-operatively.

Some of you remember back in October 2007, we created Code 88.59 for intra-operative fluorescence (vascular) angiography to specifically identify the IVFA or spy technology. That code is currently used for both coronary and non-coronary surgical procedures. Because IVFA and the other coronary angiography are used for intra-operative assessment of coronary vessels during course of a CABG surgery a code was requested to specifically identify intra-operative coronary angiography. In addition, another part of the request was to report intra-operative angiography in non-coronary applications including breast cancer surgery and some tissue reconstruction procedures.

So, I have two speakers that will discuss those aspects. We have Dr. Bruce Ferguson from East Carolina Heart Institute and Dr. Michael Zenn from Duke University Medical Center.

Bruce Ferguson: Thank you, Mady. We appreciate the opportunity to be able to discuss this today. I'm a cardiothoracic surgeon. I'm Chairman of the Cardiovascular Sciences at the East Carolina Heart Institute and have spent well over 15 years of my career working in quality improvement in cardiac surgery.

By way of disclosure, I am a consultant for (Novadeck) which is the tech – the company that produces the spy technology and as you'll see, I am the principal investigator of the Victoria Registry. The issue that really is before us today is that ICD-9 does not reflect the current evolving practice in CABG

and the reason is because there is this entity out there now which is CABG plus completion angiography.

And from our perspective in the cardiothoracic surgical world, understanding and appreciating this development is critical since, as I'll show you, it impacts directly on the quality of CABG care, on the safety of patients who undergo coronary artery bypass surgery and impacts directly on the access of patients to CABG quality technologies. This has come about because of the clinical allusion in coronary bypass surgery.

Intra-operative completion angiography is an important evolving standard in CABG to address quality and effectiveness. There are two technical advances that have enabled this evolution in care. First, as (Maddie) mentioned, is intra-operative fluorescence vascular angiography or IFVA, which can be performed in traditional operating rooms. And secondly, conventional X-ray angiography in so-called hybrid operating rooms, that is operating rooms with installed conventional angiographic equipment such as exists in a cardiac catheterization laboratory.

Now, in terms of quality, the predicate for angiographic evaluation is based upon the current indications from the eighth AHA and ACC guidelines published in circulation and other peer review journals, for post-op angiographic evaluation in coronary bypass patients. So these are patients who've had surgery but have problems – what are the indications for doing angiography on them?

And they are suspected closure of a graft, evidence of silent ischemia, acute coronary syndrome – so a subsequent heart attack – and perioperative MI, an operate – an MI that occurs at the time of the operation itself – recurrent angina, ventricular arrhythmias or evidence of hemodynamic instability. These new technologies enable immediate intraoperative completion angiography in both traditional and hybrid operating rooms to identify and prevent these clinical circumstances from developing post-operatively.

And because we can identify and prevent these, in many cases, intraoperative completion angiography documents the level of quality of that bypass

procedure. Intraoperative completion angiography as an evolutionary quality metric in CABG is, in fact, substantially different than diagnostic cardiac catheterization. Indeed, intraoperative completion angiography is already a standard of care in interventional cardiology and in vascular surgery and neurosurgery.

You would never consider putting a stent in a patient and not doing completion angiography to document the placement of that stent. Recent randomized clinical trials have demonstrated that the incidence and clinical consequences of perioperative MI and early graft failure represent a critical quality improvement opportunity in coronary bypass surgery. And as a leader of many of those trials, it's difficult to emphasize how large this opportunity is to improve the quality of bypass surgery through these and other technologies.

The coronary bypass surgery plus intraoperative completion angiography facilitates immediate identification and correction of technical issues with bypass grafts and intraoperative assessment and completion angiography creates the opportunity to address these quality issues at the time of coronary bypass, which is really the only time they can be effectively addressed. So, one procedure, that of intraoperative completion angiography, can address quality and IFVA and x-ray technology are substantially equivalent for intraoperative graft assessment during the course of bypass procedures.

This is the x-ray here taken from data from Sunnyside Hospital in Toronto. It shows a kink in the graft. This is traditional x-ray angiography and here's exactly the same image from exactly the same patient taken at almost exactly the same time which shows the kink in the graft using IFVA technology. However, CMS currently only tracks one of these in ICD-9.

Intraoperative fluorescence vascular angiography was approved for cardiothoracic use in 2005. It's been approved for use in pediatric surgery and as you'll see in a minute from (Michael)'s presentation, in the wide variety of plastic and reconstructive applications. It is a form of angiography that is safe for all patients and practical for use in a variety of surgical settings.

It is still angiography in – related specifically to coronary bypass surgery; it is one of two forms of completion angiography. And these are typical images that can be attained. This is the left anterior descending coronary and these are diagonal branches of the left anterior descending coronary.

This is before and this is after bypass grafting. This dark area here is an internal mammary artery pedicle that has been anastomosed to the anterior descending coronary. And you can see that degree of luminescence here is much greater than it is here, indicating an improvement in myocardial perfusion after bypass grafting.

These are data also showing that the two techniques are comparable. This is an ICD intraoperative image showing a sequential bypass to this first (circ) marginal vessel and a second (circ) marginal vessel with a skeletonized radiograph. And this shows the same image from a post-op angiogram done three days post-op showing the same sequential graft here and here. The reason these are reversed is because all fluoroscopic images are reversed, but they are the same patient imaging the same bypass graft.

So, if we think for a moment – look for a minute about the differences and similarities between these two technologies that are used for intraoperative completion angiography, x-ray, as I said, is done in a hybrid operating room setting; IFVA can be done in any operating room. There are relative contraindications – I'll speak more about that in just a second.

With regard to x-ray angiography there are really no contraindications to fluorescence angiography. There are clinical risks in terms of radiation exposure and invasiveness for – with x-ray angiography that don't exist with fluorescence. The key benefit is that x-ray angiography is the gold standard by which we evaluate coronary anatomy and characterize blockages.

Fluorescence is evolving as a standard intraoperatively used to identify and characterize these blockages. And there are differences in applicability with regard to the fact that x-ray angiography is limited to patients in special facilities. Less than five percent of hospitals today currently have hybrid

operating room facilities and fluorescence angiography is appropriate for all operating room facilities and is safe for all patients.

Some of the similarities and differences in terms of these technologies include the fact that they're in the same procedure category. They relate to the same body system. They are the same imaging procedure type and they use the same delivery technologies to be able to perform both types of studies.

Some of the differences relate to the contrast toxicity. X-ray non-ionic contrasts are metabolized by the kidney and as you know, can be highly nephrotoxic. IFVA is metabolized by the liver and has no toxicity profile. The imaging technique uses x-ray and it emits ionizing radiation and is captured on a camera. IFVA emits infrared light and is captured on a camera. The root imaging operation is x-ray with fluoroscopy and IFVA uses no radiation and the catheter engagements are slightly different. For x-ray, you engage the ostium of the coronary or saphenous vein graft via catheter placed into the central aorta. Whereas, IFVA can be accomplished by engaging the ostium of the saphenous vein connected to a coronary artery or via a central venous catheter and/or by injecting the dye into the cardiopulmonary bypass circuit.

There's a safety issue here as well. Radiation exposure and non-ionic x-ray contrast materials can put many of the higher risk coronary bypass patients at significantly further increased risk by superimposing x-ray technology on top of their bypass procedure. IFVA is safe for all patients including those in these high risk categories.

We have analyzed now over 500 patients in the Victoria clinical IFVA registry. This is a post-market registry which is sponsored by Novadaq, it is multi-center and what we – what I'll show you in the next slide is a data that compares a coronary bypass – isolated coronary bypass procedures undergoing (SPY) completion angiography; the data from the STS National Database for 2007, 2008 and 2009 as benchmarks.

This is an interim analysis of 360 patients undergoing isolated coronary bypass surgery. Zero to one is the O/E ratio. So, an O/E ratio of one indicates the patients are getting the therapy that they should be by the predictive models that we have. Anything less than one is a better outcome than would be predicted by the STS risk models.

And you can see for re-operation, permanent stroke, renal failure, prolonged ventilation, deep sternal wound infection, mortality or morbidity – mortality, short length of stay and long length of stay. The blue column here is the registry group and in all cases, those values are less than the national STS benchmarks. Now, this could be that the sites that are participating in the registry are just better sites; they have better quality of care.

But it also it could be related to the fact that the use of completion angiography is resulting in those better outcomes. In terms of safety, we think that the surgeon's choice of the technology should be driven by the patient's clinical characteristics. X-ray angiography is in fact contraindicated in over 50 percent of the patients who currently come to coronary bypass revascularization.

These include patients with acute renal failure or chronic renal failure, sometimes secondary to diabetes and this is now up to about 40 percent of patients who undergo coronary bypass surgery in this country. Peripheral vascular disease is a relative contraindication in up to 10 percent of patients because of vascular aspects – access issues and decompensated heart failure or pulmonary edema is in excess of five percent of patients and appears to be increasing.

Most importantly, the inappropriate utilization of x-ray angiography in CABG patients might significantly increase their perioperative risk and we need to be able to identify this. Access is also an issue for patients undergoing bypass surgery. As I mentioned, most CABG procedures are performed in traditional operating rooms; hybrid ORs enable performance of diagnostic interventional cardiovascular and cardiac surgical procedures together or separately in one setting. Because of completion angiography and the evolution of

percutaneous valve procedures and technologies, the number of hybrid ORs is increasing around the country.

In the ideal settings, surgeons who have both hybrid and traditional ORs available to them will select the appropriate completion angiography technology to fit the patients' clinical condition. Failure to resolve confusion surrounding coding for this quality metric, however, will assure that ongoing access to this quality metric of completion angiography will remain uncertain for coronary bypass patients.

Data from CABG with intraoperative completion angiography using both techniques are needed to study the following circumstances; hospital resource utilization costs and length of stay at the – the use of these technologies increases; rates and re-hospitalization and re-intervention to determine if in fact completion angiography drives those complications down.

Impact on graph patency rates, and a very important issue because the randomized trial studies that we've done show that, at one year up to one quarter of the bypass graphs that are placed are actually occluded or probably non-functional. And finally, morbidity and mortality outcomes both short and long term following coronary bypass surgery. And I'll turn that one around, the opportunity for angiographic evaluation at the time of surgery has opened up a huge window of opportunity to learn a lot more about bypass surgery than we've ever been able to learn because we never could do this before.

Failure to establish coding to identify and follow this increasing number of CABG plus completion angiography procedures will adversely impact CABG quality and patient safety and limit access to an evolving quality of care metric. Intraoperative completion angiography is substantially different in diagnostic coronary angiography, also known as cardiac catheterization.

In terms of setting, completion angiography is done in the operating room during the operation versus the cath lab. In terms of patients, these are patients already undergoing coronary bypass surgery versus those undergoing diagnostic evaluation for coronary artery disease. In terms of indication, for intraoperative completion angiography in coronary bypass surgery, it should

be done for suspected technical issues that could lead to post-op complications and less optimal short and long term outcomes and to document the quality of the CABG procedure.

There is currently no (ICDM) procedure code available to capture all intraoperative completion angiography in CABG. In summary, completion angiography is increasingly performed; in conjunction with coronary artery bypass surgery, it's a significant advance in patient care quality. Two similar technologies are used to perform intraoperative completion angiography.

These technologies have different infrastructure requirements and risk profiles for CABG patients. Intraoperative completion angiography must be distinguished from diagnostic coronary angiography. It should be collected in all settings, both traditional and hybrid operating rooms, and the opportunity to perform completion angiography has quality, safety, and access implications for bypass surgery patients and this inadequate and incomplete coding is an impediment to the evolution of CABG quality of care. Coding must be established for all forms of completion angiography in coronary bypass surgery.

It's now my pleasure to introduced Dr. Michael Zenn, who will talk about use of IFEA in the setting of plastic and reconstructive surgery, Michael?

Michael Zenn: Good afternoon. My name is Michael Zenn and I'm an associate professor of plastic and reconstructive surgery at Duke University. I – my disclosure for today is that Novadaq who makes the spy system does supply educational funds for studying spy technology. I have published in peer literature on our results of spy technology.

Now, we became accustomed with spy technology about three years ago when the machine was brought in for the cardiac surgeons and Dr. (Ferguson) has shown you some of the incredible use for this. But as plastic surgeons, the Holy Grail is what is the blood supply to the tissues that we're trying to use for reconstructive surgery; now I mainly do reconstruct surgery in cancer patients and accident victims and congenital – people with congenital birth

problems; and we are taking tissues from one part of the body and moving them somewhere else.

And this is the first technology that's ever really been show us intraoperatively where the blood supply is and how to safely capture it. So this is a little different than a coronary application which you just heard about. What we're doing with this spy technology is we're actually looking at blood flow, real time in the operating room.

Some examples of this, when a mastectomy is performed, that mastectomy removes the breast tissue; that skin has very poor blood supply to it. If you were to know where the blood supply is good in that tissue versus bad, you'd know where to remove tissue and potentially save problems and complications from surgery such as losing some of that skin or having skin necrosis.

It's important to know where within the flaps of tissue or if we're taking a block of tissue from one part of the body and moving it to the other, where is the best blood supply within that tissue and there's really no other technology that shows us this. We also have the added benefit preoperatively of studying an area that we want to use for reconstruction and seeing what the anatomy is, seeing where those perforating blood vessels are that we'd like to capture for reconstruction.

During the microsurgery part where we actually take blood vessels and reconnect blood vessels, we can actually look and see blood flow within these vessels, and that's similar to the coronary application that you saw. And there's even the possibility of looking at blood flow in these tissues after surgery. So really a whole host of applications from one technology and this is just a – an example to show you the types of things that we run into when we don't know what the blood supply is.

The top picture on the left is a patient that I reconstructed using her abdominal tissue to build breast mounds after reconstruction. Now, before spy technology, we would look at the skin. We would see if there was bleeding and if it looked like it was bleeding OK, we would go ahead and use that tissue, oftentimes getting rid of a lot of the skin we could have saved for the

reconstruction and this is what results when there is bad blood supply, this tissue needs to be removed – this patient more than likely needs to get another surgery and possibly future surgeries for reshaping. The bottom picture is a learning curve for me. This is a picture of a flap of tissue that I took from a patient's buttocks to build the breast mound.

We were using spy technology early on. The tissue looked pretty good to me. We did a spy study and it showed that a portion of the – of this tissue and the tissue I'm talking about is right on the corner here. Looked perfectly good to me.

This spy study showed that there was very little flow in that area, and I said, well, I never had problems with this before and I used, and sure enough the spy was right. For now, we tend to rely on the spy technology very much. If it shows that there's little perfusion in the area, we take it very seriously.

But it is complications that we're trying to avoid, and almost every complication, not only in plastic surgery, if you think about in all aspects of surgery. Even say, bowel surgery where someone is trying to put two pieces of bowel together, when that anastomosis fails more often than not it's because of blood supply, and now we have general surgeons using this technology to look at blood flow even within the bowels.

This is what I see clinically. Here is an example of breast reconstruction where I take the belly tissue and I use it and fashion it into a breast and this flap of tissue, it looks pretty uniform. In fact, if you rough up the edges you can see bleeding in this area. Normally, this is what I would use for reconstruction. But this is the spy image of that same flap and what it shows me is that there are areas of the flap which has very good blood supply, acceptable blood supply and I need to get rid of this part here, and we've never had this before.

This is an incredible, incredible technology and it's real time, I can do it right in the operating room and it doesn't rely on a study that's done at another time when it may not even be applicable. Now with the new software that goes

along with this, it's getting easier and easier for surgeons to see which areas are going to survive and which aren't.

And as I said before, the added benefit sometimes in the study even before I even start the operation is I'll get a spy skin and I can actually see where the feeding blood vessels are for the flaps that I'd like to use, and I can ensure that I'll incorporate them in the flaps of tissue that I'll use for a reconstructive procedure. So in summary, this is a phenomenal technology but I think – I hope you can appreciate.

This is being used in a completely different way than it is for coronary angiography; it's used in cancer surgeries. Any surgeon that really has issues with complications and blood supply, I think will ultimately adapt this type of technology, so this is just the beginning for us. The problem is that we really need to know what this data means and I think with its unique code, we'll be able to follow these patients and isolate them and then compare them to patients, perhaps, who were not using this technology and see the true value of this. Thank you.

Mady Hue: We'll now go ahead and talk about the coding options on page 45. Option one is, do not create new codes. Continue to use code 8859 intraoperative fluorescence (inaudible) angiography or (IFVA) which was created on October 2007 to identify that (IFVA) was utilized on both coronary and non-coronary arteries. And in addition, you would use the code to identify the appropriate coronary arteriography code.

Option two is to create new codes to distinguish intraoperative coronary angiography from those angiographies that are not performed in conjunction with surgery. We'd create similar new codes to distinguish intraoperative non-coronary angiography versus those not performed in conjunction with the surgery. So the proposal from the requester is to revise code 8859 to make that non-coronary intraoperative fluorescence (inaudible) angiography and revise the inclusive terms.

We would also have to add an exclusion term for existing code 8857 and they are also requesting that that code be revised to add all of the inclusion terms

that you see listed, it would identify both intraoperative coronary angiography as well as intraoperative fluorescence coronary arteriography.

Option two establishes one code for (IFVA) and non-coronary applications and assigns the (IFVA) coronary angiography and intraoperative coronary x-ray angiography also known as the coronary artery bypass completion angiography to existing code 8857, other and unspecified coronary arteriography.

Option three would be to create a new code for coronary artery bypass completion angiography and this new code if it found a place would incorporate both intraoperative coronary angiography as well as intraoperative fluorescence coronary angiography. Existing code 8859 would be revised to identify non-coronary intraoperative fluorescence (inaudible) angiography used.

The rationale for option three would be to establish the one code 8859 for non-coronary application and would incorporate the (IFVA) coronary angiography and intraoperative x-ray angiography into one code. Our CMS recommendation is option one, not to disrupt the 30 years of data that we have on angiography by differentiating the location of the procedure. However, we have reviewed a little bit more and we've also looked at the potential benefit to option three. So we would like to hear input on those options. We have a comment from the floor?

Operator: At this time, I would like to remind everyone, in order to make a comment, press star then the number one on your telephone keypad. At this time, there are no questions in the queue.

Mady Hue: OK, thank you. Go ahead.

Female: OK. I'm really confused by the proposal because I'm trying to kind of think historically what happened, because we had some questions that came in to through the editorial advisory board for coding clinic and my recollection in checking with a couple of other people here with much better memories than I do, we thought that this spy procedure that originally – the question came in with, was for coronary. And a result of that discussion when there was no

code specific to intraoperative fluorescence vascular angiography, we thought that the best code at that time was 8857.

But people thought that, you know, that wasn't good enough and that's why there was proposal to create 8859. Now, we're kind of flipping it around and saying 8859 is not for coronary, it's going to be non-coronary. And now coronary is going into – based on a proposal, it's going to 8857 which people originally did not like.

I'm trying to kind of figure out what are we trying to distinguish here, is it the fact that the it's intraoperative or is it the fluorescence. And what's really the intent – and which is coronary and non-coronary because it seems like now we're kind of – I agree there was this issue of disrupting data because I think that when we started 8859 was for spy, it was fluorescence, it was intraoperative and it was coronary.

And the non-coronary was going to be something that would be coming along later in the future and now the future is here and all of a sudden it's non-coronary. So, is someone could clarify what we're trying to do because I think this could end up being a lot more confusing and not only disrupting the data, but we won't even know what the codes mean after all.

Mady Hue: All right. This is a complicated proposal, I will say that. I'll answer from the coding standpoint and then I'll let one of the doctors maybe elaborate for the clinical part.

My understanding and working with requester is that the goal is to have one unique code to identify all forms of intraoperative angiography. So, in looking at option three, that would accomplish that goal. So, both the (IFVA) cor–, it would be revised to identify coronary angiography in that category, in that code as well as just intraoperative coronary angiography meaning the x-ray angiography.

If that's done then existing code 8859 would need to be revised to identify (IFVA) for non-coronary application so that they could track it, is that a correct description? OK. I'll let him discuss the clinical...

Dr. Ferguson: Well, I think the two, so – what we're struggling with here, I think, collectively is that the fact that that things are moving along pretty quickly. So when the 8859 piece came on board, the application of spy to these other areas was still something that was frankly experimental even though it was only two and a half, three years ago.

The two issues are separate. One is, there are rapidly developing applications of spy angiography outside of the coronary arena that would – that are clearly demonstrating benefit and that will continue to increase to the point where there maybe literally 100 or hundreds of codes that need to be created to track those.

Within the coronary space, the issue is that there is now with the evolution of spy completion angiography and hybrid operating rooms, a subset of patients that are not being captured, and they are the highest risk coronary bypass patients who could be made even worse by undergoing inappropriate x-ray angiography for completion angiography. And right now, those patients cannot be captured and distinguished because their codes are just like the patients who come into the hospital for a card, diagnostic cardiac catheterization and go to the operating room, and so that's why the, the advocacy for a single completion angiography mechanism through coding to be able to identify patients who get completion angiography in conjunction with coronary by-passer.

Mady Hue: Go ahead.

Lisa Taylor: This is Lisa Taylor from resolution help and I am concerned about option three because of the creation of the new code will not – we will lose the ability to distinguish between the procedure that involves radiation and the procedure that that does not involve radiation which is one of the concerns with patients safety indicators.

Mady Hue: OK, so...

Lisa Taylor: We want to be able to track which of the procedures are involving radiation.

Dr. Ferguson: They would both be tracked together – sorry.

Lisa Taylor: You don't have to. Right. So we wouldn't be able to distinguish which of the patients got the coronary completion angiography that involves radiation from those that got the coronary completion angiography that involves the...

Dr. Ferguson: Well, I'm not a coding expert but, not at this level of coding but there are other things that would occur at the time of the hospitalization where that code was captured that you would be able to distinguish between those two. And that's in come to distinction to the current scenario where you cannot capture those patients and you can't group them together.

So, if you went into the coding data to look for all the patients that got completion angiography is not possible to put that data set together.

Lisa Taylor: Right. But option three has a new code (xx.xx) that includes both the intraoperative coronary angiography and the intraoperative fluorescence coronary angiography. So you wouldn't be able to distinguish the ones that are having the coronary completion angiography, which ones got radiation and which ones did not, am I reading this correctly?

Mady Hue: You are. I don't think that was their concern, that's why their request was just to have one code for all, but we certainly appreciate the comments. And if, you'd like to submit more extensive comments in writing, we'd be glad to review them.

Lori Swalm: (Inaudible), from Novadaq, I just wanted to clarify a couple of things. Originally, we had code 8890 which was a nonspecific imaging code. So it was important at that time, in 2007, to establish a code that would distinguish patients that had this angiography from other nonspecific imaging technologies.

And secondly, at this time, the reason we favor option two or option three over one is that what we're seeking is to have a distinction between diagnostic coronary angiography and completion coronary angiography by either technique. And then, secondly, in terms of the plastic and reconstructive procedures, those are procedures where angiography is not currently used. We would like to establish coding for that.

Female: I'm sorry, but I'm still confused because I think I heard the doctor say that 8859 at that time, it was only being done on coronary. And so, I guess my question is, why is 8859 being proposed as non-coronary. It seems like that should stay as coronary because that's how it started and for the most part, it's probably coronary that's being reported with that code.

And that's – and Mady, you know, that's probably a question for the requestors because I'm not sure – I mean, I don't really have a strong feeling about whether, you know, you need two codes, three codes, however many, but it seems like for the sake of data integrity, 8859 – if you're going to split, you know, coronary and non-coronary, that the 8859 should stay coronary.

Dr. Ferguson: Again, I'm not a coding expert, but it's my understanding that there's no way to capture the hybrid operating room setting with conventional angiography in the descriptor that currently exists for 8859. And, again, that's the subset of patients in completion angiography that we are missing under the current coding circumstance.

Mady Hue: Yes – no, I just took that from that coding part. I think you're right, when we initially discussed it as a proposal (inaudible), the application was more for coronary but, through discussion I don't remember exactly, but, I think we made a decision not to specifically include coronary in the title because there was the potential for non-coronary application. So, I don't know if that helps or not.

Mady Hue: One more clarification on the request. I think the reason that came out the way it did is because there were already – there are existing coronary angiography codes to identify both techniques when used for completion angiography. And 8859 which was specific to fluorescence angiography could then exclude the coronary procedures, so that was the thought process.

Female: Yes.

Mady Hue: I think with this topic, and it wouldn't be the first time, it is possible that it could be brought back for another meeting to discuss. We can go ahead and

try the phone lines again to see if there's any other comments before I wrap it up. Operator?

Operator: At this time, I would like to remind everyone in order to make a comment; press star then the number one on your telephone keypad. At this time, there are no comments in the queue.

Mady Hue: OK, thank you. OK, what I would encourage you to do, like I usually do, is to submit your written comments and we will carefully review them. Thank you.

OK. We're going to go ahead and move to the addenda, it's on page 47. And I'm going to go over a few things and then invite Ann to come up and go over a couple of her things.

OK. So at code 3762, the proposal is to delete the two inclusion terms of that code and – for most of you, you know the history with that. And then, we'll move to spinal fusion. This is brought back from the September meeting. And I'm happy to report that there are only a couple minor revisions that we were asked to propose. One of them is – as you see, right under there; the note.

We had some proposed language revisions received. So, this is just to further define what a spine fusion is, it throws out a couple more terms than what the original proposal had. So, I'm not going to read through all that. And again, the proposal for the spinal fusion, all of this would apply to the re-fusion codes as well at 81.3.

OK, so moving down 81.02 the revision would be to include the anterior column, and the newer revision would be to replace the word technique with fusion. For the remainder, I'll just make a general statement about the column. At the last meeting and after the meeting, we received comments that were pretty much in favor of identifying the column being fused so, I'm not going to go through every single code and talk about the column.

The next code 81.04; we had discussion at that meeting in September to add inclusion term for extracavitary technique. And again, right above that the proposal to replace technique with fusion. Now, for some of these there aren't

any changes from the last meeting but, we also had requests just to see it in full because there was a lot of discussion at that meeting, so it's really just for cosmetic purposes.

OK, moving down at 81.05. The proposal is still to delete the inclusion term of posterior interbody technique. And then we have code 81.06, and this is where the newer revision proposal comes into play. At axial lumbar inter body fusion; the axialif.

At the last meeting, this procedure was proposed to be indexed at code 81.08 and we received comments that similar to the DLIF and XLIF, that the approach to the spine for the axialif is a retroperitoneal approach and that it belongs clinically in 81.06. So that is being proposed.

Code 81.07 that's just – so that you can view what it would look like, most – everybody supported that from the last meeting. And then the 81.08, you would see the change – we would remove technique and then delete the postero-lateral technique, and obviously that actually would – wouldn't be indexed there. We got through fusion. OK, all right. Come on, Linda.

Linda Holtzman: I like it.

Mady Hue: Great.

Linda Holtzman: There's two comments.

Mady Hue: OK.

Linda Holtzman: And they're small.

Mady Hue: All right.

Linda Holtzman: Oh – did I mention I like it?

Mady Hue: Yes, thank you.

Linda Holtzman: On 8104.

Mady Hue: Yes?

Linda Holtzman: Yes. I do agree with putting the extracavitary technique here in 8104. I agree, but, I kind of like to do something with the title because when you come down to it the extracavitary technique; it is a fusion of the anterior column. No question about it, but it's actually coming in more from a posterior direction.

We don't really have the option to create something in, you know, in this code range for dorsal – anterior column posterior technique, there's no room. And since extracavitary isn't done that often it's – there's no harm in putting it in 8104 but, just to be on the safe side, I'd like to see it say, dorsal and dorsal lumbar fusion of the anterior column, anterior technique or posterior technique.

And the reason I say that is because on October 1st, 2013, people will have the option to indicate if it's an anterior technique versus the posterior technique for the thoracic or dorsal region. And, I'm a little concerned that if they spend the next two or three years coding it here they'll get that in their heads that's it's an anterior, anterior which it really isn't, it's an anterior posterior. I know I should have thought of that before but, I – it occurred to me recently that they want to do that.

Mady Hue: Thank you.

Linda Holtzman: You know, because 8105 is a posterior column, posterior technique so you'd almost need three codes there, an anterior column, anterior technique, anterior column, posterior column, posterior technique and an anterior column, posterior technique. That's where the problem is.

We have the room to do that for lumbar and that's where most of the anterior column, posterior technique takes place. So – but we don't have the room to do it in thoracics. So I'd just kind of like to add anterior or posterior technique just to cover it clinically.

The – I said that I only had two comments. I didn't say they were short.

About the axialif, I don't have any strong feelings one way or the other if it should be in 8106 or 8108. But I will just mention that if people aren't – well, what I usually teach people when I'm giving in-services on spine fusion is if you can't tell whether they're doing a posterior technique or an anterior technique, in other words if they're coming in from the back or they're coming in from the front, how is the patient positioned?

If the patient is belly down, it's a posterior approach, OK? If the patient is belly up, it's – well, maybe I shouldn't use that terminology – if the patient is lying on their back – the patient with belly up's got a bigger problem than that but if the patient is lying on their back then it's an anterior approach.

The thing with axialif is that these are patients who are lying on their bellies. And I know we all just had lunch and everything, but you're going to prop up their butt basically and then drill in from behind. So you're kind of – they're lying on their belly so you're coming in sort from behind but then you're going under and up.

So I was kind of perceiving that as a posterior approach because they're lying on their belly. Can you speak more to how people came to see this as an anterior approach or do you have any pictures or anything?

Mady Hue: I don't have any pictures.

Linda Holtzman: Thank God.

Mady Hue: If you remember the September meeting, it was proposed for 8108 but we did receive a comment after that from a source, I'll say. And they did indicate that to access the column, which is what we clarified at that meeting is we're identifying how the column is being approached because of the whole discussion between technique and approach that we had and that it is the retroperitoneal approach. So that's why we brought it back. And I'm happy to listen to more comments.

John: Well, I won't use the same terminology that Linda was using. But I don't remember the difference between prone and supine. So, how the patient is positioned and where you're going through does have a big impact on

outcomes. Anywhere where you're going through any of the anterior organs and moving them aside to get to where you're going has big implications for length of stay and outcomes and so on.

And so I'm not comfortable having an anterior code used for someone who is getting an approach from behind. I know we're not supposed to use the R word but you may have people that look anterior-posterior that are only in one position on the table and I'm not sure I'm comfortable with that either.

Mady Hue: Thank you.

Linda Holtzman: Just to follow up on that. Thank you for articulating it that way, John because when somebody is coming in from a posterior approach, you don't have to move, for example the aorta out of the way. I mean that's one of the great advantages of doing a posterior, that you don't have to mess around with the abdominal contents or the major blood vessels that are through there.

It's true. I mean in axialif, they're – they're lying on their belly and it's true you're coming up and around but one of the selling points so to speak of an axialif is that – is that you're just going to drill up through the spine and you don't have to touch any of that stuff in the belly or the aorta or anything like that. I mean that's – that's one of the things that they say is a benefit of this procedure. So it – yes, there might be an issue in putting it as an anterior-anterior as opposed to an anterior-posterior.

Mady Hue: Thank you. Any other comments from the floor regarding the spinal fusion?

Operator: At this time...

Linda Holtzman: I have another one, which is real quick. Whatever you decide, thank you for deciding it. Let's get this in for October 1st.

Mady Hue: OK. Operator, did you have somebody on the line?

Operator: No, there's no comment. There's none at this time.

Mady Hue: OK. All, right. Now, we'll move on to the index and I'll just start off with – we had a discussion at EAB, a case that we decided we needed to have a

better index than there is for angiography of all things by magnetic resonance. So we would propose to add that subterm to see imaging then magnetic resonance by sight, OK, because it dealt with a cardiac angiography, was the question, and we definitely want to ensure that coders are instructed to code it to the proper imaging code and not the cardiac cath codes.

OK, now I'm going to invite Ann up to go over some heart addenda things.

Ann Fagan: OK. When we we're talking about maze and what do we want to do with it and all that kind of thing, someone in the room said, "Well, how do you get there?" So I said, "Well, sometimes you just know how to get there." But that really wasn't good enough.

So we had to actually add some information. And so basically what I've done here is to stick in some place markers and we're clearly not done if we do in fact decide to add a thoracoscopic approach. But under excision, on page 48, then moving to lesion-heart, we made the default 3734, the closed procedure and then added the subterms underneath the Cox-maze, maze modified in the vascular, maze modified-open, open and other closed. And then, of course, if there were the 3337, then those would be folded in appropriately, and then under maze, which is not indicated.

But, you know, you want to make it as easy as possible for the coders to find what they're looking for. So M is logical. That works for me. So under maze, you know, an additional set of instruction about – yes, you're in the right spot. This is what you use. So – are you done – so – oh, Linda. Oh, pardon me. Linda?

Linda Holtzman: Hi Ann.

Ann Fagan: Hi.

Linda Holtzman: I hear that's coming. I really – of course, agree with adding entries in the index. People need to be able to find this. Yes, but not yet. I know that you'll be looking at this again in terms of the thoracoscopic proposal that was earlier today. But I just want to comment that I would – I would like to suggest that you get rid of any default.

Ann Fagan: Get rid of what?

Linda Holtzman: Any default.

Ann Fagan: Any default? Oh.

Linda Holtzman: So in other words, excision lesion-heart is defaulted into 3734. I wouldn't default it at all.

Ann Fagan: OK.

Linda Holtzman: If you can't tell the difference between a median sternotomy, a procedure in the EPS lab, and a thoracoscope, then you need to send a query or get another job. And – I mean, you should be able to tell. And those – those are the approaches. Those are the only ones that exist.

So – and the same thing with having other approach or using the word closed. I mean, there shouldn't be any other at this point. So that's kind of a default too. And with using the word closed, then you get into issues – do you mean vascular or thoracoscopic? So I just like to suggest that you avoid that term too.

Ann Fagan: OK. Well, Marge Zernott, who is not here, likes defaults. So I will take that under advisement.

Ann Fagan: OK. Any other comments from the floor? Any comments from our phone listeners?

Operator: Not at this time.

Ann Fagan: Thank you very much. Pat, do you have some conclusion remark – concluding remarks?

Pat Brooks: Well, thank you everyone for sticking it out and I'll just state one more time, on April 2nd, we want things in writing. And particularly for the ones where you weren't too talkative or where you were confused and confused thoughts, we really need to hear firm suggestions about how we should proceed. And if

you have a third alternative where we suggested only two, we can take those in writing too.

Also, just to let you know, we do have the 5010 bottles here and outside. There are many of them. If you want to take some for your coworkers who would like to have a good website about 5010, help yourself. And we also have a number of the ICD-10 fact sheets outside if you want to take some of those for some of your co-workers who might be interested in GEM.

We will start tomorrow at 9 am and Donna Pickett will take over and will be doing all the diagnosis as far as the meeting. So thank you for coming.

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

END