

Centers for Medicare & Medicaid Services

Moderator: Pat Brooks
September 15, 2010
8:00 a.m. CT

- Operator: Good morning, my name is Sarah and I will be your conference operator today. At this time I would like to welcome everyone to the ICD-9-CM Coordination and Maintenance Committee Meeting. All lines have been placed on mute to prevent any background noise. After the speakers' remarks there will be a question and answer session. If you would like to ask a question during this time simply press star then the number one on your telephone keypad and if you would like to withdraw your question press the pound key. Thank you, Ms. Pat Brooks, you may begin.
- Pat Brooks: Thank you very much. Good morning, everyone, my name is Pat Brooks with CMS and I would like to welcome everyone to the ICD-9-CM Coordination and Maintenance Committee Meeting this morning, or as we refer to it, the C&M meeting. The purpose of this meeting is to discuss updates to ICD-9-CM and ICD-10 coding systems. Approximately 330 participants registered to attend the meeting this morning. CMS was also able to provide 225 phone lines on a first come first serve basis for callers to participate in the presentation. Those participating by conference line should note that there are four separate conference ID numbers for each segment of the meeting and these are listed on page three of your handouts. This morning's meeting will run from 9:00 a.m. to 12:30 p.m. at which time we'll break for lunch. Callers must call in again at 1:30 for the afternoon session which will run until 4:45 p.m. The afternoon conference ID number is 88803327. Please refer to the participant dial in number information posted on the ICD-9 website or in your hand out for the call in number and conference ID numbers for each of the four sections of this meeting.

Tomorrow's meeting will begin at 9:00 a.m. and will run to the lunch break at 12:30. The afternoon session will begin at 1:30 and will end at 3:15 p.m. A written and audio transcript of the entire meeting will be posted on CMS' and CDC's ICD-9 website under the ICD-9-CM Coordination and Maintenance Committee Meeting page.

The agenda and handouts were posted on CMS' and CDC's website in advance of the meeting to allow listeners to follow the discussions. This included an updated version of the 2010 General Equivalence Mappings, the GEMs. And this included responses that we received from you after the last two meetings and suggestions to update the GEMs. We hope that this advanced posting of the updated 2010 GEMs will facilitate this morning's discussion of GEM update. The PowerPoint slides used by the clinical presenters for this afternoon's session could not be posted on the website since they did not meet our posting restrictions.

Callers will be able to make comments or ask questions during the meeting and everyone, those in the audience and those on the phone are encouraged to send their written comments after the meeting. CMS and CDC have gone green for this meeting and they began doing so at the March 2010 C&M meeting. We no longer prepare paper handouts to the proposal package and this information was included in our meeting announcements on the website. Those who wish to have handouts in the meeting need to print their own copies prior to the meeting. To facilitate discussion, PowerPoint slides have the coding options and CMS' recommendations were included.

This morning's meeting will be devoted to ICD-10 topics including the ICD-10-CM and -PCS updates as well as the maintenance and updates to the GEMs. We will also be discussing the ICD-10 version of the MS-DRGs which use the GEMs from the conversion process. Discussion of the ICD-10 topics will be lead jointly by CMS and CDC and you'll see Donna Pickett sitting down at the table.

The ICD-9-CM procedure portion of the meeting will begin at the conclusion of the ICD-10 topics. This will more than likely be after the lunch break at

1:30. The procedure section of the meeting will be conducted by CMS staff and the ICD-9-CM diagnosis portion of the meeting will begin at the conclusion of the ICD-9 procedure topics. That could be either late this afternoon or first thing tomorrow morning and that will be conducted by CDC staff.

The ICD-9-CM procedure codes discussed at this meeting are being considered for implementation on October 1, 2011. The participants are encouraged to review the timeline beginning on page four for details. I'll go through a few important dates that I want you to notice. First, October 8, 2010, in the time line. That is the deadline for receipt of public comments on proposed ICD-9 CM revisions discussed at this meeting for implementation on April 1, 2011.

I should note that we have not received any official requests for any April 1, 2011 code implementation. So unless someone raises their request today or tomorrow for Donna's CDC day there will be no April 1, 2011 update.

Now if a request does come up and the audience supports it and the comments we receive support it then in November 2010 we would announce those April 1 updates. November 12, 2010 is the deadline for receipt of suggestions and recommendations for updating the GEMs. So that's November 12 – after the meeting you have until November the 12 for the 2011 GEM updates. November 19 is the deadline for comments on the proposed ICD-9 code revisions discussed at the meetings today and tomorrow.

January the 7, 2011 is the deadline to request topics to be presented at our March C&M meeting and you'll note that March the 9 to 10, 2011 is our next meeting. I would encourage you to review the posted timeline for additional information about ICD-9- CM including finalization of code titles, topics for the agenda, and the process for requesting code revisions. The Coordination and Maintenance Committee is a public forum to discuss proposed revisions to ICD-9 and ICD 10- for you in the public to offer comments and ask questions, and send comments later.

No final decisions on code revisions take place at this meeting. We do review your comments later and your additionally written comments. So we do encourage you to send your comments either by mail or email but we greatly appreciate e-mail because it's quicker and sometimes there's significant delays in us getting paper copies. Comments on procedure code issues should go to me, Pat Brooks, address indicated in your handouts. Comments on diagnosis code issues should go to Donna Pickett at CDC in her handout.

We'll now move on to the first topic of our meeting today which I think many of you have been looking forward to hearing about and that's the code freeze, item one. At the September 2009 C&M meetings we had extensive discussions on whether or not we should have a partial freeze of ICD-9 and or ICD-10- CM /PCS prior to the implementation of ICD-10 on October 1, 2013. There was considerable interest expressed in dramatically reducing the number of annual updates to both coding systems and it was suggested that a reduction in code updates will allow vendors, providers, system maintainers, payors and educators a better opportunity to prepare for the implementation of ICD-10. Subsequent to this meeting additional comments of the issue were received. Most of the comments supported a limited freeze of those ICD-9 and ICD-10 coding systems. So after carefully reviewing the oral and written comments the ICD-9 Coordination and Maintenance Committee with CMS and CDC finalizes a decision for a partial code freeze for ICD-9- CM and ICD-10. Information on this code freeze is included in the partial code freeze document in agenda and handouts starting on page 10 of your handouts.

The ICD-9- CM Coordination and Maintenance Committee will implement a partial freeze of the ICD-9 and ICD-10 codes that's ICD-10- CM and ICD- 10- PCS prior to the implementation of ICD-10 on October 1, 2013. There was considerable support for this partial freeze. The partial freeze will be implemented as follows. The last regular annual update to both ICD-9 and ICD-10 code sets will be made on October 1, 2011. And we hear applause in the room. On October 1, 2012 there will be only limited code updates to both ICD-9- CM and ICD- 10 code sets to capture new technology and new diseases as required by section 503A of public law 108173. On October 1, 2013 there will be only limited code updates to ICD-10 code sets to capture

new technology and new diseases. There will be no updates to ICD-9 -CM on October 1, 2013 as the system will no longer be a HIPAA standard.

On October 1, 2014 regular updates to ICD-10 will begin. The ICD-9 Coordination and Maintenance Committee will continue to meet twice a year during the freeze. At these meetings the public will be allowed to comment on whether or not requests for new diagnosis and procedure codes should be created based on the criteria- the need to capture new technology or disease. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on or after October 1, 2014 once the partial freeze is ended.

Codes discussed at the September 15 through 16, 2010 and the March 9 through 10, 2011 ICD-9 Coordination and Maintenance Committee Meeting will be considered for implementation on October 1, 2011. Code requests discussed at September 14 through 15, 2011 meetings and additional meetings during the freeze will be evaluated for either the limited updates to capture new technologies and diseases during the freeze period or for implementation after the freeze on October 1, 2014. The public will be actively involved in discussing the merits of any request during this freeze period.

At this point I would like to ask if anyone has any questions or comments about this partial freeze if you understand it and to emphasize once again that you the members of the public who come to these meetings will help us to evaluate each and every request for implementation during the freeze period. If you have a comment we ask for you to come to the microphone in the middle and to state your name and then make your comments or questions if there are any.

So no comments here wait a minute we do have one.

Terry Kitchens: Hi, Terry Kitchens, DeLoitte Consulting. I have a question about the mapping, are you also going to freeze mapping at the same time you are freezing the code sets?

Pat Brooks: We'll be discussing the GEMs mapping later but we will be doing annual updates to the GEMs depending on what happens with the code freeze. So

we'll discuss that detail. Thank you for raising that question. Any other question besides the applause that we heard earlier? Operator, are there any questions or comments from the phone lines? Well thank you and we'll assume that everyone is very happy or wants to send us any questions later. We will be discussing the freeze at each Coordination and Maintenance Committee Meeting during this period so working out the details.

Let's move on to the second item on our agenda today, the General Equivalence Mappings. The 2010 ICD-10 CM and PCS GEM, General Equivalence Mappings, are posted on CMS' website at the address given in your handouts and on CDC's website. Providers and payers are beginning to use these GEMs to convert their payment systems, their edits, their quality measures and other systems from ICD-9 to ICD-10. By doing so, issues and questions about the GEMs have been raised. Based on these questions and feedback, CMS has updated the 2010 GEMs in response to these issues and posted the files on the CMS – C&M website for this meeting. The file names for these GEM documents in case you have not seen them – you want to look at them after the meeting, for the diagnosis GEM the updated 2010 version, the files and its file names are 2010_I10GEM.txt and 2010_I9GEM.txt.

The procedure GEMs that are posted on the C&M website are GEM_I9PCS.txt and GEM_PCSI9.txt. We hope that the availability of these updated files will facilitate our discussion today and many of you in the audience today will recognize issues you've brought to our attention for which we have already made GEM updates. We greatly appreciate the feedback received and welcome any additional feedback as others apply the GEMs to their conversion activities.

I would encourage you to review another technical document that we also posted on our CMS C&M website. And this document is called General Equivalence Mapping documentation of technical users and has the file name GEMtechdoc.pdf. This 31 page technical document was developed to assist users in understanding the purpose of GEMs and how to use them. We hope that this document will be of great assistance as others begin to convert data and policy statements from ICD-9 to ICD-10 using the GEMs.

We'll now move to the ACA requirements for the GEMs crosswalk. Section 10109(c) of the Affordable Care Act (ACA) requires the Secretary of Health and Human Services to task the C&M committee to convene a meeting prior to January 1, 2011 to receive stakeholder input regarding the crosswalk between the 9th and 10th revision of ICD-9 CM and ICD-10. And these GEMs have been posted on CMS' website for some time. And the purpose is to make appropriate revisions to these crosswalks. Section 10109(c) further requires that any revised crosswalk be treated as a code set for which a national standard has been adopted by the Secretary and that revisions to this crosswalk be posted to CMS' website. The C&M committee will use the first half of this meeting today to discuss GEM issues and to fulfill the above referenced ACA requirements for the meeting to be held prior to January 1, 2011.

We will receive public input regarding the GEMs. No other meeting will be convened by the C&M committee for this ACA purpose. Interested parties and other stakeholders are requested to send their written comments and other relevant documentation at the meeting or no later than November 12, 2010 to me, Pat Brooks, or to Donna Pickett, CDC, at the email addresses provided in the agenda. Those suggestions will be considered for the 2011 GEM updates which will be posted January 2011.

The ACA requirements for the crosswalk refer to the General Equivalence Mapping. The GEMs were created to assist the industry in converting ICD-9 applications to ICD-10. The ACA requirements do not cover the reimbursement mappings. The reimbursement mappings were created as a supplemental tool at the request of a private payer. Donna Pickett from CDC, Rhonda Butler from 3M, who is sitting at the table and I will describe an update to the 2010 GEMs based on the comments you made, and suggestions we received over the past couple of months. We'll be going over a highlight of some, but those of you after the meeting may want to look to these GEMs to see if your suggestions were there or not and if you like the way we've responded to your suggestions.

After this update we'll give you an opportunity to bring additional suggestions and feedback about the GEMs to the floor and we welcome receiving this

feedback. While this meeting will fulfill the ACA requirements for the GEMs we will continue to encourage comments on the GEM updates at all future meetings of the C&M committee. We are now three years away from the implementation of ICD-10 so we should use this time to prepare for the transition to ICD-10 and with this in mind we'll now turn to the ICD-10 GEM 2010 version update document that begins on page 11 of your agenda and handout.

As you see from this first slide for those of you in the audience we did post the GEMs documentation for technical users on our website as shown in here and within your handout and this includes entry, inclusion criteria and provides examples that we feel like will be helpful for those of you who have not yet used the GEMs. It also discusses the GEM flags in more detail and gives examples once again so that those of you who are working we believe that this will help you to use the GEM. We also answer some frequently asked questions that we received and we also discuss some translation tools for obstetrics and angioplasty.

Also posted with this meeting was the 2010 updated GEM policies I've just mentioned. So we had the regular 2010 GEM file on our website and for this meeting we have text files I talked about that included those that you sent excellent suggestions in the past few weeks and months about updates or concerns. Some additional changes were made of our own internal review and we'll go through some of those and you want to look through those also. An example that we've put down of a suggestion we got from the public concerns the procedure code for control of hemorrhage code. And this basically -just to keep this in simple terms- comment is the code range from I-9 to 10 was not inclusive enough, it wasn't broad enough and you can read in your documents and background what that involved. But basically you'll see how we've added some more examples for repair because sometimes you do repair to control bleeding. So based on the very good suggestion we had from one reviewer we did broaden the codes and give a different range.

Now, Donna Pickett, do you want to go through cerebral palsy - that issue first please?

Donna Pickett: Yes, for cerebral palsy and thank you to the person who submitted that because I know she's sitting in the audience. This is a simple typographical error but it's always good to have comments come in on that because sometimes you just really can't find them that easily particularly when you are looking at a large body of work. So for the eagle eyes out there again I'd like to express my thanks as Pat has for the excellent comments and work that everyone has done and forwarded to us- the comments for consideration. This slide is self explanatory so I won't read anything here because all of you can do that on your own but again some of the things that were found were – needed corrections, others were just typographical errors and we know that for future meetings you'll be forwarding additional comments as we go along.

Pat Brooks: The next issue is one that CMS received several comments from various angles and this is partial shoulder replacement and we're going to be discussing this as part of a GEM update and also Rhonda Butler is going to go through some 2011 PCS updates because the issue involved concerns about the way the Mapping works and the way the mapping works we didn't do a great job of that. We included two broad of range of codes that really weren't capturing the typical partial shoulder replacement so thank you for bringing that issue up and then also several of you when you were looking at this how you really should code those in PCS and so we looked at the index that we hadn't done the best job of and so we decided to improve the index and this we further looked into and we thought about some updates to the system. Those are procedure codes that we'll discuss this afternoon.

When we make updates to PCS' system then changes to the GEM will follow if we do modify things we have to look at that to the next update to the GEM which you'll see thanks to several of you who approached this partial shoulder issue we are making changes as proposed to those GEM and to ICD-10- PCS 2011 and I won't go through those but you'll notice that we've significantly reduced those and captured what would be more typically considered a partial shoulder replacement.

And now Donna I think will talk about ankle sprain.

Donna Pickett: OK, one of the comments that we had received was asking us to look at the GEM or ankle sprain NOS and as you can see in the comments the index in 9-CM indicates that both strains and sprains are classified to the same code. So in 10-CM the GEM has been modified to show the unspecified muscle and tendon strain as an added translation option in the next update. So very simple is just looking at the index, seeing what goes where and making sure that the GEM accurately represents that.

Pat Brooks: OK, Donna now would you move on to the hemiplegia and CVA example.

Donna Pickett: OK, on this one the codes in ICD-10-CM for hemiplegia contain an axis of classification for the specific cerebral vascular disease that preceded the hemiplegia and ICD-9-CM does not. However, because of the expanded detail, modifications have been made to the GEMs so that there's more accurate translation of the possibilities in the mapping of the 9-CM codes and the 10-CM codes. And as you can see in the columns, in column one it is showing what the entry had been and in column two what the updated entry would be. And again thank you – OK, we have a question.

Linda Holtzman: No I want to hold it, thanks.

Donna Pickett: OK.

Pat Brooks: And say your name first please for the operator.

Linda Holtzman: This is Linda Holtzman, Clarity Coding. I have a particular interest in this because I'm the person that submitted this request. I appreciate that this change had been made on the, I guess it's a backward GEM from ICD-10 to ICD-9 but I think there was also issues in the forward GEM from ICD-9 to ICD-10. And I checked the updated GEM yesterday and the issues in the forward GEM from 9 to 10 don't seem to have been addressed. I don't know if that was intentional on your part or if you just decided, you didn't happen to see it or whatever.

Pat Brooks: Are you planning to send us your written comment after the meeting so that we can – excellent that'll work.

Linda Holtzman: OK, thanks.

Pat Brooks: And the rest of you too if you disagree with the approaches and feel like it's not inclusive enough we're just trying to help you focus on some areas and just like Linda has, some of you who didn't see the text file, the GEMs, we would encourage you also to go back and look at it and see if you think we've approached this in the best way or not. We have another – no, we don't.

OK, so we will move on to the next one which is a procedure issue and I think a couple of people brought this up questioning the way we did a mapping for the venous catheterization there's sort of two approaches to this. One said we didn't follow our own rule or criteria, two ways that if they got too specific and non specific you're only supposed to use the less specific entry, good point and so we made corrections and also other people mentioned the issue of probably we should have included the VAD with these and the reason it's given in that paper and that also felt like it was a good example to include. So we've made those two modifications for venous catheterization.

Well move on to another procedure issue five and one knee repair and this is an issue that I'm going to call a typo input. It's a little embarrassing but you know we're not perfect but a five in one procedure code really takes five codes. It's like an ICD-10-PCS cluster. So we have those for your right knee – people are laughing while reading this – you have the five codes for your right knee and five codes for your left knee and unfortunately we mixed them up a little bit and we had some left with right and that wasn't right. So we're streamlining those and realize that all of them together should either be the right knee or the left knee and thank you for the person who found that, you are very good.

Donna, do you want to go through the major depressive disorder?

Donna Pickett: For major depressive disorder, unspecified, in ICD-9 CM code 311, classified Depressive Disorder NEC, however in 10 - CM there is not a separate code. Instead the includes notes at F32.9 actually includes Depression NOS and Depressive Disorder NOS, therefore, for 9-CM, code 311 is a plausible translation alternative translation for F32.9 based on the complete meaning of

the code so that modification is being made in GEMs as well. And again this one is fairly straight forward it's a matter of having something in one code set and not the other or looking at the inclusion terms to make sure that everything's being captured.

Pat Brooks: OK, and Donna, if you'll now go through the uncontrolled diabetes issue.

Donna Pickett: As many of you know the concept of uncontrolled diabetes that existed in 9-CM was not carried forward into ICD-10-CM which makes of course an interesting translation when you're going to clean the code sets. In ICD-10-CM the index gives the following instruction under the main terms and the three sub terms below so if diabetes inadequately controlled, code to type – diabetes by type with hyperglycemia, out of control -to code diabetes by type with hyperglycemia And poorly controlled, code to diabetes by type with hyperglycemia. So the modifications are being made to the GEMs to make sure that concepts that were previously captured using uncontrolled are handled in the GEM so that you're actually going in the right direction and capturing the information as appropriate.

Pat Brooks: And Donna in your next talk can you leave your microphone in front of your face a little more when you turn your head I'm not sure that the operator is getting all of that. Thank you. So the next procedure issue is endovascular graft in aorta and I complement the person that discovered this for us, there's a couple issues. One has to do with a question that these are abdominal thoracic aorta and do we – where the device is or whether the approach is involved and the other issue involved, they believed that 39.71 did not include the root operation Supplement and 39.73 incorrectly included the operation of replacement so we have corrected all those thanks to the excellent feedback we got on this issue and you can look at those codes in detail later.

Next procedure issue is intracardiac echocardiogram and this was once more a typographical error that some of you who are using these graciously brought to our attention. And so we have corrected these as you see here. And Donna, you have genitourinary symptoms.

Donna Pickett: The other genitourinary symptom again it was a typographical error that was pointed out to us. So it has been removed and updated into the entry. So very straight forward.

Pat Brooks: And now Donna, other problems with newborn?

Donna Pickett: In ICD-10-CM code P84, the Tabular and Index instruction includes acidosis of newborn. So in 9-CM, code 775.81 was added as a translational alternative in the updated entry so that you can see in the updated 2010 entry 768.9 or 770.88 or the 775.81 so all that information is now captured.

Pat Brooks: And Donna, if you'll do cutaneous abscess of the hand.

Donna Pickett: OK, in ICD-9-CM code 681.10 was included as the translation alternative due to a typographical error so that has been removed and in the updated entries. Lots of typos, lots of eagle eyes. Thank you.

Pat Brooks: OK, our next issue is a procedure issue - incision of body part and once again in this one we were too broad. A person pointed that out and it should not have included all these entries so we have streamlined that based on the excellent feedback we've received.

OK, and this last example other operational body parts once again those people who gave us feedback said they believed that it was too broad and they were true and we have streamlined those to include only the PCS root operations repair code that are appropriate instead of the more specific ones that meet our criteria for how we do these mappings. Now we didn't go through every single change we received from all of you, we just tried to bring a few to illustrate the kind of changes we've had and we know this is extremely technical and difficult without your books there to review. But we just wanted to point out that we appreciate the comments you've brought. We have put in as many as we could figure out quickly for this meeting and obviously for Linda as we didn't have time to think through the issue of going backwards so thank you Linda for following up on issues you've raised to look at what we've done and if we haven't got it right. We absolutely do want your feedback and we can use it through November 12 to get the 2011 updates

improved. If you send it to us later that's fine too because we're in this business for the long haul and we just might have to do it in 2012.

But the more of you who get out there and try to convert things you use then the better this GEM tool is going to be. So at this point Donna and I would greatly appreciate hearing several things from you in the audience. First of all your experience with using the GEMs - did you find it to be a good tool or not? And if you've discovered other issues, problems, we'd like you to bring them to the microphone and explain them to us. We may have trouble although we have excellent assistance of Rhonda Butler here from 3M to try to take down the notes but we would encourage you to in addition to send an email afterwards with the technical issue you want done so that there's no confusion and so we absolutely are clear about your excellent suggestion. So if anyone has any feedback from their using the GEM or any suggestions for the future please come to the microphone now and state your name first.

Sue Bowman: Sue Bowman, American Health Information Management Association, and I just have a general comment that I've been using the GEM for a variety of projects and I really commend those at CMS and CDC for the excellent job they have done. It's a fabulous tool to use to help us all through the ICD-10 transition period and I just think it's a wonderful thing to have provided that to the industry.

Pat Brooks: Thank you, Sue.

Nelly Leon-Chisen: Nelly Leon-Chisen, American Hospital Association. Although it's a little bit early for our members to actually be using the GEMs I also have been using them personally for internal projects whether it's been for audio seminars or guidelines or looking at examples of old coding clinic advice or even the coding handbook and I have to say that it's an unbelievable work it's done in terms of how much thinking you have to go through to kind of get some of the – there's mapping all the permutations, all the possibilities but I do warn that people need to understand both the ICD-9 codes and ICD-10 in order to make sense out of the GEM. You can't just go to it blindly and not even know what coding is and so I just want to commend you and thank you for such a wonderful job. Yes, we've seen a few typos here today, a few

examples that need to be corrected but I think overall it's a very, very good tool so thank you for putting all this effort into the mapping.

Pat Brooks: Thank you.

Jeanne Yoder: Jeanne Yoder, the TRICARE Management Activity, and number one thank you, it's awesome. Sorry that I haven't even gotten to the procedures yet. I've only been messing with Donna's stuff but – there's plenty there – so as an aside just so people know the V codes have become the Z codes and it's really awesome because now they're organized because the V codes we kept kind of like put it at the end. OK, and so that's going on and it's really important that everybody understands that these Z codes – for instance now there is a code for somebody coming in to have an elective abortion and that is not up in the obstetric area it's back in the Z. Only I did notice that the Zs go clear down to the 99 so I don't know where we're going to put anymore factors that influence health afterwards and I was wondering what the plan for when we like fill up the Zs but that's OK, ...

Pat Brooks: We'll discuss that in the C&M part.

Jeanne Yoder: The Z codes are really great. I mean thank you so much for reorganizing those and getting those straightened out.

Pat Brooks: Thank you, next.

David Freedman: Hi I'm David Freedman, I'm with American Podiatric Medical Association. I had a chance to review a lot of the codes and had some questions about them so I hope this is a good time to bring them up. First of all we found that when reviewing the GEMs that we lost some codes. The first one is bunion. In ICD-9 there's 727.1 and in the current it's mapped to hallux valgus and bunion and hallux valgus are not the same thing. The other thing that we're finding too is a lot of the translations that go from 9 to 10 always go to an unspecified code. So I have a concern that payers are not going to accept those if doctors use the unspecified code in a translation when there's right and left. The other problem that we found is that we use a lot of bilateral and with the specificity of the new code there's no bilateral options in a lot of foot and ankle codes and are in other parts the ICD-10. We found that in the ICD-10 translation that

again that the bilateral is a big issue- things with like hammer toes and bunions. So that was one of the things we saw.

The other thing we saw was pain in the foot and ankle. There are ICD-9 codes that go from each joint down to the ankle and the new translation only stops at the ankle. When you look at foot or toes it automatically takes as generalized pain of foot and toes which are not the same thing as joint pain and we've lost that code in ICD-10.

Another code that we have a problem with is 726.72 in the ICD-9. It maps to a non-specific code in ICD-10 which is M76.81. We've lost metatarsalgia 726.70; the index translates 9 to the 10 to M7740, 41 and 42 but the mapping has it at M76869 which is not the correct mapping. I can go on if you don't mind.

Pat Brooks: I wish you would so that everyone could hear and then afterwards you are going to send that in writing. Thank you.

David Freedman: Yes we will send this in writing as a report.

Pat Brooks: But it's good to have – if you found something you save everyone else looking.

Donna Pickett: I mean we're taking notes fast and furious. But, please send the written copy.

David Freedman: So I'll continue on. ICD-9 727.02, which is giant cell tumor, there is no specific ICD-10 code in ICD-10 under neoplasms for that tumor. In ICD-9 there's 726.79, and in the index, that is used as a syndrome sinus tarsi- we use it as a sinus tarsi syndrome as a diagnosis. In 10 it translates to tarsal tunnel syndrome and tarsal tunnel syndrome is a neurological problem. Sinus tarsi is a musculoskeletal problem so the mapping does not take it to the correct code of the index of the draft text that we saw.

Again I mentioned bunion. A problem exists with pressure ulcers in 707.20 through 707.25 with the staging. In GEMs it says there's no code and then we go look later and the pressures, there's pressure and others non pressure and pressure ulcers. In the non pressure codes which we use for diabetic patients

they will map only as chronic ulcers. Well we see patients everyday that come in with acute ulcer and I know acute ulcer exist. Either acute ulcer has to be added as a separate list or we take out the word chronic because I don't know if that's important to put acute or chronic just that it's a fact it is an ulcer there and that's important that that exist as well. We saw with 681.11 Onychia and paronychia is an inflammation- currently it translates only to cellulitis in the L03.031 through 39 codes and to us that is incorrect.

Another one Charcot's arthropathy.

Pat Brooks: And to the extent when you write in, you are going to tell us which one would be correct too, when you write to us later.

David Freedman: There is not one available right now.

Pat Brooks: OK, and when you write if you ever have an opinion that they are wrong, you can give us hints or if you want us to just look at it, you just let us know.

David Freedman: I appreciate that. Charcot's arthropathy, a common condition with diabetics currently is one for foot and ankle in one code and the pattern and the code for specificity is not as specific as it should be. We use the code called shin splints ICD-9-CM 844.9 and in ICD-10 it translates to T79.6 which is ischemia of a muscle and has nothing to do with ischemia of a muscle and we looked under S86.911A which is strain on unspecified muscles and tendon in the foot and leg and it kind of takes it to initial encounter area so it's not in the right place there.

Salter Harris fractures which are at the epiphyseal or physeal fractures -seems that there should be an option for other bone besides tibia and fibula, it only gives us tibia and fibula. 730.30 through 730.39 that's on periostitis. Periostitis maps to ICD-10 M869 which is Osteomyelitis and periostitis is not correctly matched it is not an Osteomyelitis. CRPS, CRPS disease, which is Complex Regional Pain Syndrome was very hard to find in the index. We did find it after much searching and when you look at it, it is really not an easy way to find in the index, I don't know if there's any way to put Complex Regional Pain Syndrome as different under Complex because it's not there, as evident and easy to see. Diagnosis code that is commonly used is 733.99

which is Sesamoiditis and that index directs us to Osteomyelitis. Sesamoiditis is not Osteomyelitis. It is inflammation of the sesamoid bones in the ball of the foot. So that was the problem, there was no code that translates to them to Sesamoiditis. 735.3 in ICD-9 Hallux malleus is flexus, it is not hammer toe but yet it translates to hammer toe. It's a different diagnosis so that was an issue with malleus I know it's in the finger side there is malleus finger so there are specific things in the hand that are there but not in foot.

Another area that came up was 754.50 Congenital talipes varus is lumped into 754.51, both are now Q660 which is not right. 754.53 is Congenital metatarsus adductus is mapping to Q662, this is Metatarsus primus varus, not the first metatarsal and all the metatarsals and options do not exist in this. So these are the some of the things we found just as I was going over this very quickly in the last month or so and I am sure we will present this in paper for you so that is enough and I am tired.

Pat Brooks: Let me mention this one issue and thank you, you are very thorough I appreciate it. As many of you know some of these issues were discovered by looking at the GEMs but they are not exactly GEM issues, it's questions about what is in ICD-10-CM or not. So it's good to bring it up we'll hear it all at once, but issues about ICD-10-CM where you feel like it's lacking it should be more specific or whatever, you really need to send those, almost like a separate piece of paper to Donna because that will go through the regular update to ICD-10-CM process where you ask for code changes. Where – once you send your excellent suggestions we'll go through them and where we believe we have made a GEM error, based on your list which is quite thorough we appreciate it, we'll look at the existing code and see if we can do better. If it involves modifying ICD-10-CM then you have two months prior to the March meeting to get your specific suggestions to Donna so she can evaluate them. Donna did you want to say a few more words about that?

Donna Pickett: I think you've covered it all Pat.

Pat Brooks: Yes. But thank you and see he did good so the rest of you can go out and do your reviews. Next?

Kathy Giannangelo: Hi, Kathy Giannangelo with Apelon and it's not specific to examples but I do have a clarification that I want to make sure I understand correctly what was in the APA or ACA. I noticed on the CMS website and I didn't pull up the actual text in the ACA but I hear a lot about the fact that the cross-walks that referred to in that Act, talks about crosswalk between 9 and 10. As far as I know there is no mention about the 10 to 9. So I want to make sure that I understand correctly the Act says the standard – the code set for that's been recognized that there is only the 9 to 10 and not the 10 to 9.

Pat Brooks: It's true that that is all it says except we want to do a better tool than that because we knew that just mapping forward is a very great tool but you still need the backward mapping so as we're maintaining both and discussions today such as the one Linda brought up, where we are missing information in the 10 to 9, we want to also have your comments from that we intend to fix all of that.

Kathy Giannangelo: But from the standpoint of the Act itself, it's only recognizing a crosswalk between 9 and 10?

Pat Brooks: Denise, do you have anything more to say about that? We have Denise from OESS. Could you go to the microphone please Denise? Or you use that one.

Denise Buenning: Yes: you're correct that in the Act it does specify the crosswalk from 9 to 10, and we're currently having that evaluated. I think that our interpretation of that is that the intent is for the crosswalk to be as broad and as flexible and as useable as possible. So I think that the interpretation and perhaps the guidance that we maybe looking at would be something along the lines of yes, it does satisfy 9 to 10, however in order for this to be a fully functional and useful crosswalk for the industry at large that would really have to be the full set 9 to 10 and 10 to 9 but we will be coming out obviously with more specific formal guidance on that as soon as these proceedings are over and we get all the rest of the comments from the industry and our interested stakeholders by the November 12 deadline.

Pat Brooks: Kindly go to the microphone for the people on the phone, they won't be able to hear you at all. And say your name again.

Kathy Giannangelo: Kathy Giannangelo a follow up to that. Is there a timeline in which we would expect to see that clarification in regard to – I'm assuming that – I don't know, because it is within an Act if you have to come up with addendum or whatever it might be to say it's just not 9 to 10 that we were referring to there, we were really referring to both 9 to 10 as well as 10 to 9?

Denise Buenning: Again I don't want to put words into our mouth but again if we go that route, if that is the determination that, that is the intent of the Act, we will try and issue this as quickly as possible, we obviously have to give Pat and Donna time to go through all the comments and they'll put any changes they deem necessary, but I believe that the act basically calls for us to post the revised GEMs on the website so in the interest of everybody having to make this transition and to get working on it as quickly as possible, we will try and put that out just as quickly as we possibly can. I can't give you a timeline...

Denise Buenning: OK, it has to go through clearances you know.

Denise Buenning: Yes, and the normal way of the world so to speak, but we would – our intent is to get it out just as quickly as we can.

Kathy Giannangelo: OK. Thank you very much. Thank you both.

Pat Brooks: Thank you and thank you Denise. Next comment or question or suggestion?

Sarah Jarvis: Good morning, my name is Sarah Jarvis. I am a registered nurse and a certified professional coder currently with LabCorp which is a member of the American Clinical Laboratory Association, ACLA. On behalf of ACLA I am pleased to have this opportunity to submit our proposal and revisions to the GEM. Between the 9 and 10 provisions of the Act of the ICD-9-CM of the 9, to 10 respectively. ACLA is an association representing clinical laboratories throughout the country including both local, regional and national laboratories. After careful review of the GEM, ACLA has identified 60 mappings which appear to be inappropriate including 50 more mappings in forward map from I-9 to I-10 and the non-mappings in the backward map from I-10 to I-9. ACLA is submitting with this statement a forward after these identified mapping issues together with proposed provisions and the rationales on which the (inaudible). For purposes of our statement today we

would like to make – to provide representative examples of the kinds of mapping issues we identified and the kind of revisions we're proposing. The inappropriate mapping that ACLA identified in the GEMs generally fall into the following categories: mapping from or to an invalid code, failure to map to an exact match where one exists, failure to map to a better match where one exists, use of “other” codes when “unspecified” codes would be more appropriate, mapping to more specific codes, specific codes reflecting unwarranted assumptions and selection of mapping despite significant ambiguity.

One example of mapping from an invalid code in the forward GEM map is the attempt to map 148.6 to I-10 code A18.32, Tuberculosis enteritis. 148.6 is not a valid I-9 code, it should not be included in the GEMs at all. An example of mapping from a valid I9 code to an invalid I10 code is the attempt to map I9 code V20.2 Routine infant or child health check to Z00.129. Z00.129 is not a valid I10 code. ACLA recommends that it be replaced with Z00.10 Encounter for routine health exam without abnormal findings. There are also several instances in which the GEM maps code is not an exact match, even though an exact match exists. For example, the forward GEMs map currently maps I9 code 117.0, Rhinosporidiosis to I10 code A15.7, Primary respiratory tuberculosis, despite the fact that an exact match B48.1 for Rhinosporidiosis exists in I10. So ACLA recommends the codes be mapped to the exact match where exact match exist. Even when there are no exact matches between code sets, some codes are clearly closer matches than others, yet in many cases the GEM mapping fails to map to the code that most closely matches the codes mapped from. For example; in the backward GEMs map I10 code E78.5, Hyperlipidemia, unspecified, is mapped to I9 code 272.9, Unspecified disorder of lipoid metabolism, despite the fact that a closer match, 272.4 Other and unspecified hyperlipidemia, exists in I9. ACLA recommends that codes be mapped to the closest match where exact matches do not exist but some matches are closer than others.

ACLA members believe that the use of “unspecified” diagnosis codes is preferable to use of other diagnosis codes in the absence of medical documentation ruling out more specified diagnosis. However, the GEMs often map to the “other” codes when mapping to an “unspecified” code would

be more appropriate. For example; in the forward GEMs map, I9 code 790.5, Other nonspecific abnormal serum enzyme levels, maps to I10 code R74.8, Abnormal levels of other serum enzymes. ACLA recommends that 790.5 map to I10 code R74.9 Abnormal serum enzyme levels, unspecified. In some cases the GEMs mappings refers to a specific code based on what appears to be an assumption that is not warranted. For example in the forward GEMs map I9 code V58.69, Long-term current use of other medications, maps to Z79.3, Long-term current use of hormonal contraceptives. ACLA is recommending that in this example that V58.69 maps to I10 code Z79.899, Other long-term current drug therapy, which like the I9 code does not assume the type of medication being used. The GEM should not make unwarranted assumptions which can lead to inaccurate and potentially harmful results. There are some codes for which there is significant ambiguity regarding the code or codes to which they might map. In such cases it is questionable whether such codes should be mapped at all in the absence of a mechanism to eliminate the ambiguity.

One example of the issue is the issue of the GEMs mapping I9 code 042 ,Human Immunodeficiency Virus, HIV, to I10, D20, Human Immunodeficiency Virus Disease. The ambiguity associated with 042 arises because an individual with HIV maybe asymptomatic which in that case the I10 code is Z21, Asymptomatic HIV infection status, would be appropriate but if they're symptomatic with AIDS then code B20 would be more appropriate. Mapping to one of the other could result in inaccurate reporting in some cases while mapping to both may produce inconsistent results. For that reason ACLA is not recommending an alternative mapping in this example but would urge the committee to develop a mechanism to provide greater specificity in the GEM to eliminate such ambiguities as they exist. On behalf of ACLA thank you for this opportunity to identify these issues in the GEM and to propose revisions to resolve them. We look forward to working with you to improve the GEMs as a useful transition to I10. Thank you.

Donna Pickett: Before you head back to your – OK.

Sarah Jarvis: Thank you.

Pat Brooks: I would like to thank you for the detail that I know we will have in that document. That would be helpful if you give us the code number and like you mentioned where you have a suggestion give that to us and if you don't have one the head's up that's extremely helpful. Thank for all the work you did on that. Donna do you have anything else to say? OK, say your name again.

Linda Holtzman: Linda Holtzman, that's a hard act to follow. I just have a few observations and a couple of suggestions; I just wanted to comment that I have been working with the GEMs for about a year at this point and my observation is that I tend to use the GEM and as a coder I'm not doing massive data transfer change or anything like that, I'm actually working for medical records and trying to code them and there are plenty of times when I am lost to know where to even start on an ICD-10 code. So the GEMs served me to get me started, to put me in the right place and I don't necessarily rely on the GEMs completely to get to the right code, it just gets me in the right place if I'm not sure which root operation this falls to. I take a look at the GEMs and I say, OK, well they've got these three root operations in the GEM so I know that I am going to be using one of these three, I hope. So I just wanted to point out that, that's one of the great uses of the GEM s, not for major data change projects but for individual coders working to assign codes to individual records.

Pat Brooks: Could you also comment from your perspective because I think you used it clearly as much as anybody like how you feel like if you had a project to use, how beneficial you feel like the GEM could be from your perspective of using them? If you were converting a large system, do you feel like it would be a useful tool?

Linda Holtzman: To tell you the truth I do have some concerns on that just because in many cases at least the prior 2010 GEM, not necessarily the one that was just posted but the prior ones sometimes a single ICD-9 code would convert to 155 ICD-10 codes and it was very difficult to try to figure out and I realized that might simply be the nature of the system, right? But one of my observations that I also wanted to mention is that I felt in many cases the conversion was too broad and an example of that was the 38.93 and the 39..71, I also saw it with like insertion of a left ventricular lead because some of the codes that it converted to were not physically possible, in other words you would never use

that approach with this code, the code was defined as percutaneous and then when you look in the GEM it had an open approach in addition to the percutaneous approach, or this body part would never be used with this particular procedure. So I did note quite a few instances of that and I commented on some of them, to tell you the truth after a while I just started ignoring them because there were a number of cases like that so I guess...

Pat Brooks: I would encourage you like in the next future update to keep emailing – keep sending us the number, we would love to have those.

Linda Holtzman: OK.

Linda Holtzman: Be careful what you wish for, you all heard it, it's in the transcript so – OK. So I do have some concerns with that in terms of large data transfer, also that it just could be overwhelming the number of codes. Having noted that I have one suggestion which is, as far as I can see there are some GEMs where the ICD-9 code encompasses several procedures that would be coded separately in ICD-10. So when I go to the GEMs I see – it appears that I am going to have to use one code from this group and one code from this group to come up with a single equivalent to single ICD-9 code and that is very confusing, I just wondered if there is some way to – I don't know if it's even possible, but if there is some way to mark those GEMs which really represent a combination of codes.

The best example for that is when I was trying to convert 86.07 which is insertion of a subcutaneous port, infusion port or an infusion reservoir and from what I can see, I don't know if I am right on this, but – which is unusual for me, but from what I can see in the updated GEMs it uses two device characters and I believe what you need to do is have one code from this device character and one code from this device character yet you have both of them together. And so is there some way to mark those GEMs? Another good example of that is codes for replacement of device, and it's very clear to me that you need to have one ICD-10 code for removal of the old one, plus an ICD-10 code for insertion of the new one and the GEMs list all those codes which may not be clear to users that you may have to pick from column A and also pick from column B, they need to – they just use one or the other.

Pat Brooks: That's a good catch, maybe we will look at that and see if that is something we would handle more on our technical document or if there is a way to make the GEMs illustrate that better. Rhonda do you have any comment on that?

Rhonda Butler: That's really what the combination flag is meant to mark, so when the combination flag is a one instead of a zero, that tells you that from the source system you have one code, in the target system you have more than one code that you need to pick from the pick list in order to equal the meaning of that source code. And then the fourth and fifth flag number those pick lists to tell you, OK, there is only one pick list, or there is two pick lists.

Linda Holtzman: I confess I had trouble with the pick markers. It's just like – there were so many numbers that I just couldn't take in all that as well so I had to look it up from a cross way.

Rhonda Butler: Yes, well – right. Looking at the raw GEMs files itself can be intimidating, but that's what is meant and it should be explained in the technical documentation as well as examples in the general GEMs documentation.

Pat Brooks: If you look – Linda, if you'll look through the updated technical documents and the guidelines and if you've got language that you think for the 2012 that leads to simpler language, or better, or clearer, we would love to have that.

Linda Holtzman: OK. I just have one more comment – two actually, the other comment that I would make is despite – or the previous comment this really is a wonderful undertaking, it really is, I think I would be completely lost in starting with ICD-10 without the GEM, so I just want to thank everyone who worked on it for what I think is a tremendous job. It really is terrific. And my last comment is, in over 25 years as a coder, hands down, the best surgical documentation that I see, hands down, comes from Podiatrists. Thank you very much Sir.

Pat Brooks: OK. We have another comment.

Kristine Weinberger: Hi, Kristine Weinberger with ACS, a Xerox Company. We have multiple lines of service but in the healthcare arena we work with a lot of hospitals,

health plans as well as Medicaid programs. I'm also the co-chair of the WEDI Sub-work group for ICD-10 cross-walks and WEDI did submit a letter with comments to your previously day email, but I just wanted to highlight one area of concern in that letter and that is the Affordable Care Act where it discusses treating the crosswalk as a code set for which a standard has been adopted. We know that we've got the GEMs which are great tools, we also have reimbursement maps that Medicare created. We've been told through the grapevine that, that comment pertains to the GEM specifically and if that's the case – regardless of whether or not that's the case, really the comment that I'm trying to express is that a crosswalk can't really be used in a transaction – in a covered transaction.

It's not like a code set, like ICD-9 code set is mandated as a code set, or CPT is mandated as a code set, or ICD-10 is mandated as a code set, those code sets are used in HIPAA covered transactions and they're required to be. When you start talking about requiring a crosswalk to be treated as a code set, the assumption is that it should be used within covered transactions which wouldn't be the case necessarily for a crosswalk since it provides the link from one code set to another. So we do have some concerns around that and we want to make sure that flexibility is allowed to entities implementing ICD-10 so that we are not tied to a particular crosswalk. The other thing I wanted to mention is I just wanted to echo comments of the previous speaker that the GEMs are very helpful tool, but they're really not a substitute for people trying to code claims or assessing ICD-10 policy. The really critical thing to look at are the coding guidelines and the ICD-10 code books. The code books give you a lot of information about what's included, what's excluded and it's really important to use that information, yes, the GEMs can help you - point you in the right direction, but if you're for example updating policies or a payer system, you don't want to rely on just what the GEMs tell you. You want to get that other information.

Pat Brooks: That's an excellent comment. Thank you for raising that again. When we have our ICD-10 outreach calls, there is a bullet I always include in every one of them and that's exactly what you have mentioned. The GEMs are not a substitute for learning how to code and thank you for bringing that up this morning. They're just a tool to help with big database conversion. I don't

know if Denise wants to say anything about the – further about the HIPAA language, but earlier today we did announce that our interpretation that ACA requirements is only for the GEMs not for our supplemental tool the reimbursement mapping. So we announced that this morning if that helps you. But thank you for raising that good point about, guys you need to learn to code. OK. Next comment, come to the floor and state your name again.

Jeanne Yoder: Jeanne Yoder, the TRICARE Management Activity. People – when you're using the GEMs you have to understand what they were developed for and how they are intended to be used and I agree with Linda, it's a great tool when you're trying to figure out where do I start with this, but what we're doing in the military is we're trying to have – because we have told everybody point blank that if you have the record in front you, you code that thing, you don't use – you just don't dump it all into a machine and expect it will code everything, that's not how GEMs are ever intended to be used because you're going to come up with silly things and Rhonda and the 3M folks have come up with a study for instance when you have the male bladder and the female bladder, you cannot dump that in there and just pick one of those codes, OK, it depends.

And so what we've had to do in the military when we were trying to get something to say, OK, if you insist on having a dump all the data in, we had to map it to a less dangerous thing and so there is nothing in 10 that has bladder not otherwise specified, I mean you either got the male or the female, it's the only options you've got and in order to get to some code that you could map that to you have to go way far up practically to the 799 – they're sick by golly - and so when you have something in 9 that is specified like some kind of specific name of a heebie jeebie and it's not in 10, if you were using the GEM it would map to "other" because it is an "other", it is not "unspecified", but the GEMs you have to look at why they were made and what they're intended for and you can't start bashing them because they don't meet your specific requirements, and so I have gone through and I have had to make a lot of things map to the "not otherwise specified" and then some of them I have to go way up because I can't – you know the (inaudible), the joints – 9 and 10 aren't the same. When you go down the shoulder and upper arm and we're looking at how do I map this elbow because it's not split up the same, you will

have to make a decision especially with the OB thing. So the GEMs were – why they were made and how they're supposed to be used, at least for me they seem to be working out the way they are but if you're trying to use them for some reason they weren't intended for, then of course they're not going to work exactly and you will have to spend some time on them.

Pat Brooks: Thank you. We will take another one – we'll have two more from the floor and then we're going to turn over and let the people on the telephone have an opportunity after these next two.

Kathy Giannangelo: Kathy Giannangelo with Apelon again.. I just have again a general kind of question in regards to the process and the development of the GEM, the National Library of Medicine published mapping assumptions and the kind of guidelines that they propose for people to go through in the development of mapping, and within that they mentioned a couple of different times involvement with you – the people who own the code sets, how important it is to people, how important it is to test and I am hearing a lot of people protesting the mappings and even coming up with specific suggestions which are great. My question has to do with validation, and I just was wondering from the standpoint of in the development of the GEMs and how we're going to – maybe it's a process in play or perhaps it was talked about within the overall development of the GEMs and it was decided not to go that level but I was just curious about whether what had happened in regards to the development up to this point and perhaps going forward if there is any work perhaps that you're going to look to in regards to actually “validating” them? And so a lot of validation occurs outside of you know the people who develop them.

Pat Brooks: All right, let me just say a couple of things about that. First we have the ACA requirement which we believe we're giving you all an opportunity to test and give us feedback and work. And as more of you in this room actually take the GEMs and convert, then we'll hear from you and that is a validation and the real world experience of what takes place. We also have a later topic this morning where we talk about the impact of converting the MS-DRGs to ICD-10 using the GEMs and I think that will help answer some of your questions so you'll probably be interested in our next topic. But any of you who have

suggestions for improving it, for the 2011, you have until November 12 to get those comments in and any that come up after that, we will value equally because we intend to keep working on the GEMs to make them work as well as we can up to the conversion time. So thank you.

Kathy Giannangelo: So you see testing and validation somewhat as a combination, you're getting the testing going on by people who are looking at the GEMs in detail and therefore that's the actual external type of validation that you are offering?

Pat Brooks: I don't know – I don't want you to put words in my mouth – except to say this, we had the ACA requirements which we're doing this morning and which we have done prior to this point and we'll continue to do that and then we internally, within our agency do conversions we'll find other issues that we need to improve. As people outside validate them by using them, I think we'll get feedback, but do we have a separate item setup that we're paying for validation under a separate contract? We don't have a separate box that I can show you.

Kathy Giannangelo: OK. And at this point there's no plans to do anything like that?

Pat Brooks: If you have a suggestion for a plan that you would like to make for us, then you should write to us and we will look at it.

Kathy Giannangelo: OK. Thank you.

Pat Brooks: Thank you.

Shelly Waynes: Good morning, Shelly Waynes from the Department of Children Affairs. I just have a question about the GEM creation with – to mitigate the ACA requirements. With the publication of the GEMs and the validation has gone on up to this point, is – you mentioned this morning that you would continue to encourage updates to that as we make changes to ICD-10, as I understand it there are no requirements to continue to publish that – that's something that we're doing?

Pat Brooks: Oh no, we intended and we said in our ICD-10 rules that we intend to keep publishing the GEMs annually. With each update to the coding system we do

it, we even made a commitment that we would do it up to three years after implementation because it's the kind of tool that helps you with data translation over a period of time. So you can go back and read our rules and you can see the statements we've made previously that we will continue to release updates until at least three years after implementation of ICD-10. That's totally separate and predates the ACA requirements.

Shelly Waynes: OK. And is that still – are we still considering three years benchmark at this point?

Pat Brooks: You guys will help us to determine that, I think when we did the final rule and Denise can agree with me, we didn't know how long in the future it would be helpful so we based it on people's comments and we said we will make this commitment. Is that enough? I don't know. I think we'll know better after implementation whether it's needed or not, or you guys probably maybe it could just die a natural death, I don't know at this point.

Shelly Waynes: OK. And the only changes after 10.1.2013 of course would be to the ICD-10 codes?

Pat Brooks: Yes.

Shelly Waynes: No changes to ICD-9-CM...

Pat Brooks: Yes. If you'll look at that code freeze document, the first one I posted in the paper, we talk about the last change for ICD-9 would be a handful of codes that occur in October 1, 2012. On 2013 the only codes that will be changed will be ICD-10.

Shelly Waynes: OK. Thank you very much.

Pat Brooks: And hopefully you guys can – I know it's a lot of material we're throwing at you this morning but hopefully these documents when you have a chance to look at them will resolve these questions. I am now going to turn to the people that are on the telephone. Operator, do we have any questions or comments from anybody participating on the telephone?

Operator: If you would like to ask a question or if you have a comment please press star then the number one on your telephone keypad. And your first question comes from the line of Rose Camilleri from Blue Cross and Blue Shield of Michigan. Your line is open.

Rose Camilleri: Hi. So prior to implementation there will not be a specified date for like the last GEM updates, correct?

Pat Brooks: Sorry, can you please restate that, I am having a little trouble hearing you and I didn't understand that question.

Rose Camilleri: OK. So prior to implementation, there is not going to be a specified date for the last GEM updates?

Pat Brooks: A last date for – did anybody understand that question? The GEM updates, OK. Let me state it this way, we update the GEMs annually, we kind of broke that rule this year for this meeting – we had - I'll call it a mid-year 2010 updates to assist with this meeting, but from here on out the GEMs will be updated annually. As we update ICD-9 and ICD-10 codes during this interim period, we'll update the GEMs annually. And we planned to do up to three years after the ICD-10 is implemented- to update the GEMs on an annual basis. Is that your question?

Rose Camilleri: So, are you saying then that even though we have the codes freeze update on 2011, we're still going to continue to update the GEMs?

Pat Brooks: Yes. Let me state it this way, we won't be totally freezing the codes, we assume that there will be a few codes each year for new technology and new diseases. I guess there's a chance that one year when we have proposals that no one will want a code during the freeze period. But if there's even one code change during the freeze period, the GEMs will be updated that year to cover that one code change. So annually, we will update ICD-9 and ICD-10, they won't be as big during the freeze, they'll be significantly smaller and we'll make comparable changes with the GEMs on an annual basis so that the GEMs are updated annually.

Rose Camilleri: OK. So, I understand then the only time the GEMs will be updated after the code freeze will be when new codes are implemented. Because we're wondering if they will continue to be updated based on the comments we're hearing today.

Pat Brooks: OK. There are two separate things you said. First of all, we will be updating the GEMs for 2011 based on all these excellent comments we've gotten this morning and some that we've got in the last two months. And we'll be getting some additional comments I hope in writing before November the 12. We'll look at all that and we'll make a significant update to the GEMs to make them even better. After that, on an annual basis, let's say we don't even have a code update for one year during the interim period, but someone finds a problem with the GEMs, we'll update those GEMs annually for those.

We will discuss at every meeting any point people raise about the GEMs that they find issues, so you should expect annual updates to the codes and the GEMs. It just may be that some years, there may not be many of them because we may not have many codes. OK, if we can move on to another question.

Operator: Your next question comes from the line of Jeffery Linzer from the American Academy of Pediatrics, your line is open.

Dr. Jeffery Linzer: Thank you very much. I just want to add to one of the comments that was made by one of the ...

Pat Brooks: Can you speak up Dr. Linzer?

Dr. Jeffery Linzer: Yes. I just wanted to add to one of the comments that was made by one of the speakers at the meeting. I think a lot of people are expecting the GEMs to be an automatic crosswalk where they put it into a computer and it will automatically give them the answer. And I think, we need to be very clear to organizations that that is not the case, that it still involves coding work and that this is not like another system that just spews information out of a computer.

And that it will take good coding effort, the GEMs will be very helpful for that and I think you guys are making a very good effort to make it as user friendly as possible. But I think we need to be very clear that this is not something that you're just going to put in a computer and have it automatically spit out.

Pat Brooks: That's an excellent point Dr. Linzer. And maybe it would be helpful at one of our future Coordination and Maintenance Committee Meetings to have another, how to use the GEM update and what it's for and not for with that, are you interested in that? So maybe we will add that to one of our future meetings just to remind people what they're all about and what their use. Thank you Dr. Linzer and we're sorry you couldn't join us today.

Dr. Jeffery Linzer: Thank you.

Pat Brooks: Next comment from the phone lines.

Operator: There are no further questions from the phones.

Pat Brooks: Thank you very much. Well, you know we have gotten a lot of excellent suggestions this morning and we greatly appreciate it and I hope it spurred the rest of you to maybe pull out your sections from the other physician specialty groups if you want to browse and look, that would be helpful. And if sometimes the issues involved such as - issues such as the partial shoulder replacement, maybe it involves a change in PCS and the GEMs, we welcome both of those issues.

We would encourage you to get your GEMs comments to us by November 12 in writing with as much detail as possible so we make sure we understand one another and we will be posting the updated 2011 GEMs in January 2011. Along with the 2011 reimbursement maps and we hope to keep those tools rolling out to you. We'll now turn to another part of the meeting that I think many of you are going to find extremely helpful, and that's item three on your agenda today, MS-DRG Impact Analysis.

During previous C&M meetings, we've discussed using the GEMs to convert policy and payment systems from ICD-9- CM to ICD-10. We've had detailed

presentations on the conversion of the MS-DRGs from ICD-9-CM to ICD-10 using the GEMs. Questions have been raised about the accuracy of using the reimbursement map posted on CMS' Website to convert ICD-10 codes back to ICD-9- CM and to continue using current payment logic. Some payers are evaluating this approach instead of converting their payment systems to ICD-10 codes in advance to the implementation of ICD-10.

CMS asked their contractor 3M to perform analysis that they would share with you this morning, of moving to an ICD-10 based, MS-DRG system that was developed using the GEMs, the project, the MS-DRG's Conversion project we've all been hearing about. We also asked 3M to compare this approach to that of converting ICD-10 codes back to ICD-9 codes and using the current payment logic.

We believe these discussions will allow the healthcare industry to more fully evaluate our efforts to data conversions using the GEMs, one more tool to validate the GEMs. The work has been summarized in an article entitled Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments and that article begins on page 21 of your handout. The methodology and results of this study will be discussed by Ron Mills and Liz McCullough from 3M and I'll ask them to come up to the podium here. And I think you're going to find this part of the meeting extremely interesting. Just push this button to go forward and you can watch the slides.

Ron Mills: The objective of this study was to estimate the impact on aggregate IPPS MS-DRG payments to hospitals and the distribution of payments across hospitals due to the transition to ICD-10. Since we can't see into the future, what did we actually do? Well, presume that hospitals were to start coding in ICD-10 tomorrow and we have the version 27 MS-DRG grouper that currently exists, and we have the set of payment policies that currently exist, what would the payments to hospitals look like with those policies and with the version 27 MS-DRGs but with records coded in ICD-10?

To do this, we'd have to have an MS-DRG grouper and there are two ways that we wanted to look at grouping this presumed ICD-10 records. One is to have an ICD-10 MS-DRG grouper that is a grouper that expects ICD-10 codes

in its input records and has its internal tables on ICD-10 and its logic based on logical ICD-10. A second way would be to take records in ICD-10, use a map to translate them back to ICD-9 codes and then group those ICD-9 codes based on the existing MS-DRG Grouper. So there's two ways of doing it. Fix the grouper or map the codes. And we'd like to see if there's any difference between those two approaches and if so what the differences might have been. To do this work, we may use clearly the currently existing I9 MS-DRG Grouper which is in the public domain and is distributed by NTIS.

We have been running some projects over the last two or three years in creating the new I-10 grouper and thus publishing the results of those projects on the CMS website. And what's currently out there is a representation of the MS-DRG grouper in ICD-10 but for version 26 of the grouper and with all of the information that was available to us at the time it was posted last year which does not include all the tables that the grouper uses. So we started with that to translate that to version 27 the current year version of the MS-DRG's and add the additional information the particularly the CC/MCC exclusion list that so that we have a full definition of the I-10 grouper.

We made considerable use in fact everything that we've done when we go back and forth between I-9 and I-10 is done in the GEMs. So there's nothing in the construction of the grouper or in the construction of the data or the analysis of the data that we've done where we have a relationship between an I-9 code and an I-10 code that we've used any relationship that is outside the GEMs. Since the GEMs often show relationships between groups of I-9 codes and I-10 codes as you've been hearing, people talk about sometimes we have to make selections within those groups. So in various cases we have used subsets of the GEMs. But never have in any of this analysis have we paired up an I-9 code and an I-10 code outside the relationships that are expressed in the GEMs. Sometimes we use the 9 to 10 relationships sometimes it's more appropriate to use the 10 to 9. Then in order to compare a grouper that is written for I-10, what we call a native I-10 MS-DRG Grouper and the process by which we take an I-10 record, translate it to I-9 and then group that we needed a map.

And the most obvious one to use one we did use was the reimbursement map that's posted on the CMS website which was developed looking at Med PAR data over last five years and where in which the choices were made generally for the usefulness for the industry but necessarily because of the data with a kind of Medicare population and inpatient point of view. The analysis we did was to compare the payments based on the MS-DRGs assigned with via the I-9 grouper what we're currently using. With the payments that we would get using the native I-10 grouper and the payments that we would get using the translations from I-10 back to I-9 and then using the I-9 grouper. Basically since the payment policies are the same in all three cases whether we're using the I-9 coded data and a I-9 grouper, or I-10 coded data I-10 grouper or mapped data in an I-9 grouper the difference is going to be in the computation of the DRGs. That's the only part that's changed is the assignments of the DRGs.

From that point forward all the same rules that are currently applied would continue to apply. For source data for this process we used approximately 11 million records, which were the MedPAR inpatient data that beginning in October 1, 2008 through September 30, 2009, fiscal year 2009, MEDPAR data. That gives us almost 11million I-9 records but where we're going to get 11 million I-10 records. This is the tricky bit. The overall process looks like this. And this is just a diagram of what we just said in the text. We start with the MedPAR data we can run it through the I-9 Grouper, we get one set of results. If we can convert the I-9 data into a set of I-10 data assuming there is a reasonable representation of how that data would have been coded or could have been coded, if it were coded in I-10 then we have a set of I-10 data we can run that through I-10 Grouper and get a set of DRGs. And finally we can take that I-10 data and say supposing we don't have an I-10 Grouper, we translate it using the reimbursement map back to I-9, run that through the I-9 Grouper and get a third set of DRGs.

Then we can compare the payment impact of these different sets of DRGs. Liz is going to talk about the results of those comparisons. I am talking about the process by which we constructed this and the difficult part was that second box down the conversion of I-9 codes to I-10. So for each MedPAR record each of the nearly 11 million records that we had in I-9, real world records, we

wanted to create an equivalent ICD-10 record. Where the equivalent is certainly within the GEM definitions - that is the definitions the GEM say given the information that you have in I-9 what can you plausibly expect might be coded in I-10. We're staying within that.

We would be tempted to say look we use the GEMs to create the I-10 MS-DRG Grouper. Why don't we just use those relationships and map the records with those relationships. Well that would beg the question because then we really wouldn't be testing anything. So what we said instead was can we use the GEMs and create I-10 records that were correct coding in I-10 that were plausible translations of the I-9 records the information in the I-9 records would be plausibly coded in an I-10 record. So that's what we went on to do and we did not look at our translations of the DRGs in doing this. We are just looking at it from the standpoint of, what would coders be thinking when they did this.

Because of the increased specificity of ICD-10, this we've been talking about a lot this morning, a single I-9 code often translates to multiple I-10 codes. So but we can only put one of those alternatives on the records. So how are we going to pick which ones we use since we're not going to look and see what we did when we converted the grouper? Well, we developed a set of specific translation rules, some clinical rules that we use to narrow down the set of alternatives in these various cases. And those rules require that we look at the incoming record not code by code but we look at the overall record. When you're trying to translate the codes on the I-9 record and the I-10, we would have to look beyond the individual code that we're trying to put into I-10.

So here are some of the rules we used. There's a small percentage of I-9 codes and a much larger percentage of I-10 codes that are one to one. Its information in the I-9 code is represented by an I-10 code with as close as the code books will tell us are the same. So when we had those situations of course we used the direct translation. For I-9 codes for which there are multiple I-10 codes that are reasonable alternatives here are some of the things that we did. I-10 procedures often are very specific about the anatomic site and I-9 procedure is not specific about an anatomic site. So what anatomic site do we want to put in our translated I-10 record? Well we use the principle

diagnosis on the record as an indicator of what the anatomic site might be and narrow the range of alternatives basis. We have I-10 codes that are gender specific and the I-9 codes are not gender specific. How do you pick the I-10 codes that's gender specific and look at the sex of the patient on the record.

And then we have clusters in both directions. We have I-9 codes that include multiple diseases or procedures and so have to be represented by multiple I-9 codes. You see those in the GEMs. Those are the GEM entries in which the combination flag is non zero. You also have in the other direction, you have I-10 codes that require multiple I-9 codes. Now the way that looks in this exercise is you would see multiple I-9 codes on the record which taken as a unit leads you to a single I-10 code. So we look for those and made use of those where they were appropriate. So that means that an I-9 record with a certain number of codes on it, your I-10, your equivalent I-10 record may have fewer codes, may have more codes, but the intent was it would have the same information. At least insofar as we can deduce what was on the medical record- behind that record in I-9. We would produce an I10 record with similar meaning.

Well these rules got us a long ways but they don't take us all the way. We still end up with situations where there are choices to be made. And very, very frequently those choices are because I-10 has an axis of classification- laterality - left or right - is a common example – there are many others that I-9 doesn't have. Now when the DRGs were developed for using I-9, the DRG logic could not make distinctions along those axis of classifications. The MS-DRG logic can only make distinctions insofar as the I-9 codes on the record allow those distinctions to be made. So the Grouper logic based on I-9 is not going to make distinctions about things that the I-10 codes represent, that the I9 code don't. Our objective here is to create an I-10 Grouper that is a replica of the I-9 Grouper. We've replicated the I-9 logic. We're not trying to go beyond the I-9 logic. We're just trying to get a Grouper that gets as close as possible the same results for records that are coded in I-10. So our I-10 Grouper cannot make distinctions using these axis of classifications where I-9 was unable to make those distinctions.

So it really doesn't matter which the remaining I-10 codes we pick in that situation. It shouldn't matter for Grouping. It can't matter in terms of the information content of the record. So we use the multicolor technique to make those final choices and we try to use a technique that would across 11 million records generally bring up every possible situation where we'd have to make an arbitrary choice. That way if we did have problems in the I-10 Grouper logic or in the mapping, they would show up in the analysis. So how did you we do? What did we get? We have to look at the answers.

Liz McCullough: Or some of them. So what this slide does is just kind of summarizes the figure that Ron had presented earlier in the slide and again the focus of this was to study the impact of aggregate payments in the Medicare world using the MedPAR database. And we used the FY 2009 data. What's in red highlighted on the screen it's just a short way of describing each of the three different simulations. So when you hear me saying native I-9 we're talking about the ICD-9 data using the ICD-9 version of the MS-DRGs. Native ICD-10 when I say it quickly is referring to the MS data of the MS-DRGs under, defined by I-10, and with the data that was translated to ICD-10. Then the mapped ICD-9 to ICD-10 simulation is the third simulation but again takes the ICD-10 coded data and maps it back using the reimbursement map back to I-9 and then run through the MS-DRG Grouper that was defined by ICD-9- CM.

So as I mentioned we did use the FY 2009 MedPAR data. We calculated inlier and outlier payments for each of the claims on the MedPAR files. And the data in doing so for the payment impacts we looked at FY 2010 MedPAR, Medicare payment rules for calculating operating and capital payment. This included indirect medical education adjustments, disproportionate share, wage index, as well as a fixed loss outlier threshold of \$12,185 in your FY 2009 final rule. The hospitals included in the study were IPPS hospitals so any of the non IPPS hospitals were excluded, Critical access hospitals, long term care hospitals, all of those were excluded and any of those hospitals that had insufficient cost report information including if they were missing IME or DSH adjustments factors. So the final data set that we used for the impact study had 3,383 hospitals and just under 11 million Medicare discharge claims.

So what are the impacts? These results shown on this table are trying to get at the overall impact comparing not only the payment impact but the number of cases that changed in the MS-DRG assignment between these different Grouping methodologies. The top row focuses in on the comparing the native I-10 versus the native I-9 in the first set of percent difference columns. And you can see that the difference in the classification of the MS-DRG between those two systems is around 1.23 percent difference and that percent difference was also pretty consistent when you not only looked at an aggregate level you also looked at the different hospital provider type. Looking at IME, breaking out disproportionate share, their location and their size. A rural hospital has the smallest difference in the number of cases that changed their MS-DRG with 1.14 percent. And a hospital that had a very high IME adjustment top 10 percent they had the largest number of cases that had a change in MS-DRG representing 1.57 percent.

Now when you look at going from the mapped I-10 data back to I-9 and compare that to the original I-9 data, all grouped under the MS-DRG I-9 version, you definitely have a significant higher number of cases that had a change in the MS-DRG assignment of 3.23 percent. Again across the different hospital types the percentage difference was very similar was consistent, the, a rural hospital again has the smallest impact in percent change of cases that had a different MS-DRG of 2.51 percent. And those hospitals that were of the largest volume hospitals, the top 10 percent - they had the largest number of cases that had a change in the MS-DRG assignment. Again when you're mapping back the I-10 data back to I-9 and running it through the MS-DRG grouper compared to the original I-9 data runs through the I-9. So there are some changes and the reimbursement map used definitely has an impact on them.

Also you can see on the percent dip payment set of columns that when you're looking at native I-10 versus native I-9 simulations, at a very aggregate level there was a very small impact and a very small increase in overall payment of 0.05 percent. And again that was pretty consistent across the different hospital types with - there was a slight decrease in the rural hospitals with the 0.01 percent payment impact and with the highest, the high 10 percent of the hospital with the highest IME had a 0.19 percent increase in the overall

payment. But in general there's minimal impact on the aggregate hospital payments and across the board. However when you look at the mapped I-10 data back to I-9 and compare it to the original I-9 data grouped under the MS-DRG I-9 version, the increase, there is a larger increase in the difference in the payment and it's a natural decrease compared to the original payment under I-9. So it's a 0.38 percent decrease in payments.

And again that is fairly consistent when you're looking at it across the different hospital types that decrease. The smallest payment decrease was with the hospitals with the top 10 percent of IME. That has the largest IME with a decrease of 0.18 percent. However those hospitals that have the smallest amount of disproportionate share adjustment had the largest payment decrease of 0.51 percent. So it kind of just in looking at it - it's just kind of gets at there is a lot of consistency when you're looking at native I-9 to native I-10 however using the reimbursement map it does have, it does result in more cases being assigned to different MS-DRGs. And those assignments are going to different MS-DRGs. They have a biased or the lower paying MS-DRG i.e. the reason for the decrease in payment when you're mapping back.

So some mapping issues, one thing I wanted to highlight here was that when mapping ICD-10 data back to ICD-9 and then using the ICD-9 grouper there is a, it can produce greater impact on aggregate hospital payment as we've seen. And again this bias was toward lower paying MS-DRGs. And that was even true knowing that this data was MedPAR data. It was using a reimbursement map that was used and developed relying on Medicare data and inpatient data. So for the most part as closely applicable and tailored to that type of patient population as it could be. And it was still a bias and a larger percent increase in the differences in the MS-DRG assignments. So in looking back one needs to be cautious as your applying these reimbursement maps to, in getting back ICD-9 data. Also in keeping in mind that if you're applying that to a different type of system non Medicare, non inpatient, if you're looking at outpatient data you're looking at an all payer data set, or children's database. Something like that.

The results could have some unintended consequences so you have to understand that, be aware of it, think through that as you're doing it. We tried

to look at that. And we've used our All Patient Refined DRGs that are an inpatient Grouper but they are for the All Patient population and they have some more details - severity of illness logic built in and when we applied the same principles and again the all patient refined is only under I-9, we needed to convert the I-10 database back to I-9 and compare the results we got an even larger percent of cases that had a different APR-DRG assignment. So in part, we're using it for a different purpose than the reimbursement map was really intended for a different population base. And we got some additional, a larger increase in the number of cases who had difference in the assignment.

So we need to be careful and need to be cautious and using these types of maps could result in some less than consistent results than you would like to see. So, in conclusion as demonstrated by the MS-DRGs, the native I-10s version of the application does produce consistent results with the ICD-9 version of the application. And however you do want to be careful again using the maps, I-10 mapping I-10 data back to I-9 because it could be less than consistent results then one would like and also you want to be cautious of that when you're applying it to a system other than an inpatient Medicare system that it was more designed for. And also in looking at the needing to understand the impact of a reimbursement map where it selects one code. It's not a, it's not the GEM where you have lots of codes and then you pick one.

You're using one that picks one single code. That single code is being applied across all DRGs, so it's not tailored and when you have alternate decisions, when you're actually designing and recreating a new classification system under I-10 or something like that. You're going to be picking the best alternatives code that fits that DRG and you're going to do it on a DRG by DRG basis. When you're using the reimbursement map you're picking a single code and you're applying it across all the DRG's and that again could have some additional impact especially when you're using it across all different hospital system types, outpatient, beyond inpatient and other things. So just keep that in mind as you're using it.

One other point that we did want to follow up on and Ron sort did touch on this, was the issue of optimization versus replication. Again the goal of doing the I-10- the native I-10 MS-DRG group was to replicate the I-9 MS-DRG

Grouper. And we needed to do that. Because you don't have a large data set in I-10 to create relative weights that take advantage of all the ICD-10 data. So you're going to have to use for the time being the I-9 version, data that slips under I-9 to calculate a set of relative weights in a set of MS-DRG. So you really want the I-10 version to replicate the I-9 version. If one were to take and optimize the I-10 you could then start to have inconsistencies in that information.

Also, just also keeping in mind that when we did this project we knew that we would not be taking advantage of the additional specificity that I-10 does bring along because we were using a replicated MS-DRG Grouper based upon I-10 codes. Again they were replicated. So we felt comfortable taking the data set converting it to I-10 and using it for these purposes. We were looking at hospital over aggregate over 11 million records trying to understand the impact.

So for those types of purposes doing this kind of data conversion works for this project but it's not really possible to reliably convert an ICD-9-CM database to do an ICD-10 database that corresponds fully to ICD-10 because of the necessary information that's in ICD-10 and it's not necessarily in ICD-9 you have to make decisions. So I just caution you on that. A lot of that was examined during the study and you just want to, as you're moving forward - keep this in mind. Thank you.

OK, are there any questions?

Nelly Leon-Chisen: Nelly Leon-Chisen, American Hospital Association. Thank you for the study and thank you for showing how a map can be used and sort of the tricky things to consider. But I do have a question I wonder if you considered there are some sequencing differences between ICD-9 and ICD-10 data inherent in the classification. For example, Anemia in neoplastic disease where the ICD-9 guidelines tell us that if the patient is submitted strictly for treatment of the anemia, the anemia gets coded first as your principal and then the neoplasm gets coded; the malignancy gets coded second. But in ICD-10-CM there's a "Code first" note that would make you put the neoplasm first. And then there are all these examples like the adverse effects where today you put the

manifestation first and now you have the T codes that identify the substance and the intent and that needs to be coded first. And it doesn't from your description it doesn't sound like you considered that or am I wrong and then I'm sorry if you did consider that and I just didn't get it?

Ron Mills: The only place it would matter in the Grouper is in the definition of what's the principal diagnosis. If the first listed code, the principal would throw you into a different MDC. In the GEMs – in the GEMs where there is an I-10 cluster so an I-9 code mapped to multiple I-10 codes- the first code in the I-10 cluster has I think by the principles in which the GEMs were created, the code first code. So to the extent that the GEMs have that in their correctly we put that code first and that would have become the principal diagnosis.

Nelly Leon-Chisen: Except in today's world it would have been one code for the anemia in neoplastic disease, and a separate code for the neoplasm, so how would the GEMs translate it into a cluster to figure out which ones go first?

Ron Mills: Rhonda's shaking her head so I'm not going to go there.

Pat Brooks: I think some of these points you mentioned you have to consider the limitations of what we did in the study and we couldn't do what you asked - foresee the future and redo sequencing. So all of that minutia is not possible, but do you want to make a guess I bet...

Nelly Leon-Chisen: Yes, I was just wondering how far the project has gone.

Rhonda Butler: It would be something we can look into, to see if assuming that the record had been coded correctly in I-9 into switching it to see what the possible impact would be. I know exactly what you're talking about Nelly with poisoning codes.

Nelly Leon-Chisen: Right, right.

Rhonda Butler: And anemia and chronic disease and you're talking sequencing and you're talking a record based translation the GEMs cannot account for it. It's always code by code. You're looking at the source code and saying what's its meaning in the other system. So a study of this when you're talking about 11

million records, we could look at a couple trouble spots and just see what's the percentage of those records might be. In fact that might be an interesting follow up. Just to look at a few of those areas and see ok what's going on here.

Nelly Leon-Chisen: Right, you know I just want, I don't now that anybody has developed a list of exactly where the differences in sequencing are but some of these are more obvious if you kind of start playing with the codes that you also start seeing a code first note. And perhaps it could be narrowed down but I think it's an interesting topic for the future.

Pat Brooks: I think what we greatly appreciate now is that you did, you were so key in working on that data guidelines for ICD-10-CM. If you could jot down to us an email, maybe in the future other areas where you think you would warrant looking at them we could consider that and...

Nelly Leon-Chisen: OK, I do have a short list and I think some of the stuff is not necessarily a guideline issue. It's embedded in the classification in ICD-10-CM. Yes but I'll get the list.

Pat Brooks: Thank you for saying that. We'll take another?

John Shaw: John Shaw from Next Wave. Sort of a follow on to that issue and following up on the trouble spots. One of the things that we're concerned about is there's a lot of different payers around the country that use DRGs for payment. And I think you mentioned in the beginning some of them may be really looking at using the 10 mapped back to 9 and not changing any of their internal systems. And I think that's a real issue, concern and worry for people so doing that trouble spot analysis would be extremely useful.

Where are those differences? It edges out over the overall average but we have a big problem in cardiac that's offset by opposite problems in respiratory. We don't know that. Is it a big problem in medical in one direction and surgical in the other way. So looking at some of that by MDC, by Medical versus Surgical, where are the trouble spots that seem to exist so that we can be conscious of it and looking at the other uses of the data.

Pat Brooks: Thank you. Operator, would you check the phone lines to see if they have any questions or comments please?

Operator: If you would like to ask a question on the phone please press star and the number one on your telephone keypad. There are no questions from the phone. Thank you.

Pat Brooks: Thank you. Thank you for the 3M staff for that very interesting discussion. That I think helps all of us focus on the GEMs and use and ramifications of doing things in different ways. And that was the whole point of this exercise to help you think through these issues as we move toward implementation. We'll now move on to item four on the agenda and that is the MS version 28.0 of ICD-10 MS-DRGs. We have included in your handout a document titled Version 28.0 ICD-10 MS-DRGs update. And that begins on page 31 of the agenda and handouts. This document provides information on our plans to produce version 28.0 of the ICD-10 MS-DRGs and I have had several emails and calls on this point recently.

The initial test conversion of the MS-DRG included the definitions and the Appendices to the definition manual except for we did not include Appendix C, the CC exclusion list. And you'll notice from this slide that we, the project began, just in 2008. Seems like yesterday we did develop version 26.0 and that's on our website that the MS-DRG website and the whole point of this project was to evaluate the effectiveness of the GEM and how best to use the GEMs in converting applications from ICD-9. And we said and I still believe that that's a good test element. If you can do something as complicated as the MS-DRGs then it all would work a lot better on something more simpler. Simpler other lists.

We've discussed continually the progress of that ICD-10 conversion project of MS-DRGs at the meeting and you can find information on the website. In order to develop a working Grouper though and people ask us for that we needed to complete conversion of the CC exclusion logic and this was done in early 2010. In addition we developed an interim conversion to the version 27.0 of MS-DRGs which Ron mentioned earlier. The next step of our ICD-10 MS-DRG conversion project involves two major initiatives.

One is developing ICD-10 MS-DRG Grouping software, and the other is updating the ICD-10 MS-DRG to Version 28.0. Based on internal review on comments we did make several changes while we were doing the preliminary ICD-10 MS-DRG Grouping software. Some logic changes were necessary to enable completion of the ICD-10 MS-DRG Grouper that met CMS' data goal of developing an ICD-10 MS-DRG Grouper that produces the same or very similar results of the ICD-9-CM MS-DRG Grouper. And some of those logics have included developing two new lists, one of those I think we just mentioned earlier.

A list of principal diagnoses that is its own MCC. Or a principal diagnosis that is its own CC. So now when you have a code that combines those two concepts, our current MS-DRG logic gives hospitals credit for a higher severity level. So we worked out those issues. We also worked on areas where multiple ICD-10-PCS codes are needed to capture a procedure. Those are called clusters. ICD-10 clusters. So we've worked those into the DRG logic. And I show on this handout and there's a lot more in the paper I mentioned of examples where clusters are need to get to the right DRG. Things such as neurostimulators, defibrillators, kidney/ pancreas transplants and others that we list in the paper.

An ICD-10-PCS delivery code was also listed helps get the correct assignment of obstetric records indicating vaginal delivery to MS-DRGs 774 and 775. So the process we used to update the ICD-10 MS-DRG Version 26 to 27 will be used to update the ICD-10 MS-DRG Version 28.0. And the process will be as follows. The 2011 version to the GEMs will be used to translate the approximately 800 ICD-9 code lists that are included in the MS-DRGs to comparable lists in ICD-10 codes. They will do initial tests to ensure that all the ICD-9 , all the ICD-10 codes are assigned to an MDC and also the ICD-10- PCS codes are represented in the logic. Then a draft converted list will be analyzed for issues such as list assignment conflicts or any needed ICD-10- PCS clusters and all issues will be resolved. Then the converted list will have, will step back and look at the Version 28.0 looks like a reasonable proximity of any clinical issues.

Here's the timeline we're operating from now and you see as usual we're quite optimistic and we move fast. August 2010 you all found out about our final decision on Version 28.0 of the ICD-9-CM MS-DRGs. They finished that before we can move forward. In October 2010 we will post the 2011 update of ICD-10-PCS. On our website many of you have noticed that we already have that slot open to post them. In January 2011 we will post the 2011 update of ICD-10-CM diagnosis and we will also post the diagnosis and procedure GEMs giving us time to get your input till November 12. We'll also this – and Liz didn't mention it but we'll also be posting the reimbursement GEMs for 2011, reimbursement GEMs at that same time.

In February 2011, we'll post Version 28.0 of the ICD-10 MS-DRGs Definitions Manual so that you can review it and see if you have issues and we'll get your feed back, and then the most exciting point is that we hope that in March 2011 to have a version 28.0 ICD-10 grouper that NTIS can distribute so some – oh, you're happy - so that if you just want to basically play with the codes quickly and see how they impact and if that will help you decide how it's working then we're very happy to do that. So that's our plan. Now does anybody here have any questions or comments about this little project to get a version 28.0 of the ICD-10 MS-DRG and if so could you come to the microphone.

Nelly Leon-Chisen: Nelly Leon-chisen, American Hospital Association. Thank you – thank you very much for working on this and getting a Grouper out early. Rather than waiting until we actually have to implement ICD-10 because some of our larger hospitals specially have been asking when are we going to get something so that they can model it and see what the financial implications will be so thank you very much.

Pat Brooks: Thank you. Any other comments from the floor here? Operator will you see if there are any comments or questions from the telephone lines.

Operator: Again if you have a comment or a question please press star then the number one from your telephone key pad and we'll pause for just a moment to compile the roster. You have a question from Julie Steiner from Ingenix consulting, your line is open.

Julie Steiner: Hi, I was wondering if you were going to be reviewing your list for CC status and MCC status for I-10. Not to take us back to feet and ankles too much but a coding question is the way you look at 711.17 and the right and left ankle in I-10 is an MCC but then you go to an unspecified ankle M02379 and that's listed with the status CC which is kind of different from how DRGs work in an I-9 usually the NOS is a lower CC status. I was wondering if those are going to be reviewed for the version 28.

Pat Brooks: Yes, thank you for that comment and I should probably point out once again that you raised a good question that when we go to our final MS-DRG logic we will be doing a formal IPPS proposed rule where we'll list out all these final decisions on something to be an MCC or CC, or what DRG assignment they will go to, so all of that will be subject to public comment. We have that this is a big and large project that we would start putting these things out to you early and if you identify based on your review of files on our website or perhaps information with the software – the NTIS software when it's available that you question some of the DRG logic or MCC or CC we would love to have you send us an email to consider that and we will keep this a work in progress and we appreciate those excellent points and details so will make a list.

We'll use all that as we refine the software and have people really comfortable with the conversion project and I believe you have to say that we have been quite open in this whole process about how we are converting it and the impact to taking your suggestions. We'll take all of this work over the next few years and then the IPPS rule for FY 2014 we will actually have proposed final DRG logic and CC and MCC and what's lower and what's not, so you have raised an excellent point that we would like to have feed back on and if you would please send me those suggestions in an email to Pat Brooks we would greatly appreciate, thank you.

Julie Steiner: Thank you.

Pat Brooks: Next phone comment.

Operator: There are no further questions from the phones.

Pat Brooks: Thank you we do have one other comment from the floor. Can you state your name first?

Dr. Ross-Davis: Hi, I'm Dr. Ross-Davis from HCSC and this question may reveal my basic ignorance but, when you did the study on the DRGs you did a translation using a reimbursement map and I'm wondering what the difference would be if the payees or the people who are submitting the claims are using the two GEMs to translate from I-9 to I-10 and then dealing with the potential confusion of number one combination code where in their minds both of those codes are the primary diagnosis when they are pressing for the system and if there will be any instructions on what to do in that case to pick one of those codes and how you identify they picked the wrong one of those codes and are you going to model the potential impact because with the reimbursement one to one and 3.23 percent change plus just re-imbursement which is one to one I would guesstimate that it's going to be worse with the GEM.

Pat Brooks: All right, I'm going to ask Ron and Liz to come up and comment but let me make one other comment to you and that's the point was brought up several times in the morning. This was a modeling exercise to try to predict the future and see using GEMs versus Mapping, back use and reimbursement what is our first initial gut reaction of how it would work and some one, I think it was John Shaw mentioned earlier, a concern that some people might have is payers may simply want to rely on just the reimbursement map and forget modeling their current payment system using ICD-10 and we have provided you information based on the way we approached it, there could be other ways that one could look at it and one might think, "I want to be cautious about simply getting ICD-10 codes and use a reimbursement mapping back and then making payment decisions." I think ours shows that there's a difference.

We anticipate going live and particularly for IPPS for MS-DRGs the people are not going to be using GEMs and they are not going to be using reimbursement maps, they're going to do just what several people have pointed out, they are going to be coding from the exact record, they are going to be using the code books and they are going to have very precise good codes. We can't do anything but simulate that now, unfortunately. We can't

go out and recode a couple of million records and try to do better, so what we have tried to do in this early stage, and I think it's explained in more detail in the paper is our attempt of modeling these two approaches of the GEMs and reimbursement mapping. Did that answer your question?

Dr. Ross-Davis: Yes, except I'm talking more about those providers you are trying to insulate their systems to maintain an I-9 and then translate and send an I-10 or those payers who are doing the same thing.

Pat Brooks: Maybe what you are asking is that you are asking me if I would advise people to use the GEMs or reimbursement. OK, good, I can answer that very easily. Use the GEM. The GEMs we're developed as the greatest tool and they require some analysis as several people had pointed out but there's a lot of information in choices and they are great.

The reimbursement was designed as a supplemental tool that we are not necessary – maybe no one will use it - but it's just a tool that gives you a simplistic approach that if you have ICD-9- the ICD –10 codes come in that you can map back to a close enough for payment ICD-9 codes. Do we suggest that everybody use it – I think you can see from the data we showed that no we don't necessarily suggest that at all and that's why we believe the gold standard as a conversion map is the GEM. And does that answer your question?

Dr. Ross-Davis: And do we have any concept of the financial impact in the ambiguity they incur with the use of the GEMs when you map.

Pat Brooks: Well we showed you our early feedback based on an inpatient analysis and I think Liz did an excellent job of saying the reimbursement mapping – we didn't go into all this today but we had prior meetings - that the reimbursement mappings were developed based on longitudinal data from in patient Medicare and if one used it for – like a national series of children's hospitals, we are the first ones to admit that our reimbursement mapping was not based on children's hospitals so we have consistently used caveats of what the reimbursement maps are and what they are based on and I have concerns

about simply using those and ignoring the GEM - the gold standard of the GEM.

Dr. Ross-Davis: Thank you.

Pat Brooks: Thank you. Well thank you for these comments today and I know some – particularly the last issue was complex and I think we'll be getting feed back from you later about approaches and maybe issues to think about in the future. We'll be happy to do that and reminding you once more that final decisions are not what was shown on the board today or posted on our website, they will go through formal rule making on what MS-DRG provide. So we'll move to item five on our agenda which is the ICD-10-PCS update and Rhonda Butler and I will be covering this. We have a document in your handouts called ICD-10-PCS FY 2011 update and it begins on page 33 of the agenda and hand out.

This is a document that summarizes some of the big changes in PCS that we are planning to make this year. Obviously it just gives you a flavor for those. And one thing I'll mention is that the number of codes changed – codes change every year, people seem surprised at that, but they do change because if we create new ICD-9- CM codes, procedure codes, which we did for October 1, then we have to add those in parallel to ICD-10-PCS. If we delete things with ICD-9 or make revisions or whatever that also affects our ICD-10-PCS and we look at internal consistency from the excellent comments all of you send us.

Bottom line, in 2010 we had 71,957 codes, in 2011 we will have 72,131 and that's because we added 496 new codes, we revised 241 and we deleted 232. We also did a project we are quite proud of, the cooperating parties got together and went through the ICD-10-PCS guidelines that was the most part imbedded in some of those other documents and some of you made a suggestion that it would be nice to pull those out and have a light load document and just flush them out.

We have done that and thank you, I know Donna and I would like to thank Nelly and Sue from the AHA and AHIMA for all their hard work on that. So

we did develop the ICD-10-PCS guidelines and they have been posted on our website, ICD-10-PCS website since June 2010. Those of you who have not seen them then I would urge you to look at the ICD-10-PCS page and look at the 2011 update where you will find the coding guidelines. If you have concerns or issues with them then great, then we would like you to review them and send us a comment that say maybe next year when you update you can be a little more clear than these words or you have missed a whole issue that's bothering me.

Some of the best suggestions we got were from the national train the trainer sessions that AHIMA has been holding because it's really only when you start going through records and discuss things in public that you realize areas that aren't really clear and confusing so I know if you want to send those through Sue I think you are members that you know areas of confusion then Sue will bring them to us and tell us that we need to work a little harder on this particular area or not. But do review those. Also included in 2011 update will be a reference manual that we will include as appendix C. We are always trying to get good tools to help you. Now I'm going to ask Rhonda Butler to come up here and she is going to give you a flavor of some of the changes that will be happening in the 2011 update.

Rhonda Butler: Thanks Pat. Apologies to those of you on the phone. This is one of those slide presentations that can't be posted because there is no hope of making these marked up tables compliant to meet the compliance standards so what I'm going to do is try and talk you through some of the examples of new PCS codes that were created in parallel with new I-9 codes this year and, hopefully it will give you a flavor of how when we all have to go through this process together, how you translate the concept of what you want in new code, where you are going to fit this in this new table structure that is becoming more familiar to a lot of you, thank heaven. A lot of you out there are becoming fellow PCS geeks and I welcome that. So we had a new ICD-9 code for reverse total shoulder replacement.

So the shoulder replacement means that they are reversing the action of the joint and they are putting the ball on the shoulder part rather than the humerus part and so we have created three new PCS qualifiers and six new PCS codes.

In addition a public request came in to specify additional details for partial shoulder joint replacement. Previously we only had that amount of detail in the hip joint replacement codes, so in the new PCS table that will be coming out and be posted in October, you will notice in the qualifier section of this table we have three new qualifiers that specify that amount of information whether it's a reverse ball in socket replacement, that's specifying the type of device that's a partial shoulder replacement it's going to tell you did they replace only the humeral surface of the joint or did they replace the glenoid surface only of the joint. So that will tell you which side of the joint that they worked on in replacing it.

The spinal fusion we have a lot of activity in the spinal fusion codes every year it seems and this year the lateral transverse process language in ICD-9 changed such that we decided to delete – we can still delete things in PCS if nobody is using this for transactions and it's still a code set under development after 2013 we'll have to be a bit more careful about that kind of thing.

But we also had a public request to simplify the interbody fusion devices in PCS, it was getting pretty hairy and a lot of people what we notice is that fusion often used several modalities to accomplish its spinal fusion so having all that detail in several codes gives the impression that many more procedures were performed than in fact were. So we are handling those combination types of modalities in guidelines rather than having all this profusion of details in the PCS codes, and so here's what it looks like in the PCS table.

This is a mock up in the PCS table I tried to do the underline and cross out thing but I haven't had as much practice in that thank heavens, PCS addenda are all automated and so those of you who want to look at the exact correct version of the addenda, you will see those posted on the website in October but I can already – after looking at this 28 times I can see an extra word in there that's a copy and pasted there but errors just happen when you are mocking these up by hand.

But basically what the changes are for those of you on the phone in the device column we are stream lining the number of explicit device codes, we are just having a single device that says it's an interbody fusion device. And so we are

getting rid of all that detail that's interbody internal fixation and interbody tissue substitute for graft or whatever, so if it's an interbody fusion device it just goes to device value three. And then in the qualifier column we are deleting this lateral transverse process approach, people found that non helpful and so we are deactivating that we are decommissioning that before people have to use it and get confused by it.

More new codes, there was a new ICD-9-CM code for cranial implantation, neurostimulator pulse generator so it's something that is implanted directly in the skull bone and so we had to add a specific device to the body part skull so there is a new element in axis six- in the sixth character, this PCS table for insertion of a neurostimulator generator directly in the skull. There was a new ICD-9 code – Central venous catheter replacement with guidance, 38.97. Now the I-9 is very fond of these includes notes, it makes one code you know a little code goes a long way in ICD-9 and we can't do that in PCS, we don't hang little note bubbles all off the table, they become unusable very soon. So this is what we had to do to replicate that amount of information to be able to capture that in PCS.

The other thing we can't do is munch together something that says, "Oh by the way we are doing an imaging procedure here" and put it in with a table that's about insertion of a device. So in PCS it will take two codes to capture this information but in the long run, the shelf life of PCS is extended because what we are adding is the functionality to capture guidance for any procedure, imaging guidance.

So what we have, for those of you on the phone, there's going to be a new qualifier in certain imaging tables and we can expand this as needed as more people see we want to capture this when the procedure is done with imaging guidance but for now we are just doing it to capture what was requested in ICD-9. So there will be a qualifier that says 'guidance' in select imaging tables, for example – the example on the slide here is imaging guidance using the modality of an EKG, so in other words – oh sorry not imaging but an EKG used for guidance of placing a device.

We also have two other tables where it has been added- in fluoroscopy, so imaging guiding for placing a device in the veins and in ultrasound guidance, for placing a device in the veins as well. And like I said that you can see for PCS the flexibility in the long range keeping of those things classified where they belong, we can hopefully live with PCS for the time that we need it and not end up in a situation that we're in with I-9 where you have got surgical codes in the eye body system that pertain to the heart or whatever. We don't want to start making it so that you can't find what you need and the data turns to mud real soon.

All right, another new ICD-9- CM code was 85.55 and 86.87 both fat graft codes. Fat graft to breast and fat graft to skin and subcutaneous tissue, and this is pretty easy to explain. This is how we handle it in PCS in the table called Replacement, the root operation is Replacement for the skin and breast, you are replacing tissue that was removed surgically and we add a new qualifier to characterize the type of autologous tissue that was used to replace this example is from the breast and there would be another, for 86.87 there would be commencing changes in the skin and subcutaneous tissue body system which would be table ORJ for those of you who are taking serious notes.

All right, there is another new ICD-9-CM code 84.94, Insertion of sternal fixation with rigid plates, and remember these are just examples this is not exhaustive, it's just meant to give you an idea of the kind of things that we do when we have new ICD-9 code updates and we say OK, where should these go in PCS. So rigid plate fixation, we are putting them in Insertion, for the body part sternal there will be a new qualifier that says rigid plate and I believe, off the top of my head, I don't like to do this since this is being recorded but I think it's also been added to the table OPS which is Reposition, so when you are using it to fix a traumatic fracture as opposed to just secure up the sternum itself post surgery or whatever you are doing.

Other changes in response to public comment, there was an area in the administration section, the root operation was called introduction, just think of it as the place you put in injections and fusions that kind of thing where you are applying something to a body part, adhesion barrier substance those kinds of

things. The codes for application of recombinant bone morphogenetic protein we were missing – they were not applied to the joints body part and that's one of the areas it's commonly used in spinal fusion for example. And so we added that. We also added the approach "Open" so we made that row of the table more complete for what's being done in the real world.

Other changes in response to public comment, there were changes to the reference manuals, this is also in line with discussion with the cooperating parties - having to do with PCS guidelines and Endarterectomy, there was some confusion over whether this should really be construed as an Excision procedure or as an Extirpation. It was decided that it would be more accurately characterized as extirpation because you are taking out the calcified gunk and you are really trying to get out what is essentially a foreign body out of that artery so there is a new coding note there to alert people that that is how we expect it to be correctly coded.

New coding examples for diagnostic heart catheterization, a coding note just to reassure coders who have spent their whole working careers in the I-9 world that we don't have separate codes for anastomotic technique and the real common example of this is when you are doing something in the intestines and there are separate ICD-9 codes when they do it side to side and anastomoses, or side to end or whatever. Just to let people know that that is not separately coded in PCS. So that's what the note says. There were some corrections to the device value example.

In updating the book they had – when new more specific values had been added, those examples had not been correctly updated so those were fixed. Also index requests- added a few additional index entries for cardiac ventriculogram, we are told that the gold standard is always to use fluoroscopy so the reference table in the index has been changed. Endarterectomy I mentioned earlier, new index entries for PCS codes. And also in response to request for changes to the PDF table navigation.

We have expanded the link to the third character level so you can allow direct – I am getting some silent applause here which is great, yes- you can get access directly to individual PCS root operation tables now through the links

in there. These two slides just mock out the navigation there, you just go section, body system and root operation and then you are able to go directly to the table 027.

This last slide just shows the resources the update is going to be posted by October 1. Note that there is a typo on there, in the order I need to switch, in fact as Pat mentioned earlier, both the GEMs and the reimbursement mapping will be posted, not on October 1 but at the end of the year annual update in concert with all the other stuff that's going on the ACA provision so that we wait till the extended comment period and make all those changes so we have one more update at the end of the year rather than two. And that's what I have and if you have any questions or comments I'm happy to take them.

Kathy Myrick: Kathy Myrick, QuadraMed Corporation. Are we going to have a list for the PCS and the CM in short descriptions any time soon?

Pat Brooks: We are working on that right now and we have to resolve it before we have the Grouper finished in March 2011. So we are working on those abbreviated titles and what the length might be, some thought we have, maybe 60 is a good limit - where is Janice Bonazelli? Sixty might be right but it might be different. Once we have finished going through and making sure what is practical and what works best we will do it so yes we will post those tables once we have abbreviated titles.

Linda Holtzman: Linda Holtzman, very simple question, I did pick up the PCS new guidelines from CMS' website. I did not see the reference manual. Is that where I'm supposed to get it, did I miss it or when is it coming out?

Pat Brooks: That's going to be part of the October 2011 posting. I'm sorry if we were not clear about that, so when you look in October, we will have a bunch of files there, updates to PCS and the reference manuals and all that. The only 2011 thing ready so far is the guidelines.

Linda Holtzman: OK. Thanks. And I just want to comment also I think that the examples that you showed of the changes that were made were beautiful. Thank you.

Pat Brooks: Thank you very much. Now we will open up the phone lines, is there anybody who has a question or comment on the phone lines on the 2011 ICD and PCS updates?

Operator: Again, if you would like to ask a question from the phone line, please press star then the number one on your telephone key pad. We will pause for a moment to compile the Q&A roster. If there are no – oh I'm sorry, you have a question from Florence Riley from United Health Care, your line is open.

Florence Riley: Good morning, it would be very helpful when you are referencing slides to let us know what page in the agenda that you are referring to as we are trying to follow on the phone.

Pat Brooks: Yes and I apologize to those on the phone that you do not have copies of our posted slides. All that information including the one we just had in the posted slide was in the papers and when I announced in the beginning what page of the hand out they were, we tried to take the examples for the power point slides from your handouts and I apologize that we didn't write down the page number in your hand out. That's the problem I guess in participating by phone lines, it is difficult to make everything visible to you.

Florence Riley: Thank you.

Pat Brooks: Well, we'll conclude that section because we need now to move to Donna Pickett's section where she is going to give us an update on ICD-10-CM for 2011.

Donna Pickett: OK, for those of you who are on the phone, the page is 36 but I am just doing slides based on what is on page 36. For the 2011 update for ICD-10-CM obviously we will be making changes based on the October 1, 2010 ICD-9-CM changes as we normally do, and there are a good number of the ICD-9-CM changes for 2010 that actually were not already represented in ICD-10-CM so you will see those changes.

Additionally, and many of you may not know this when we update ICD-10-CM we also update it to include the revisions that have been made by the World Health Organization to the WHO ICD-10. They also have a parallel

updating process so as they update and create new codes and also make modifications we also move those changes where appropriate into ICD-10-CM. Fortunately this year we don't have a number of new codes coming over from WHO and some of the changes that they did approve for October 2009 actually included some new codes that were based on things that were already in ICD-10-CM so we are fortunate in that regard that we did not get a huge body of work.

Other changes for ICD-10-CM update includes revisions to instructional notes and descriptors for consistency and standardization of codetitles and some of those suggestions were actually submitted by several of you some who may be in the audience or on the telephone. The standardization of the code titles will be basically an on-going endeavor. We couldn't do everything given the number of codes but we did start with modifications to codes related to laterality and to the .8 "other", but again these will be on-going modifications and thanks all of you who submitted recommendations for changes.

And also for industry feed back, I would like to thank, as Pat did, AHIMA for bringing forward a number of very helpful suggestions that have come through the academy, so that has been very helpful. And we have received a lot of input from others in the audience and though we usually don't necessarily indicate a particular person, the one who has been very prolific and that I would like to acknowledge is Kathy Myrick. Thank you, Kathy. Your eye for detail has been excellent as has Linda Holtzman's. I have a body of work to prove how much time they have been devoting to this so again thank you both.

So what we will be posting in January or perhaps a little bit sooner, will be updated files and these will be for the tabular list, the alphabetical index for diseases and injuries, updates to the table of neoplasms and the table of drugs and chemicals, also updates to the external causes injury index, cooperating parties will be working on updates to the ICD-10-CM guidelines, again we have received a lot of input and feedback from a number of folks who have already looked at this in some detail and some of them have been approaching me at some of the meetings and I ask that when you do that please remember to send an email so that we make sure that we are capturing everything that is

of concern to you. I won't go into the updates on the General Equivalence Maps because I think we have covered that quite keenly in previous discussion.

And again, for those who had – were going to make comments about the GEMs but also had some possible recommendations for updates to 10-CM, we would welcome those and we would just ask, would you please separate them to make it easier to identify which things are GEMs and which things really relate to ICD-10-CM itself so that we can possibly bring those forward to future meetings of the Coordination and Maintenance Committee.

A couple of other things, and let me just go back to this slide if I – I can thank you, Charlie. One of the things that I – several things that I did not include in terms of what we will be posting related to ICD-10-CM updates, in addition to the PDF file for ICD-10-CM that you've all seen, we will – we are planning to post machine readable files in XML. We've gotten a lot of calls and emails about, I see the heads nodding, OK.

We've gotten a lot of calls requesting other formats because I know PDF is quite difficult to work with for some, if not almost impossible. So we will be bringing those files for our work for this year. The long descriptions – obviously, Pat has just covered information about the short descriptors but the full code title files will also be available on the Website and we'll be updating the user guide for the GEMs as appropriate based on any changes that we make to the GEM files this year.

And then working with Rhonda, we've also identified that – maybe some additional language that we can include to help make it easier for people to understand the use of the GEMs and maybe some enhancements to specifically identify anything that you think is lacking or not well defined within the user guide.

And for tomorrow, and this is kind of like, please come back tomorrow, there has been a lot of comments made about some other changes that industry would like to see in ICD-10-CM. And for those of you who have gone up on the Website and seen our topic package, I think you have noticed that there

are a number of ICD-10-CM related proposals that will be discussed for tomorrow. Those proposals will not be part of the 2011 update but will be looked at toward the October 1, 2011 update.

So, again, please come back or if you're not able to attend tomorrow, please go back to the Website, look at the proposals and give us your comments in writing. And some other things that we're also noted for change and again, just so you all didn't think that we thought question marks were appropriate ways of denoting things in the classification. We actually had some gremlins creep in, special characters were somehow interestingly displayed with question marks.

So, you'll see that there will be a lot of error corrections in that way and typos and such. So, we're very happy to have had all the comments that we've received come to us and we encourage you to continue to provide us your comments so that we can make the classification the best that it can be. And with that, I don't have any additional information so from the floor if there are any questions, I'd be pleased to take the questions.

Dr. David Freedman: Thanks, Donna. David Freedman again, with the American Podiatric Medical Association, quick question. If we provide this information that I reviewed earlier and it does not show up going forward and we still have concerns that there are issues with what's being printed in the – an online file, how do we then again, re-bring the same issue again if we think that they're being overlooked or could we address that, is this all to you?

Donna Pickett: Yes, you would address that to me. And again, it appears that you've already got a large body of work, the sooner that you can get that to us the better, clearly, it can't be presented tomorrow but the deadline for proposals for the March 2011 meeting, is in January so if you could find the time to incorporate all of that and send it to us, that would be great. It would also allow us time to actually be back in touch with you if we had questions.

Dr. David Freedman: OK, thank you.

Donna Pickett: OK, one more question or possibly two.

Kathy Myrick: Kathy Myrick, wearing the other hat as instructor San Diego Mesa Community College, I see that we're now moving things on to a fiscal year for updates. So, for our students are getting ready to have books for them, when you say it's available for October 1, 2011, will that be out to the publishers like we have it in June this year for the addenda or are we still trying to cycle in to that?

Donna Pickett: I think there's still room for discussion there but Kathy, I would love to hear what your thoughts are about that, I mean if you're prepared to make them now, that would be good but don't want to put you on the spot. So if you wanted to send us something in writing ...

Kathy Myrick: Yes, I'll send some in writing, thanks.

Donna Pickett: OK.

Stephanie Stinchcomb: Stephanie Stinchcomb, American Urological Association. I know we talked about the GEMs all morning and you're asking for input from us and since it's up there, I figure I would say a little – from what I've seen – all I see are the codes themselves, is there any way, and I don't know how difficult it would be to put a short descriptor with those so it would make it easier for us instead of having to go back and forth between the books?

Donna Pickett: I am – OK. Stephanie, I'm not sure I'm understanding it.

Stephanie Stinchcomb: For the GEMs that you're talking about having short descriptors as part of, OK.

Pat Brooks: The GEMs files that we posted the logic and we also, both of us agencies post separate full titles and we will be posting separately abbreviated titles. We in HHS aren't in the business of making tools for you to use, now you can obviously merge those yourself but we hear what you say but I don't know that we will be making various versions for you to add as a stand-alone user tool.

Probably the thing you're talking about is what some vendors apply this to make something more user friendly and they do that with Groupers and

Encoders or whatever, they should do that. What we do, is we come up with the final GEM logic and code titles and so we don't have a plan to modify that to make it more of an advanced tool for you to use.

Stephanie Stinchcomb: All right, thank you.

Donna Pickett: If there are no other questions on the floor, moderator, could you open up the phone lines for questions?

Operator: If you would like to ask a question from the phone, please press star then the number one on your telephone keypad. And we'll pause for just a moment to compile the roster. Your first question comes from the line of Pat King from the South Carolina Department of Mental Health, your line is open.

Pat King: Thank you for taking my call. What I was going to ask about is the DSM-4-TR codes that we use, is there – there's not – is there a mapping available using those codes or do we have to rebuild with ICD-9 but we still use the DSM-4 codes?

Donna Pickett: I'm not aware that anyone is doing a mapping between DSM-4 and ICD-10-CM but there is someone in the audience who may be able to help with that question and then Dr. Darrel Regier over here from the American Psychiatric Association, and he is moving to the microphone.

Pat King: Thank you.

Dr. Darrel Regier: Hi, it's Darrel over here from the APA. As you know, we are currently working on the DSM-5 and I've been in touch with Donna about actually trying to anticipate the DSM-5 changes in time for the ICD-10-CM and we've been working with the WHO Department of Mental Health and Substance Abuse that is also working on the ICD-11. So, we will have something ready to propose to Donna that would be coming in, probably in November at the earliest and certainly in January for any particular changes.

Now, in terms of a coding – kind of a crosswalk between the current DSM-4 and the ICD-10-CM, the ICD-10-CM essentially incorporates the DSM-4 names and already has in it the, I would say probably 99 percent of the

translations that would be appropriate. We actually published an international version of the DSM-4 back in the early 1990s when ICD-10 was available, so that international colleagues could use the definitions and the DSM and apply them to the ICD-10.

So the crosswalk has essentially been ready since the early 1990s for the major codes and in the current ICD-10. Our hope is as I said, that we would be able to actually make a modification to that current ICD-10 for the ICD-10-CM implementation which takes place in October 1 2013, about four months after the May 2013 release of the IC – excuse me, DSM-5.

Donna Pickett: Thank you Dr. Regier. Were there any other questions online?

Operator: There are no further questions from the phone.

Donna Pickett: There is one more question, Dr. Friedman.

Dr. David Friedman: Thank you. I got a text from my association. They want to know why we're going to ICD-10 and not going to ICD-11?

Donna Pickett: That's always a fun question. OK, I see the – well, let me give you a little background on how ICD-10-CM is developed and how that would relate to an ICD-11. WHO (World Health Organization) in the past has released their published version of the ICD, after which it is evaluated by different member states including the U.S. to see if that version is actually detailed enough for what each country uses it for.

So for ICD-10, when it was released by WHO, we had a roughly two-year evaluation of ICD-10 to determine whether or not ICD-10 as published by WHO, would actually work for us here in the U.S. for all of the reasons we currently use it and no, it didn't. And so we spent obviously, a number of years working on modifications to ICD-10-CM to make it useful for use in the U.S. A similar process would have to be followed for ICD-11.

And while I know they're looking to make it more expansive, at its core, it's still primarily a mortality based classification which doesn't work for all of the morbidity applications that we would need here in the U.S. for

administrative financial transactions, quality benchmarking, statistical purposes, NCHS is a statistical agency. So the number of purposes that a clinical modification would be used for in the U.S., ICD-11 would have to be evaluated for that as well.

Now, the current timetable I believe, for ICD-11 is 2014 to the World Health Assembly, which basically means it wouldn't roll out for another two years after that. If you were to wait and try to continue to use a very flawed ICD-9-CM in anticipation of an ICD-11, which still might need clinical modifications, say here in the U.S., I can stand here and tell you that there is nothing that I could continue to do to ICD-9-CM to make it useful for all the purposes that it's currently used for.

But we will be guided by what WHO is doing, the U.S. does participate in that work, the North American Collaborating Center for ICD and ICF is housed at NCHS. So we will be working closely with WHO in the formation of what is in ICD-11, but will also give us a benefit of seeing what may be going into ICD-11 that could find its way into ICD-10-CM simultaneously. Were there any other questions? OK, well I'm going to turn the podium back over to Pat.

Pat Brooks: Well, you've done well. We've completed our ICD-10 part this morning and since we do have the phone lines for another half hour, we're actually going to move to our first ICD-9-CM topic. And so before we do that, I would like to introduce a new member of our staff, it's Celeste Beauregard would you please stand up? We're really pleased -because we feel like we're overworked- to have Celeste to join our group.

She's going to be doing coding and DRG issues and in addition, she's going to be the lead analyst on our staff for hospital acquired conditions. So those of you who have a chance during the meeting, might want to step up and meet Celeste during the break. OK, so we're now going to invite Amy Gruber to come to the podium and she's going to be discussing implantable hemodynamic monitoring system.

Amy Gruber: This issue can be found on page 38 of your handout. The issue is: Effective October 1, 2006 two new procedure codes were created to identify the intra-

cardiac hemodynamic monitoring system. Code 00.56, Insertion or replacement of implantable pressure sensor, (lead) in parentheses for intra-cardiac or great vessel hemodynamic monitoring, and code 00.57, Implantation or replacement of a subcutaneous device for intracardiac or great vessel hemodynamic monitoring.

These codes identify the two components of the system that are implantable. The insertion of the sensor and the implantation of the monitor subcutaneously. Effective October 1, 2009 the terms “or great vessel” were added to the code titles to include other sites where the sensor may be inserted. Newer systems are being developed where one component in the system is implantable, only the sensor is implanted into a great vessel.

An external monitor is used to communicate wirelessly with the sensor. The question before you: Should new codes to be created to distinguish between these monitoring systems. There will be a new tech application for this system and the requester is requesting an October 2011 implementation date if approved. Here to provide us with a clinical presentation about the system is Dr. Jay Yadav, who is the CEO of CardioMEMS. Dr. Yadav.

Dr. Jay Yadav: Thank you Amy, I appreciate getting squeezed in before lunch time. A lot of people left, it's really not going to be that boring, I'm going to try to make it interesting. And I'll go fairly fast so you can all get to lunch. Most of my talk will really be focused on the clinical trial that we completed this year with some very exciting results. I'll give you some background on heart failure also and the nature of our technology.

So CardioMEMS has been around since 2001. It's based in Atlanta on the Georgia Tech Campus. The fundamental technology comes from Georgia Tech and MIT and the basic size was funded by the Department of Defense for creating a new type of wireless sensing technology for the inside of jet engines. It turns out that in that location in that temperature and pressure, you really can't use traditional sensors or wire connections.

And I found that interesting. I'm a cardiologist but I found that very interesting cause we would really like to be able to put things like that in a

human body also that don't require us to put in leads and other things which we know we have issues with over time. So that submitted very interesting for us and we're able to license that technology from Georgia and MIT and then use that as a foundation for CardioMEMS.

I think most of you are familiar with the nature of heart failure and the scope of the problem, it really is a large problem. About six million people in the U.S. with heart failure, about 700,000 new cases each year, over a million hospitalizations and it's very expensive also. The total cost is about 40 billion. Hospitalizations by themselves, are about 20 billion. So it's really a big public health clinical problem.

And heart failure hospitalizations is where you're at the center of it from the clinical perspective but I noticed back in – around 1998, 2000 when I started thinking about this, was seeing more and more of my patients in the hospital, more and more frequently for a heart failure. And they'd end up in the CCU – in the ICU and this was just recurring, it was very traumatic for the patient, it was very burdensome for our hospital also.

So how do you go about reducing heart failure hospitalization? This clearly people have thought about this for quite a while and a lot of work has been done on this. And there are many different approaches, certainly increased clinical management using call centers, calling patients, intensifying the interaction with nurses and doctors. That can work, it tends to be rather intensive, labor intensive and as you know, we have a nursing shortage already. So, it's not been feasible to apply that broadly and it's not clear if it's cost effective.

Other means, such as measuring impedance in the skin or BNP have not been shown in randomized trials to reduce heart failure hospitalizations. What I came back to – was the right heart catheterizations that we do, so if you get sick with heart failure and you're in the hospital, we will very frequently do what's called a right heart catheterization or Swan-Ganz catheter after Doctors Swan and Ganz, which is the catheter which goes into the heart in the pulmonary artery and measures the pressure and cardiac output in the heart.

And this is a very precise way to figure out in that patient, what is going on? Cause it is often difficult for us, by examining a patient, listening to their lungs, et cetera, to really tell where they are and what treatment do they need. Cause they're already on a lot of medications so it's not like we're just going to put them a new medication. So definitely typically do this, so the question that I ask, was there any conceivable way we could get that type of right heart catheter information all the time? Cause we can only do a right catheterization in the ICU or cath lab.

And it seemed like a crazy question but we work and then we're able to get that type of information that we'd get in the cath lab now, everyday from the patient's home. That's what CardioMEMS technology is all about. So that the whole thesis behind CardioMEMS is that having this information, comparable to the right heart cath, hemodynamic pressure monitoring on a daily basis from the patient's home, would allow the doctors and nurses to manage these patients better and prevent them from decompensating, ending up in the hospital. That was the idea which we tested in this clinical trial.

There are three components to this system. The implantable piece is a central monitor which both sensors information and then transmits it out and – so that's also in the patients in the pulmonary artery. Then outside, we have an external transmitter which takes that information from the patient, it's hooked up to a phone line or wireless type settings and it transmits that information to a database. The database is accessible to the patient's doctor and nurses where they can see the special information.

The clinical trial that we did, which we did – took us about three years and we just finished it this spring and the data was presented in Berlin at the European Heart Failure meeting, the principal investigator is Dr. Bill Abraham from Ohio State and Dr. Phil Adamson from Oklahoma. And what this study tested was, is this a safe device? Is it also efficacious in reducing heart failure hospitalizations? The primary efficacy was heart failure related hospitalizations at six months and the treatment group compared to control group. The control group also had a sensor and also took readings but that information was not accessible to the physicians or nurses.

So the control group was managed using a current traditional metric that we use talking to the patients, examining the patient, the treatment group had the traditional information but in addition, this pulmonary artery pressure information. This was done at 64 centers in the U.S. All patients, as I said, got a sensor and as the sensor implanted was randomized with treatment or control groups and they were all followed in a blinded fashion until the last patient reached six months.

The major eligibility criteria were as follows, I'll just – let's just focus on the top two. They had to have Class III heart failure and they had to be on optimal pharmacological therapy which is defined by the ACC & AHA, ace-inhibitors beta-blockers, there are clear guidelines for that. And they had to have the hospitalization for a heart failure within the last year. Those are the major two criteria, the rest are more – we don't need to go into those but the first two are the major criteria.

The safety was measured in two ways, one was freedom from device system related complications which the FDA set at the 80 percent level. Meaning 80 percent of the patients could not have a device system related complication. And then the second one was the failure of the implantable component which the FDA set the 90 percent level, so 90 percent of these devices had to be working at the six month time point in the end of trial.

The efficacy endpoint was the rate of heart failure related hospitalization for six months. There are multiple secondary endpoints which are of interest to us, the change in the pressure, whether it be the pressure go down, the number of patients hospitalized. Remember the primary endpoint, it'd be number of hospitalizations, one could also look at the number of patients being hospitalized cause many of these patients have more than one hospitalization, days alive outside the hospital and quality of life as you're familiar with.

This is the overall flow of the trial 550 patients are implanted, 270 in the treatment group, 280 in the control group and the primary endpoints I discussed. Now, because we follow the patients up to when the last patient reached six months, we actually ended up with a lot more follow ups than six

months. So the average follow up in the trial was actually 15 months, we have some longer term data on these patients that I think is very helpful.

Just looking at the base line demographics, the age is about 60 so the patients keep getting younger as I keep getting older. The typical distribution that we see in heart failure trials, many of the patients did have devices, if you noticed CRT or ICD devices, many of them were on appropriate medications which were the diuretics and the ACE inhibitors and beta-blockers. And the two groups are well balanced, the two groups are quite similar in these types of treatments at base line.

Here the primary safety endpoint, if we just look at the last column, all patients, there were eight device system related complications or 1.4 percent, so much lower than the 80 percent bar set by the FDA so it's highly statistically significant. The second one was failure of the device, did you have to go back in and replace the device? None of the patients had to have the device replaced, all the devices are functioning, which is pretty unusual for cardiac devices and in my experience and yours too, I'm sure. So that was highly significant at the $p < .01$ level.

Now, for the efficacy, was there a benefit to the treatment group? At the six months primary endpoint, there were 83 hospitalizations for heart failure in the treatment group and 120 in the control group. So, a dramatic reduction in the number of hospitalizations which was highly significant, very low p value. Then we followed them out, as I said, to 15 months was the average follow up and what was reassuring was that at 15 months, the number of hospitalizations attributed was 153, in the control group it was 253.

So the difference actually got bigger over time. Not only the treatment was robust, sustainable and actually seemed to be more efficacious and that was also highly significant. The last column, there is NNT or Number Needed to Treat and you may be familiar with that calculation, it wasn't required by the FDA but it's a common calculation particularly in Europe, looking at cost effectiveness and societal cost of technology. So this is a number of patients unique to treat to prevent one event. OK.

So the six month time point is eight patients, after 15 months, it's four patients, these are really low number needed to treat. Most devices and drugs to be used are in the 20, 30, 40 type of patient number needed to treat. So just that as a public health application, this is an efficient solution, cause you could have a clinical trial for example where you have a big relative risk production but the disease is infrequent. I hear it occurs twice in a million patients, you cut it down to one in a million patients, so you have a 50 percent reduction but your number needed to treat is a million patients, so that just gives some perspective.

This is the graphical representation of the data, so what we see is that starting in six, starting really about three months, the group sort of diverged. At six months, there's a significant divergence which continues over time, so over time, the treatment group continues to do better than the control group it's a sustainable benefit. For some of the secondary endpoints, the first one was reduction in pressure, and I'll show you a graph that helps explain that a little bit better.

But what happened over time is that if you took zero as the base line when the patient entered the trial, what happens over time? So minus number means that their pressure went down over time, plus means it actually kept going up. So the treatment group had a reduction in pressure overall and the control group had a continued slight increase in pressure, which is what one expects from a natural history of heart failure.

The second one is the number of patients hospitalized, and there were 54 on the treatment group and 80 in the control. So, not only do a reduction in number of hospitalizations but also in the number of patients being hospitalized which was also significant. And the last one is the number of days alive outside the hospital, six months, just a little complicated analysis but this is the number of patients staying out of the hospital and staying alive. And that also was higher in the treatment group than in the control group at six months.

And the last one is the Minnesota quality of life or heart failure questionnaire, and the treatment group did record feeling better than the control as one would

expect. This is the pressure curve that I mentioned to you, which we're seeing the blue line of control and the dash line is base line where they come in with the study and what you notice is that the control group tends to drift slightly up over time and the treatment group's pressures go down over time.

One other important question is, well OK, you're reducing heart failure hospitalization but are you increasing other hospitalizations? Are you causing some collateral unexpected side effect and we're used to seeing that in medicine particularly cardiology, it's like a balloon. You push it on one spot and blows it out to somewhere else, right? So we really wanted to test with that and what you see here, if you look at the bold lines here, at six months, the non heart failure hospitalizations were the same in both groups.

So above that, you see HFR's heart failure related hospitalization which is much more than treatment group but the non heart failure hospitalizations did not go up in the treatment cause there's no compensatory increase in other types of events happening. Similarly, at all days at the bottom, you again see that the non heart failure hospitalizations are essentially the same in both arms.

So, in conclusion to clinical trial, the trial met its primary safety endpoints very strongly as well as the efficacy endpoint very strongly. There's a 30 percent reduction in heart failure hospitalization at six months and a 38 percent reduction at the all day time periods which was approximately 15 months. Some of the secondary measures that the FDA was interested in were also positive in regard to pressure, the number of patients being hospitalized and quality of life.

Let me just – so this slide kind of ties it all together, you have a sequence of events where the pressure information used by the doctors and nurses to manage medications which leads to pulmonary acute pressure reduction, which leads to a hospitalization reduction which also as an ancillary benefit, the patient feels better. Let me just describe to you the conclusion of the technology before I turn it back over to Amy.

So historically, for cardiac electrical devices, we've had a two part implantable, we've had a can and a lead, and they work together. What we had done with this technology – and this sensor by the way is made on a wafer, it is the first chip type – fully chip type device for medical devices so it's like a chip in your laptop, et cetera, it has no moving components to it. So what we have done is combine those pieces into one device, both the sensing and the monitoring aspects are combined into one implantable device.

If they hear just to make it more obvious here, so you've got the implantable component which is the CardioMEMS device has those features to it, traditional devices. And then outside the patient, you got a transmitter which is used to communicate with the device which is intermediary between the device and the patient and the database that resides, CardioMEMS will access to a secure Web based platform by the doctors and nurses. So that's – I think that's all I have, I'm happy to answer any questions or I'll turn it over to Amy.

Amy Gruber: We will now move on to the coding options and then we will open up the floor for comments or questions for the doctor. There are two coding options there before you. Coding option one is to not create a new code, continue to assign procedure codes 00.56 and 00.57 for the implantable hemodynamic monitoring system. Option two would be to create a new code under category 38.2, Diagnostic procedures on blood vessels, for the insertion of the implantable wireless pressure sensor.

The next available code in 38 would be 38.26 and the title would be “Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring”. There were several inclusion terms which would identify that it is the combination wireless pressure sensor and internal monitor, identifies that it will be placed in great vessels or branches thereof, as well as it identifies that it doesn't have batteries or lead.

And the standard exclusion notes that would appear under the new code appear currently under 00.56. CMS' recommendation at this time is option two; I'd like to open up the floor for any comments.

Nelly Leon-Chisen: This is more of a question. This new device is wireless, so there are no leads at all and that's why the new codes set without battery for leads, so then the interim coding would only be for the subcutaneous device rather than both codes with one with the lead insertion, I mean, right? So it would only be one code in terms of the interim coding?

Amy Gruber: For the total system to identify that it was – it is a total system and that it is combination of the sensor in terms of monitoring, the best thing that we can suggest at this time would be code both.

Nelly Leon-Chisen: Yes. But I guess – what I'm not understanding and forgive me because this is – it's wireless and there's no lead. So in the interim coding, why would you use a code for insertion of leads?

Amy Gruber: To identify the sensor aspect as well as the internal monitor aspect, this is what we've identified as the best codes available at this time. Pat's going to provide you further guidance.

Nelly Leon-Chisen: OK, all right.

Pat Brooks: Nelly, we would be happy for you to suggest something if you feel stagnant on this advice. It's a tricky situation because this one device contains two things. So we were thinking, for now, we don't want people to believe you're simply putting in a device and the patient doesn't have any leads, it sounds like a replacement to the older one. And we didn't know what to do to substitute for a total unit, so that's our best guess of an interim thing.

And then the new code would be more clear because it would show there's no need to code a separate device lead because you're not putting one in. But you're correct, we did struggle with this concept and we would love to have discussion, even if you wanted to put this on the Coding Clinic agenda for November to discuss interim advice. We would happy to discuss it more.

Nelly Leon-Chisen: Yes. Cause I think it's a little bit confusing cause if you hear, there's no leads and the description talks about wireless, that's why I was sort of thinking, where is the coder going to make the leap to say, "I also need to assign a code for the lead insertion and ..."

Pat Brooks: You're right, it's a problematic area right now.

Nelly Leon-Chisen: All right, OK. All right, thank you.

Linda Holtzman: Linda Holtzman, Clarity Coding. In the interest of full disclosure, I want to point out that I sometimes do consulting for Medtronic, including the cardiac rhythm management division, which by the way, the picture of the old technology was actually a Medtronic device. So, it seems reasonable to me to have a new code for this, I mean it is very different technology. And especially since the applicant is looking for a new tech add on, then you need a new code so, that's fine.

My issue is the wording on the code to make the distinction between 38.26 and the older technology more clear. As the doctor went through his presentation and as I saw, and then you then discussed the inclusion notes, it started to become clear to me. But when I first looked at this, I was like, what's the difference? So I'm not sure I have any specific wording at this point, though I'll probably write to you but I think we need to do something with the wording here to make it more clear.

Also I think, we're going to need something – some kind of revision to the code description on 00.56 and maybe an exclusion note on 00.56 or in 00.57 to make clear that these are related but distinct devices. Also, I'm with Nelly, I have a lot of concerns on the interim coding. In some ways, I'd be more inclined to just use 00.56 by itself even though that code is defined as leaded, also defined as sensor.

So if I were to see this new device, I would probably say, OK, well, it's a sensor and it's in there so I'll use the 00.56, then I would really be troubled to use the 00.57. I realize the new device has a monitor associated with it but 00.57 is specifically for inserting something in a subcutaneous pocket and that's not happening here. So, I'm not sure what to do with that either but that's a real issue.

Amy Gruber: OK. We understand your concerns.

Dr. David Berglund: I'm David Berglund with CDC/NCHS, and just had a couple of comments related to Nelly's comment. I would imagine that this device in some ways would act like the tip of the lead and that it has the sensor in it but it's got everything in one place. So we're seeing the whole device a lot smaller as I understand and what we would have had in the past, which does make for a little different way of looking at things.

I was a little curious about how long the batteries would last in this and what would happen to it when they ran out. Would it be replaced using a similar approach? Do we need a code for replacement too or would we use the same code? And I'm curious about that, I don't know how long the device would last or if we had comments on that, I'd be interested. And on how we code if it needed replacing.

Dr. Yadav: Thank you, thanks Amy. That's a great question and I actually don't know. It doesn't have a battery, so that limitation doesn't exist. In the clinical trial, we had patients - I think the longest patient was out three and a half years and feasibility of that patient went out almost five years. So I'm not saying that it never would need replacing, I'm sure everything needs to be replaced but it isn't a part of – it doesn't have a built in requirement to be replaced. So I will leave it up to the coding experts on that one but that's the medical perspective.

Linda Holtzman: I have a clinical question then. Just out of curiosity ...

Pat Brooks: Say your name please.

Linda Holtzman: I'm sorry, it's Linda Holtzman. If it does – I'm just curious, if it doesn't have a battery, how is it powered?

Dr. Yadav: It stores energy, so it has capacitor storage, and so it stores energy inside the device.

Linda Holtzman: Polar energy, I mean ...

Dr. Yadav: No, from the external transmitter.

Linda Holtzman: Oh, the external transmitter. OK, thank you.

- Sue Bowman: Sue Bowman from AHIMA, response to the – to follow up on the previous comments about distinguishing this from the older technology. When you're looking at the re-wording of the code I would also suggest looking at the wording of the last excludes note that is being proposed because when you read that, that sounds every similar to the new code descriptor with the omission of the word wireless, so it's kind of like, OK, insertion of implantable pressure sensor for et cetera, that's what this is. So I think there needs to be more wording there too, to just make it really clear what the difference between this code is and the older codes.
- Amy Gruber: And we welcome your suggestions on the re-wording. We struggled with that combo versus non-combo, so. Any other questions or comments? Operator, at this time, can you please open up the phone lines.
- Operator: If you would like to ask a question, please press star then the number one on your telephone keypad and we'll pause for just a moment to compile the Q&A roster. There are no questions from the phones.
- Pat Brooks: Thank you. OK, everyone, we will now break for lunch and we'll start back up again at 1:30 and I want to remind everyone on the telephone to please refer to your agenda for the ID number for the afternoon which is different than for the morning. So we'll see you back here at 1:30.

END