DEPARTMENT OF HEALTH AND HUMAN SERVICE
National committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards

ICD-11 Expert Roundtable Meeting

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CASET Associates, Ltd.
caset@caset.net

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P R O C E E D I N G S (9:05 a.m.)

Agenda Item: Welcome

DR. STEAD: Welcome. We will begin with roll call. **I** am Bill Stead, Vanderbilt University, chair of the Full Committee. No conflicts.

MR. LANDEN: Rich Landen, member of the Full Committee, co-chair Standards Subcommittee. No conflicts.

MS. GOSS: Alix Goss, member of the Full Committee, member of the Executive Committee, co-chair of the Standards Subcommittee. No conflicts.

DR. CORNELIUS: Lee Cornelius, member of the Full committee, Population Health Subcommittee, no conflicts.

DR. MAYS: Vickie Mays, member of the Full Committee, and no conflicts.

MS. LOVE: Denise Love. National Association of Health Data Organizations. I am a member of the Full Committee and a member of the Standards Subcommittee. No conflicts.

MS. HINES: Do we have any members on the phone this morning?

MR. PASQUALE: This is Frank Pasquale. I am a member of the Full Committee and co-chair and chair of the Privacy and Security subcommittee. No conflicts.

MS. STRICKLAND: Deb Strickland. I am member of the Full Committee, member of the Standard Subcommittee and member of the Pop Health and I have no conflicts.

MS. HINES: Nick, are you on? Any other members on the phone?

(Music playing)

MS. HINES: Just to get us in the frame of mind we need to be in to think creatively today, we have right on cue, a little creative energy making music.

Good morning, Rebecca Hines, I am the executive secretary for the National Committee and I would like to welcome you all. I would like to introduce two staff in the room.

MS. DOO: Good morning, this is Lorraine Doo with the Centers for Medicare Medicaid Services, Division of National Standards. Lead staff to the Standards Subcommittee.

MS. JACKSON: Debbie Jackson, NCHS, CDC, staff.

MS. HINES: Thank you. I know we have at least one more member who is planning to be here this morning, but we will have her report in – we have another NCHS person who can say good morning.

MS. PICKETT: Good morning. Donna Pickett, National Center for Health Statistics.

MS. HINES: Thank you, Donna. Just before I turn it over to our moderators, as you just saw, the mics have a little button there that – it looks like somebody speaking. You need to press that. It is a toggle switch and because we are recording this and writing a summary, really would appreciate it if you would make the effort to speak into the mic when you do speak. It just helps us overall. So thank you.

DR. STEAD: Good morning again. We will give each of you an opportunity to introduce yourself in a minute. I wanted to first just sort of set the stage for the meeting. I want to welcome so many of you back. Good to see those of you who were with us last July 17 and 18, have come back to join us, in addition to several additional people that have brought different expertise into the room.

To anchor our work in the charge to NCVHS related to data standards, we are formally supposed to study issues related to the adoption of uniformed data standards for patient medical record information. Love the historic words. And the electronic exchange of such information and report to the Secretary of HHS recommendations and legislative proposals for such standards and electronic exchange.

We are to advise the Department on health data collection needs and strategies; review and monitor the

Department's data and information systems to identify needs, opportunities and problems.

In 2017, the National Committee scoped a project to begin to take a contemporary look at health terminology and vocabulary landscape. We have not delved into this space since the early 2000's. This was a fresh look and we wanted to see if the changing environment had implications for timing and approach to health terminology and vocabulary standards adoption. Whether there were needs, opportunities and problems related to the development, dissemination, maintenance and adoption of health terminology and vocabulary standards. And actions HHS might take to improve development, dissemination, maintenance, and adoption of the standards.

I hope that you feel that over the last two years we have accomplished something. First the very detailed environmental scan. Thank you to our colleagues at NLM, Susie Roy, who has since left NLM, and Vivian Auld, who is here, were driving that for us. And the rest of the team, Olivia, Clem, others, Patrick, to that scan.

We then hosted the Roundtable and mapped out short-term, mid-term, and longer-term strategies, and published a report that I hope you have had a chance to reread. As I reread it yesterday, I think it gets most of the big issues out on the table. We also drafted at the

Roundtable and then turned into a formal attachment to the Letter to the Secretary, new criteria for adoption of terminology standards. And for the first time, guidelines for the curation of dissemination of standards, of the standard terminologies, and we have viewed those criteria and guidelines as a basis for research questions and communication topics that we are trying to narrow in on today.

We also wrote a Letter to the Secretary with sort of the first step in trying to simplify and streamline the regulations, which was to say, lets try and change the regulations so that we don't actually have to go through rulemaking at the same level, to deal with updates which should be much more continuous and let us clarify that despite the fact that ICD-10 PCS has ICD-10 in the name, it has nothing to do with the transition to ICD-11. It can be deal with completely separately. So let's focus in on ICD-11 for mortality and for morbidity. That is why you begin to see us focusing in on the work we are doing here today and tomorrow.

Our meeting objectives are, we hope, sufficiently narrow, that we will walk out of here with real agreement on what the key questions and communication issues are so that work can proceed in getting them deal with.

We are going to start by trying to get a shared understanding in the room of the lessons from the ICD-10 planning process and transition the differences between ICD-10 and 11. I want to thank Donna and her – Donna Pickett and her colleagues at CMS, for building the very detailed timelines that were in your pre-reads. I hope that you noticed that they have links. This makes it very easy to go into the source material from a number of years ago, to see how the work was actually done.

Sheila, from our Center for Knowledge Management, and that team, have done a detailed literature review, that was also in your pre-read. We will go through that this morning. So it lets us know what we know about the transition in terms of the published in grey literature.

NCHS, Donna and Bob Anderson, have laid out a concise view from the view of the development of ICD-11 about what it is and how it differs from ICD-10. The NLM team, this time led by Olivia, has done the first sort of fundamental analysis of what is in ICD-11, and begun to identify key evaluation and communication questions.

So there has been a lot of pre-work. You have seen it in quite a few pages of pre-reads, and we are going to try and turn that into the deliverables, which are the research question to be answered to inform the evaluation of cost benefit of the transition of ICD-10 to 11 for

morbidity, for mortality and morbidity, and to identify the impacts of not moving to ICD-11 for morbidity.

To unpack the reason for that wording, as a member of the World Health Organization, the US is already committed to implementing ICD-11 for mortality. That is a given. The only thing that we can try to influence is the timeline and method of implementation. The other evaluation issues all surround morbidity. Which, because there are any number of questions; does there need to be an ICD-11 CM. How do we evaluate the fitness of ICD-11 for morbidity as it stands?

Then we need to identify the key communication topics. Because from our conversations with stakeholders, they are beginning to be aware that this is coming, but at this juncture, they have very little understanding of what the implications might be, and we need to clarify that. That is what we are about.

First just a bit of process. NCVHS has three primary standing subcommittees. One on Population Health, one on Privacy, Confidentiality and Security, and one on Standards. This work is being done as part of the Standards Subcommittee agenda. All the recommendations that we make to the Secretary are approved by the Full Committee, therefore many members of the Full Committee participate in

the sausage making so that we are already to deal with the approval when we have to begin to carry it forward.

With that, if the slides will let us keep going, I will turn it over to Rich Landen, who is co-chair of the Standards Subcommittee, and my co-conspirator in facilitating this Roundtable.

MR. LANDEN: Thank you, Bill. I want to welcome you all and everything said goes for me as well. ICD-10, ICD-10-CM, ICD-10-PCS, are all named code sets under HIPAA. So we do have on the mortality side the processes that Bill is referring to for NPRM and Final Rulemaking there.

Note that the PCS is Procedure Coding System, that is not part of ICD-11 and that is not part of what we are considering today and tomorrow. A lot has changed since we were in this position talking about the upcoming ICD-10. Many of us were around at that time, both from the rosters and from knowing many of you personally, we were all at different places – well, some of us were in the same place at a different time, others of us were in very different places with very different perspectives. There are a few faces in the room that I suspect were not really around much and even for ICD-10, certainly not for ICD-9. So things have changed.

What part of our task is, is to learn from the past, but not necessarily replicate it. The saying that the

generals are always preparing to fight the last war – that is something we kind of need to avoid. We need to take a step back and not necessarily consider doing things the same way we did for 10. There is a lot that is different in our ecology, particularly the computability aspects of the coding classification systems now on mortality. When we did 10 we were thinking that the technology in health care and health care delivery was still coming off of main frames. Going into PCs, we are in a very different world now. We have clinical decision support. We have got interoperability, that CMS and ONC are working on as a high priority federal level.

So there are new opportunities, new uses. Bill mentioned a term, fit for purpose. Part of that is to understand what the purpose of 11 is going to be and whether or not that is just a redo of 10 or something that adds the new aspects, like the computability artificial intelligence.

So without belaboring the introductions any further, what I would like to do now is just go around the room and have everyone introduce themselves. What your name is. What your current role is. Importantly then, at the end of this meeting, I hope we will have discussed. While the outcome of today and tomorrow needs to be a fairly focused set of questions that NCVHS will try and incorporate into a

research request, our start here needs to be much more broader. It is just not the narrow, we need to start broad and then work through everything possible what it is that is critical to get into the research paper.

I see one new face that we need to read in. Vickie, do you want to read yourself in with the no conflict and then we will do the introductions.

DR. MAYS: Good morning. Vickie Mays, University of California, Los Angeles. I am a member of the Full Committee, Privacy, Confidentiality and Security and Population Health, and I have no conflicts.

MS. GOSS: Rich, if I may just chime in. This is Alix, just letting you know that Nick Coussoule has been on the line. Unfortunately, our WebEx issues have impacted his ability to announce himself.

MR. LANDEN: Thank you. Most of you understand that this is federal protocol. That the members have to introduce themselves and do a statement of conflict of interest.

If we are ready, lets go around the room. If we can begin with the technical issues and opportunities table.

DR. BODENREIDER: I am Olivier Bodenreider. I am the Acting Director of the Lister Hill National Center for Biomedical Communications at the National Library of

Medicine. I am also a researcher doing research on terminologies non-terminologies, and I will present this morning.

MR. CAMPBELL: Good morning. I am Keith Campbell. I am Director of Informatics Architecture at the Veterans Health Administration. I have been doing terminology for a long, long, long, long time. So I do hold some other hats.

I am an advisory member to the SNOMED Editorial Advisory Group. At this end of this meeting, I hoped to have discussed how we can leverage the current efforts of trying to improve our interoperability between systems to also focus mortality, morbidity, and outcomes, at a more detailed level than what we provide with ICD-11. We are going to 11, right?

MR. MCLAUGHLIN: Patrick McLaughlin with the National Library of Medicine. My role is Head of Terminology QA & User Services supporting RxNORM, VSAC, SNOMED CT and UMLS. I hope to discuss among many other things, the lessons learned from the ICD-10 implementation and CM implementation.

DR. CHUTE: Chris Chute, Chief Research Information Officer, Johns Hopkins. I was also the former chair of the Revision Steering Group of the ICD-11 Development at WHO. I am presently co-chair of the Medical Scientific Advisory Committee at WHO for ICD.

I hope at the end of the meeting we can understand the relative merits and advantages of ICD-11 with respect to the current situation.

DR. PINCUS: I Harold Pincus. I am Professor and Vice Chair of Psychiatry at Columbia University. Co-Director of the Irving Institute for Clinical and Translational Research. I am also a Senior Scientist at the RAND Corporation. I was for WHO and the ICD-11, I was co-chair of the Quality and Patient Safety Topic. I am also involved with a number of different quality related committees with CMS.

DR. STEAD: What do you hope to obtain by the end of the day?

DR. PINCUS: I think to get a better understanding of some of the innovations that have been put forward in ICD-11, particularly with regard to quality and patient safety.

DR. CLARKE: Good morning, everyone. I am Diana Clarke. I am the Deputy Director of Research at the American Psychiatric Association. I am also an Assistant Professor at Johns Hopkins School of Public Health. At the APA I work on the DSM-V, so understanding ICD-11 with interoperability with DSM is very important.

Also, another hat that I do wear is developing quality measures for behavioral health through a grant from

CMS. Just understanding how all the changes in what is happening in ICD and how that will impact on quality and patient safety is also important.

DR. TCHENG: Good morning. I am James Tcheng. I am a Interventional Cardiologist at Duke University and Informatician Terminologist. I have been working pretty actively in this space for a better part of two decades from primarily two perspectives. One is the clinical – I would call it clinical society perspective. I a key member of the American College of Cardiology's National Cardiovascular Data Registry. Then also from the Device Surveillance side, the FDA sponsored medical device epidemiology network, in terms of trying to capture real-world data and then generate real-world evidence.

The thing that I would like to have discussed is our destination. How ICD-11 is going to have a different focus and a different contribution to healthcare beyond what it is we use for ICD-10 today, which is primarily just for billing purposes.

DR. ROMANO: Hello, I am Patrick Romano. I am a General Internist and General Pediatrician based at the University of California, Davis, Health in Sacramento. I work on developing, testing and validating quality measures in healthcare. I am mostly in partnerships with federal

agencies like AHRQ and CMS. In that space, I have extensive experience with ICD-9, now ICD-10 based measures.

I served on the Quality and Safety Topic Advisory Group for WHO, under Dr. Pincus' leadership. I also happen to co-edit the Journal of Health Services Research, which is an arcane academic journal in the field of health services research. I don't have anything to add to what Dr. Pincus and Dr. Chute said, I agree completely.

DR. MCDONALD: Clem McDonald. I am the Chief, Clinical Data Science Officer at the National Library of Medicine. I am involved in medical records and standards, I think since I was born, actually. I am very active in HL-7 and I have worked heavily with ICD's through the Medicare's enclave for doing research on that big database.

What I would like to see is a faster timeline than for ICD-10.

MS. NARCISI: Hi, I am Jean Narcisi. I am Director of Dental Informatics for the American Dental Association. I would like to hear a little bit about post-coordination. I think Donna touched on that at a previous meeting, how that would be able to map to SNOMED.

DR. BROWN: Steven Brown, Department of Veterans Affairs at Vanderbilt University. I am a 24 year practicing primary care doc at the VA and I run an office in health

informatics, called Knowledge Based Systems, which mostly deals with sort of the technical deep end of informatics.

I will occasionally get to carry Keith's luggage. For this meeting, what I hoped we will have discussed is reducing the administrative burden and mayhem that happened with the introduction of ICD-10 in clinic and how we will also use better data to decrease cognitive load going forward.

DR. WANG: Good morning. Phil Wang. I mam Deputy Medical Director and Director of Research at the American Psychiatric Association. I guess I am understanding, what I hope we discuss is, how to harmonize with other nosologies, such as DSM. And going forward, we obviously had a good relationship with ICD-10 CM in terms of that harmonization, and understanding how to continue that good relationship.

DR. ANDERSON: Good morning. My name is Bob Anderson. I am Chief of the Mortality Statistics Branch at the National Center for Health Statistics. I actually experienced transition from ICD-9 to ICD-10 for mortality. We made that transition in 1999. That was one of my first assignments at NCHS.

I also served on the Joint Task Force, WHO's Joint Task Force for ICD-11, and was co-chair for the Mortality Topic Advisory Group, and currently serve as the co-chair of the Mortality Reference Group for WHO, as well.

DR. RILEY: I am Bill Riley, Associate Director for Behavioral and Social Sciences Research at the NIH. I hope that we discuss by the end of this meeting, interoperability and its impact on researchers trying to balance ICD-10 codes and ICD-11 codes coming from different places.

DR. KUSNOOR: I am Sheila Kusnoor. I am a Senior Research Information Scientist at the Center for Knowledge Management at Vanderbilt University Medical Center.

Today I am going to be talking about what are our team has done. So the findings from our literature review on the impact of the transition to ICD-10.

MS. AULD: Good morning. I am Vivian Auld from the US National Library of Medicine.

MS. LEON-CHISEN: Nelly Leon-Chisen, Director of Coding and Classification at the American Hospital Association. Executive Editor for the Coding Clinic Publication. I represent the AHA in the cooperating parties that develop the ICD-10 CM official guidelines.

I have been at this so long that when I looked at the timeline I said, when they try to figure out what to say at my funeral, they can just read through that. Sue and I sort of have that honor. So I guess our funerals would look sort of similar.

I hope that we will discuss how to shorten the timeline because I don't think we want to wait 25 years to implement ICD-11 because I think we have gone through this process. We went through this process for ICD-10 and we thought we would get our hospitals ready. It got to the point where we were crying wolf because we were saying, yea, yea, yea, you keep telling us it is coming. Hopefully we will be much more deliberate about ICD-11.

MS. BOWMAN: I am Sue Bowman, Senior Director of Coding Policy and Compliance for the American Health Information Management Association. Also one of the cooperating parties that works on the coding guidelines. As Nelly mentioned, I have also been involved in the very long transition to ICD-10. I have also participated on WHO's Morbidity Topical Advisory Group. Now it is called Morbidity Reference Group for working on IC-11 and for morbidity use cases internationally.

I hope by the end of this meeting, that we will have discussed not only the lessons learned from the very painful and long transition to ICD-10, but also how we can avoid those hiccups going forward and make the process smoother and easier, and maybe how changes in our current healthcare environment, will hopefully help facilitate that transition process.

MS. SKURKA: Hi, I am Margaret Skurka and I am a retired University Professor from Indiana University. I now work in a consulting capacity on a full-time basis.

I have been around a long time, too, I am one of those old girls. When I was an undergrad, I learned ICD-8. Then I was on the road for AHIMA teaching 9 and 10, the academies. I probably did 45 to 50 academy, 3-day academies around the country, teaching 10. That is not going to work with 11. So what is important to me is to discuss the electronic nature of the system and how that will translate into education and it won't be books and workbooks in major US cities.

MS. KLOSS: I am Linda Kloss. I am a consultant also. I completed my term on NCVHS last Wednesday. So I am a private citizen and I had the privilege of working on this NCVHS initiative with regard to vocabularies and classifications.

What I would like to see come out of this meeting is a sense of how we communicate the transition to 11 as part of the whole environment of vocabularies and terminologies and begin to step up the level of understanding and education across stakeholders. I am very interested in tomorrow morning's discussion.

Then I would also like there to be capturing our ideas for where we think NCVHS should go next on this

initiative. I don’t think this is a journey that even this meeting will conclude.

DR. WATZLAF: Good morning. I am Valerie Watzlaf. I am the current AHIMA President and Chair of the Board of Directors. I am also the Vice Chair of Education in Health Information Management and Associate Professor at the University of Pittsburgh.

I echo everyone’s comments here at this table, as well as I would like to see the research that could be done when we look at the difference between 10 and 11 in relation to coding productivity and accuracy.

MS. PRELLWITZ: Good morning everyone. I am Leslie Prellwitz. I am Director for CPT Content Management & Development at the American Medical Association. I have been in this industry for over 20 years. While my current role is maintaining the accuracy of the CPT code set and also doing education and training as Managing Editor of CPT Assistant, and secretary to that editorial board, from a previous life I am also a dual hemo certified coder, and actually personally lived through the 9 to 10 transition. And yes, somewhere I still have my workbooks back in the closet.

In addition to that I have also spent quite a bit of time working with many academic medical centers on coding improvement outcomes management and patient quality

and safety. I am interested at the end of this session, I would like to discuss not only effective training and implementation from lessons learned, but making sure that we are truly capturing the benefits of I-11 from the education and training beginning, so that we can see the benefits all the way down through research and outcomes and all of the other benefits we hope to get. As everyone who has research knows, if you don't have good data to start with you are really behind the eight ball, going forward. I would like to see us make sure we get everything right at the beginning.

MR. LANDEN: Is there anyone that we missed? Okay, I thank you all.

MR. PASQUALE: By the way, this is Frank Pasquale on the phone and I a Professor of Law at the University of Maryland and just interested in the development of the standard. Just listening for law and policy issues. That is my part.

Agenda Item: NCVHS ICD-11 Project and Roundtable Meeting Design

MR. LANDEN: Okay, we have got quite the group assembled. All of you have voiced at least one thing that you are interested in getting out of this. We, as the committee, have many things we need to get out of it, but I think we have got the right group assembled.

I would like to digress for one second and just acknowledge again, Linda Kloss, who is as she mentioned, has stepped down from an official role. I have been volun- told that I will fill her shoes. Good luck with that Rich, thank you very much. Nonetheless, between Linda and Bill and the rest of the group helping us out and the full NCVHS Standards Subcommittee and the Full Committee, I think we are in a good spot. We have got plenty of momentum. It is well organized- thank you Linda and Bill – I think we are well poised to get done what we need to get done today and tomorrow.

This slide will look familiar. Bill went through this earlier, but we think it is important that we reiterate the meeting objectives. First, to develop shared understanding of lessons learned from ICD-10 in the planning and implementation processes and noting differences between 10 and 11.

Second, to reach consensus on the research q1uestions to be answered and to inform evaluation of cost and benefit transition from ICD-10 to ICD-11 mortality and morbidity – and obviously mortality is a different path than morbidity. And to identify the impacts of not moving to ICD-11 for morbidity.

Third, identify key topics and messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

Our agenda today, we have gone through our first step already. We will be learning more about the lessons we learned from ICD-10. We will be talking about changes between 10 and 11. We will do the background and set-up for the two roundtables. We will do two cycles of roundtable brainstorming today, followed by full group discussion. At the end of the day we will recap what we have learned from today.

Tomorrow, we will resume the roundtables, do more brainstorming on the communication. How we reach out to the industry to get the ball rolling there and engage stakeholders. Then we will do some prioritizing, some synthesis, and then following that the NCVHS Standard Subcommittee members will come together in a working session and try to start taking everything we have learned over the past day-and-a-half, and putting it into a document for our next steps.

Finally, we will close with the usual public comment, so everyone in the room and everyone listening in on the webcast, can make themselves and their comments public and part of the record. Then we will close it out.

Any questions on the path for today and tomorrow?

Okay. Ground rules. Tent cards. It is the custom of the NCVHS to use your tent cards. If you want to speak simply raise your tent card and the chair will acknowledge. Then use your microphones to speak, not only for the recording purposes but so that those listening in on the webcast can hear.

Breakout discussions are designed to be less formal so everyone can contribute. You are at small group tables. You can self-manage. You have all been around the block before, so I have no concerns there. You can self-organize.

Chair reserves the right to move us along to stay on topic and schedule. We don't want to get bogged down with any one issue, as important as that one issue might be, because at the end of the day that means there are other important issues that may get short shrift. So it is Bill and my obligation to see that that doesn't happen.

You have got a very wide range of perspectives, as you have already heard, so please listen carefully and respectfully to each other's views, but feel free to discuss and disagree collegially.

What we've learned thus far. NCVHS has had briefing from the National Center for Health Statistics. One that you all will hear shortly. In addition, the National Center for Health Statistics has prepared

comprehensive timetable on the steps leading to adoption of ICD-10.

We also had the opportunity to review what's been learned about ICD-10 through the look back on published articles about ICD-10 prepared by the Vanderbilt researchers. We want to thank Dr. Sheila Kusnoor who is here today, and her colleagues for doing this timely and very illustrative work. Research by the National Library of Medicine, you will also hear in the next step.

DR. STEAD: Thanks, Rich. You had in your pre-reads a very detailed timeline. I spent a Sunday afternoon sort of trying to step-back from them and say what are the key milestones, particularly with regard to the questions we are trying to ask today and tomorrow, around evaluation and issues. I summarize on these slides.

As you know, 1988 was when NCVHS recommended that the WHO copyright not be allowed to be a barrier for implementation in the US. I believe that is an issue we will have to deal with again this round.

Then 1990, the World Health Assembly endorsed ICD-10 for mortality and morbidity. That is where we are. That just took place for ICD-11.

Then in 1990, NCVHS did its initial review of ICD-10 for both mortality and morbidity and we looked at the CPT-4 and the ICD-9-CM procedure coding volume, found

structural issues and recommended that HCFA, which was the predecessor of CMS, evaluate the feasibility of a uniformed procedure code.

’93, NCVHS recommended that HCFA study the feasibility of implementing ICD-10 for mortality, which would have meant implementing ICD-10, not developing ACM. Held a number of meetings and working sessions to develop recommended topics, steps, to create a single procedure coding system for the US.

1994, the National Center for Health Statistics awarded the contract to the Center for Health Policy Studies to evaluate ICD-10 compared to ICD-9-CM for morbidity. And it developed the prototype of ICD-10 for morbidity. Then we went into a period of where the National Center did development of iterative versions of ICD-10-CM, obtained public comment, revised, and ultimately got where a tabular form was posted. This flowed into the HHS HIPAA rulemaking process. One of the key branchpoints in that, was the recommendation informed by hearings by NCVHS, that we should go ahead and implement the existing ICD-9 related code sets as part of the initial HIPAA standards, and then come back and update to implement the ICD-10.

Then the timeline through which we implemented ICD-10 first for mortality in 1999, and then released ICD-10-CM in 2002, pre-released, posted on the website. Hearing

and in many ways, I think the level of evaluation we need to be doing now, even though we are relative to the World Health Assembly, wherein, in 1990, I think if you look at that NCVHS was doing in 2002, that is what we need to be doing now.

And basically, that recommendation recommended implementation, and I do think it was interesting. I don't know who was representing Blue Cross at the time, but whoever they were, should be found and put a star on their head because they were really the one person that spoke up and said, this is going to be harder than people think. I think they were correct. They advocated that NCVHS issue – do a formal study before proceeding with recommendations to implement.

That then led to NCVHS contract with RAND to do the analysis, that I reread last night, and that led ultimately to the recommendation to proceed and then the long process that we all are familiar with, that ultimately resulted in the transition to ICD-10 in October 2015. After a number of delays.

As I went through all of this over the last couple of days, I basically came down to the following short list of observations.

First, ICD updates took place without problem, every nine to ten years, from 1900 to 1975, through World War I and World War II.

It was with ICD-9, it took us 15 years for the assembling to approve ICD-10. With ICD-11, it has been 30 years. So what has happened? What has happened is the introduction of computer systems and the extension to deal with mobility and procedure coding.

So ICD-11, the world has worked very hard, many people in this room, for 12 years, to build ICD-11. One of the things that has been done is to focus on the computable foundation that is intended to make transitions and then continuous updates much easier. So I think we need to pause.

Another thing I observed when I read the RAND study, which was done in, I think, a reasonable fashion. But as we think about what we are getting ready to do, how could we have been off on the cost by an order of magnitude? We need to keep that in mind.

What does that mean for the questions we want to pose over the next day or two? What are the research questions we need to pose that would allow us to evaluate whether ICD-11 is in fact, fit for purpose, purposes, and whether the computerable foundation will in fact allow an easier transition?

If it will, what are the questions we need to pose today that might really inform the cost and benefit trade-offs of very different implementation options that are in front of us.

And what might make us off by an order of magnitude this time?

Those were my thoughts. With that, I will turn this over to Sheila Kusnoor. She already introduced herself, but I want to make one other point you may or may not know, given her role as a senior Research Information Scientist, she holds a Doctorate in Cellular and Molecular Neuroscience. She knows something about the underpinnings of what we are talking about.

Thank you, Sheila.

Agenda Item: What We've Learned Thus Far: The Highlights

DR. KUSNOOR: Thank you. So, our team at the Center for Knowledge Management has been working on a literature review on the Impact of the ICD-10 Transition. We had presented our findings on this topic during the June NCVHS meeting, and we also made changed to the full report, which you all should have received, based on the feedback that we had received.

So one of the things that we have updated, which you can now see just by looking at this first slide, is the

title of report. Now you can see that the review focuses on the ICD-10 transition and the transition to ICD-10 clinical modification and procedure coding system. Today I am going to summarize what we found from the literature review.

To start, I wanted to remind you about the methods that we had used for this review. So this was a search of both the published and the grey literature. So we searched three databases, which are listed here. Those are PubMed, Web of Science, and Business Source Complete. So the searches were done using comprehensive search strategies, so they included both controlled vocabulary and keywords.

Then the grey literature search involved a review of government websites. Websites of professional associations, and then news websites. So in total this represented 41 different websites.

Then we supplemented the grey literature search by also using Google. So by using Google to search for white papers and presentations. Then the last step in this process was hand-searching the references. This means we scanned the references of on-target articles to make sure that we had not missed anything critical.

The search ad process occurred from March through May of 2019. During this process we identified over 2000 documents. So then then the next step was to screen those

documents. So we had defined eligibility criteria in advance, prior to conducting the review. The main criteria was it had to address the impact of the transition. So includes information about costs, benefits, and problems.

We did the screening process using single-reviewer screening. So that means that one individual looked at each article to decide whether or not it had met the eligibility criteria. But we had five different people who were involved in the screening process.

When we first got started working on this, we looked closely at our inter rater agreement and we worked until we had reached at least 85 percent concordance.

So now what we are working on is adapting this full report into a manuscript that we will submit to a peer reviewed journal.

The last point that I wanted to emphasize on the methods, is that while we did use a systematic approach to identifying and screening articles, this was not a systematic review. So we had decided from the beginning that a comprehensive literature review would be more appropriate for this topic considering how broad it was. Also when we began working on the report and identifying the literature, it became even more apparent that it would not be possible to do the formal assessments of quality that are required in a systematic review.

Based on the types of reports that we are finding the way that the data was collected and reported, we also saw it would not be feasible to do a meta-analysis.

This table summarizes the key reports that we identified in this literature review. So key reports are those reports that directly address the impact of the transition.

In the full report that you received, we also included information about other related topics, such as the timing of training and the importance of testing. So those are not represented in this table.

This table is showing you that we identified nine broad areas of impact. The areas are listed based on the amount of literature found per area. So you can see here we found 24 reports about morbidity surveillance and only one report on staffing.

So the table also gives you the number and the percentage that were related to the US conversion to ICD-10-CM and PCS, the US implementation of ICD-10, and then finally in that last column, the international reports.

So you can see looking at this table, that most of this literature that we found, was based on this more recent conversion to ICD-10-CM and PCS. But the exception is exactly what you would expect. So for the articles on mortality surveillance, we found several international

reports discussing this impact and also several US studies on ICD-10.

So now I just wanted to briefly summarize what we found specifically, regarding the impact of the ICD-10 transition. The ICD-10-CM and PCS transition. So for morbidity surveillance, we saw that it had an impact on some health outcomes. I have two examples to share on the ways in which it impacted morbidity.

One was a recently published study that had looked at inpatient Medicare administrative data from 2012 to 2015. So in this study they found that there was sudden changes in the frequency of certain diseases in the fourth quarter of 2015. So this is when ICD-10-CM and PCS were implemented.

So the discontinuity ranged from minus 8.9 percent for cardiac arrhythmias to plus 10.9 percent for psychosis.

So then there is another study that had compared data on 34 chronic conditions. They used a random sample of a million patients in the Veterans Affairs Health System. This was from 2014 to 2016. So they saw that the diagnoses were fairly consistent across the transition period, but there were some exceptions. So those include higher odds of Alzheimer’s Disease. Another example is lower odds of arthritis measurement.

So then for reimbursement. We found that the results overall were mixed. So there were mixed findings on the impact of claims rejections or denials. Then there were also several survey studies that had looked at reimbursement. There are two survey studies where over half of the participants had reported minimal or no impact on revenue.

So those included a December 2015 survey study of 360 healthcare organizations. In that survey over half of the respondents were from organizations with one to 10 providers.

Then there is another survey, this was the Physician's Foundation in 2016 Survey, that had included over 17,000 physicians. Then for productivity, we saw that there were reports of productivity losses by both coders and providers. And productivity was mainly measured in the period up to a year after implementation. So there were some reports that while it had initially decreased, it then improved over time.

For coding accuracy, we saw that the changes in coding accuracy were mainly assessed through survey reports. So this introduces some subjectivity. So the other ways in which coding accuracy was assessed were through coding contest and training programs, instead of in a real-world setting.

Then for cost, the data on cost overall was weak. So a lot of the data that we found was based on survey reports. These surveys were often not published in the peer reviewed literature, so we had very little information about the methods. Sometimes the results weren't fully described.

So one of the better studies that we found was a survey. This was conducted from December 2014 to January 2015. So this is still before the actual implementation. But they were reporting the actual costs.

So this was for small practices. So this means six or fewer providers. They found that the average cost due to the implementation were approximately $3,400 per provider. Then we also found a few studies that supported that the implementation delays increased costs. So the implementation of ICD-10-CM-PCS had been delayed a few times. So one of the reasons for this increase in cost was partly due to the need to extend training.

So we did not find much information about the breakdown in cost due to training, system changes, and testing.

So for mapping we found literature showing the challenge in mapping between ICD-9-CM and ICD-10-CM and PCS. So this created a challenge for researchers because many of the codes did not have straightforward mappings.

Then for patient care, there were a few physician surveys where many of the respondents had indicated that the time spent with patients or patient care, was negatively impacted as a result of the transition. So this might not be completely unexpected. So given the need for training, it makes sense that time spent with patient – time for patient care, could have been impacted.

Then, finally, for staffing, there was only one study that we identified with post-implementation data on staffing. This was a survey of billing companies where they had reported the number that had hired more coders, outsources coding, or added automated coding tools. So I feel like we can't really make any generalizable findings about this one study. But it had been anticipated that staffing could be impacted by the transition.

One example was December 2011 to February 2012 survey, of Alabama hospitals where they had reported the percentage that planned to hire more coders or planned to increase hours of coding stuff. But we did not see a post-implementation study showing us what actually happened.

Now I wanted to just summarize just briefly what we found about the impact, specifically on mortality surveillance. So I have a few examples to share. I also had not talked about any of these examples during the June meeting.

So the first example that you can see is a study that had reported preliminary data on the impact of the ICD-10 transition. This was based on an evaluation of US death certificates from 1996. They saw that there was discontinuities in cause-of-death trends. So substantial discontinuities were found for certain conditions such Alzheimer's disease and influenza and pneumonia. They saw that this impacted the rankings of the top 10 leading causes of death. So it effected positions six through 10, which you can see on that table on the right. Position six and seven switched places, and then it also resulted in Alzheimer's disease becoming added into the top 10.

Then on the bottom you can see another example. This was a study that had analyzed data from 1994 to 2005, National Vital Statistics Reports. They were looking at the impact of the 1999 ICD-10 transition on hypertension related mortality in the Southeast. They found that the mortality rates for diabetes, heart disease, and cerebrovascular disease were impacted. They saw in their analysis they saw that it was leading to an overestimation of diabetes mortality rates, and underestimation of heart disease and cerebrovascular mortality rates.

Now I just wanted to briefly summarize; we were able to identify a number of knowledge gaps from this literature review. So the costs due to ICD-10 specifically,

we did not find any information about this. Then the costs for ICD-10-CM and PCS, we did not find much information about how the costs differed based on organization size.

Then for the impact on staffing, there really just wasn't enough data on that to make any conclusions.

The impact on coding accuracy. It would have been nice to have seen this addressed using real data.

Then how patient care was impacted. It would have been nice to have seen more quantitative studies looking at the impact on time spent with patients or the impact on patient outcomes.

Finally, the extent of the disruptions in morbidity and mortality surveillance.

I have just a few concluding comments, so we were able to identify a number of significant gaps in the literature for most outcomes of interest. So this reveals opportunities for future research and knowledge sharing. I think that knowledge sharing aspect is really key because there is a lot of data on this topic that just hasn't been publicly reported.

Another point is that a lot of this data was qualitative. The main problem with the qualitative nature is that it inserts subjectivity. So things that really aren't subjective, like cost and time. Then the last point is this need for better reporting of data. So a lot of this

data that we identified on the topic was in the grey literature. It had not gone through peer review. We did not have information about the methods. So it is hard to try and rely on this information and feel confident in the conclusions that you are making.

So I think that when we think about the transition to ICD-11, it would be helpful to think from the beginning about how the impact of this transition will also be addressed to help ensure that quality data is collected and reported.

Are there any questions?

DR. MCDONALD: The shift between 9 and 10, might not be anything to do with 9 and 10. There has been major shifts in those diseases and death rates in that same timeframe. Heart attacks dropped 60 percent in the last 20 years or so. Of course, Alzheimer’s became more aware – everybody became more aware of it. I wouldn’t blame those or attribute those to changing coding and all that is possible. I think it was more like these were secular trends.

DR. MAYS: you have a slide in which you talked about the coding not mapping well. Can you give any insights about whether or not it is within particular discipline, particular disorders? Because there has been some thought that certain disciplines have that mapped –

have the codes mapped as well. They keep after the release needing to refine the codes. So you have any additional information?

DR. KUSNOOR: There are two studies that have looked at this mapping and report of the percentage of codes that map. I think those were the Boyd et al studies. We had described those in the full report. I think that you are right that it did vary based on the condition, but I can't comment specifically on the ones that were more convoluted and areas that were straightforward. But people have been studying that.

DR. ANDERSON: Sheila, can you go to the mortality slide. I just wanted to point out a couple of things there.

The change in ranks, I want to say the change in rankings is not due to secular trends. It is actually because we are actually looking at a single year and coding of both ways. So it is just using 1996 data, and they do the rankings and you do the rankings. This is my study.

DR. KUSNOOR: Yes, I saw that.

DR. ANDERSON: I want to point out also that these changes are due to changes in the rules for selecting the underlying cause of death. So they are not strictly changes in the coding, per se, but in those rules for which condition will get selected as the underlying cause of death as defined by the classification.

WHO has a set of rules in each revision of the ICD for selecting the underlying cause of death. There were some significant changes with regard to some of these causes. Alzheimer's disease was more of a coding issue, but influenza and pneumonia for example, dropped because it is considered in ICD-10 to be an obvious consequence of a whole bunch of other diseases then it was in ICD-9. We could go through all of that but I don't think we are going to have time.

The other thing I wanted to point out is with this other study that you showed here – and this is a common mistake made in this type of study, is they will say something like they overestimate diabetes. Where it doesn't really overestimate diabetes. I guess it does relative to the previous revision, but if you take ICD-10 for example, as the better version, which it is generally considered a better version than ICD-9, well it is not really overestimating. What it is saying is that ICD-9 underestimated.

So the conclusions are a little off. What they are trying to do is they are trying to evaluate ICD-10 using ICD-9 as the gold standard. You really should not do it that way because ICD-10 is supposed to be better than ICD-9, otherwise they wouldn't have implemented ICD-10.

DR. PINCUS: I just want to reemphasize the points that were made there because it is not just about the coding and classification itself, but it is about the instructions for how to use it and the rules associated with it, that may be at least as important. That is something that we have to consider because there is a whole sort of large volume about instructions for use that comes with the ICD that is important.

Secondly, I think it is also important to think about the various use cases in terms of as you were going through the evolution of ICD-8, to 9, to 10, and so on. One of the biggest changes has been the use case – the types of use cases has vastly multiplied and that has really had a big impact both in terms of the structure of the classifications, but also in terms of how it is used and misused in terms of thinking about its importance for example, for reimbursement. Its importance for disability determination. Its importance for quality and safety measurement.

All of these things have impacted on the use in ways that were never intended way back with ICD-8, which was mostly looking at mortality from that point of view.

DR. WATZLAF: First I wanted to tell you that was a very nice review that you did. So thank you for that. I just wondered, with some of your broad topic areas, did you

look at technology that went in the changes that the coders may use in technology? Did that go across those areas or was that something that you wanted to pick out separately?

DR. KUSNOOR: With the technology changes, we did not see that teased apart for these types of outcomes – how that was impacting them.

DR. WATZLAF: The other thing I was wondering, if you saw any differences as far as the coder characteristics like their experience, their education, their credentials, that kind of thing? Did that come up at all?

DR. KUSNOOR: There just wasn’t data on that. A lot of the data that I talked about, so there were studies looking at the impact on training. So those are going to be with people that don’t have experience in reporting their accuracy.

DR. WATZLAF: Do you remember if that was pulled out – I guess is my question.

DR. KUSNOOR: I would need to go back and check. We have described everything thing that we did find in our full report. So I would feel more comfortable looking back at it before telling you something.

DR. WATZLAF: And I can look at it.

DR. KUSNOOR: Yes, you have it as well.

DR. ROMANO: Dr. Stead said something earlier, the implementation cost of ICD-10 ended up being an order of

magnitude greater than what was anticipated. I think you cited Blue Cross in that. Did that come up in your literature review? I was wondering sort of what the source of that order of magnitude estimate was?

DR. STEAD: That is me. If you look at what the RAND study said, and I think its upper limit was what $7 billion? I think it was $700 million to $7 billion. I know what Vanderbilt spent. It was off by an order of magnitude.

The real take-home I get from the literature review is to me it is mind boggling that this country, not to mention the world, would implement something that costs billions and took years, and there is no data. It has not been evaluated at any sense of scale. That is stunning.

And so what I take from this really, it never crossed my mind when we set out to do this that we wouldn't find useful answers. So what I take away from it is as we figure out these research questions, and they do need to be based, I think, on use cases for example, but as we figure them out can we frame them in a way that would allow the evaluation we do as we get ready and figure out how to tune the implementation, to actually be the basis for the learning iterative feedback and evaluation that would be a learning system.

Can we in essence, begin to frame the questions that will build and inform self-correction so that when

somebody is here thinking about ICD-12, you have a very different set of data, much as computability foundation of ICD-11 presents a very different thing.

I just think, there is something about the fact that the country hasn't evaluated this, it tells us something about this whole ecosystem that I, at least, have not appreciated.

MR. LANDEN: We have got two more questions in the room then we will go to the phone. Denise.

MS. LOVE: Thank you. I think measuring cost is going to be overwhelmingly difficult because we can't really get a handle on what we are spending on health care in macro level, or even primary care. I think that will have to be thought through.

One of the metrics going forward, I just wanted to raise a question, could be a reduction in the number of measures that have to be abstracted and calculated as a cost/benefit for ICD-11 going forward, because I think that is a huge impetus and cost savings for any future coding.

MS. KLOSS: Thank you. Again, I thank you for this research and share everyone's surprise that there has not been more deliberate study of these important issues.

NCVHS made a recommendation, a deliberate recommendation, to CMS that plans be made to evaluate the impact of ICD after implementation. But when I think about

when we did that, it was kind of in the middle of the delay cycle. Everyone was kind of focused on that rather than what happens after – after implementation occurs.

So I think going back to the timeline, your are right, this is kind of the 2002 moment and this is when the expectation of evaluation should begin.

Second point, I suspect that the evaluations will continue to trickle out. That is it may yet be too soon to really understand what the full impact of this has been on construction of DRG groupings or reimbursement. So I think that there perhaps is some recommendation that could be made that this continue to be evaluated now. You have started something, but I think we are just probably at the early side of it.

MR. LANDEN: Any questions from the participants on the phone? Hearing none from the phone, one last one in the room.

DR. BROWN: I was wondering if you found anything that defined the constituency that was impacted by the change and attempted to quantify it? Also, if you found any evidence of impacts on those constituencies – say like, front line clinicians. I would expect that the very bottom of the pyramid of those impacted would be every doc, every clinic, using it every day.

Where is that? I am not at all, frankly, not at all surprised, given the attention that we have discussed even to this moment, on that, that it was off by a power of ten, frankly.

I guess the other thing I would want to ask is – any impacts on repair and reconfiguration of information systems. So for all the uses in decision support and the like, where reporting and the like were – these codes, these serialized codes were updated, changed widely. Does anyone have any idea?

DR. KUSNOOR: So for your question about the different constituencies that were impacted – so there were those large survey studies that we had identified. So those were surveys of physician practices. There was also a survey of billing companies. So they had reported on several different outcomes there.

So for your other question, I am not sure. So about the systems that were used, we did not find much on that particular issue.

DR. MCDONALD: I was in the room when the decision was made to go to ICD-10. It was not – I don't want to say this wrong – but it was not the most rational process. It was decided by one strong personality. It was tipping back and forth. Worse, it was chosen because of the coding for procedures, which it did not actually get to. That was the

big damning feature of the current ICD-9, that only had 3,000 code for procedures.

So it is an interesting world, but it happens across the board, not just with ICD-9 and ICD-10 coding.

MR. LANDEN: Anytime anyone uses the word "rational" with US healthcare system, --

Dr. Kusnoor, thank you very, very much and your team for the research you have done. We will go to a 15 minute break. If you would, we will resume at 10:40 a.m.

(Break)

MR. LANDEN: I think we are ready to start up again. It is my pleasure for the second half of the morning to introduce Donna Pickett from the National Center for Health Statistics and also Bob Anderson, National Center for Health Statistics. Donna, I think you are going to be the lead speaker here. First up anyway.

MS. PICKETT: Good morning, everyone. We are going to give you the highlights of some of the changes between ICD-10 and ICD-11 and some of the development history. Some of you may have seen the slides that were presented at the June Full Committee Meeting and you also would have received it in your pre-read. Again, due to the length of time, we really cannot do a deep dive, as many of you know. We can do three hours easily just on some on the basic concepts related to ICD-11, but that is not our purpose

here today. Again, we are looking to do the highlights and I will try to cover some of the history of it. Bob will be covering mortality specific, which I am very happy to have Bob doing that because I think there is probably less knowledge about the mortality implementation of ICD-10 in the US.

For those who really are interested in the mortality side and have not had an opportunity to hear that side of the pathway because many of you as we work together because I have worked with many of you in the room, we have always pretty much focused on the morbidity side. Bob will be covering in detail some of the information about the mortality side.

For those who have followed National Committee and NCHS presentations before, this slide looks very familiar I am sure because we use it all the time. The new item at the bottom, however, is ICD-11. Again, it was adopted this year by the World Health Assembly in May. But of course, the columns for the year of implementation for mortality and morbidity are question marks because that is partly what we are here to talk about are what are the pathways particularly for morbidity. Again, mortality will have a slightly different pathway and is not a HIPAA-covered standard.

History. ICD-10. Everybody knows it has been around for a while. Yes, the US for morbidity purposes just implemented October 1, 2015. Other countries though have a longer history in the use of ICD-10. As you can see, its effective date is 1993. Again, it has been more than 25 years since people have been using it in other countries and for mortality here in the US since 1999.

Needless to say with the history of the use of ICD-10, changes have been recommended to ICD-10 through the useful history, some of which could not be accommodated in ICD-10 because it would have made major structural changes, which is typically not done within a particular revision. Capture advances in health science and medical practice. Improve integration with other classifications and terminologies were also a key goal. Address persistent major gaps in basic use for mortality statistics, but also a nod toward the expanded use for morbidity purposes. It goes well beyond.

As people have mentioned earlier, it does go beyond inpatient acute care hospital use. It now at least for the US is inpatient, outpatient, rehab, home health. If there is a use for ICD coded data related to diagnosis, ICD has been the code set for use in that regard. Again, this is a little different for many countries. Currently, maybe using it for inpatient acute care only. Some who are now

migrating toward also using for physician office and some outpatient. But in terms of the expanded use for how we use it in the United States, it is quite different from many countries.

This is just a visual of one of the intents of ICD-11 and how it is intended to be better integrated with classifications and terminologies including terminologies such as SNOMED-CT. But also some of the other classification for which WHO is responsible, which includes the International Classification of Functioning and Disabilities, also the developmental of an International Classification for Health Interventions, which is a procedure coding system for international use.

You will also see derived classifications. Some of those are derived directly from ICD-10, but expanded. And some of them also contain expanded detail in terms of its usage like the application for neurology.

The development process included the standing of cross-cutting topic advisory groups basically set up by specialty or by chapter. But content was built around a foundation layer with descriptions of what is contained in that particular concept and then there are the content model parameters.

For structure, again, when looking at the various versions that can be derived from ICD-11 from the

foundation, it is focusing on mortality, morbidity, primary care, and quality/patient safety.

After the sun setting of the cross-cutting topic advisory groups, the Joint Task Force was stood up and that Joint Task Force was comprised of the mortality and morbidity experts including statistical experts.

US involvement. This was a question that came up at last June's meeting. We have expanded it a bit so that we can recognize some of the other US participants. Chris, you had included as part of his introduction. Chris was the chair of the Revision Steering Group. I had the pleasure of serving on the Small Executive Group out of RSG. Bob Anderson was co-chair of the Mortality TAG. Cille Kennedy from ASPE, located here in this building, was co-chair of the Functioning and Disability Topic Advisory Group. And from the US, we also had a co-chair for the Pediatrics TAG from the American Academy of Pediatrics. And we also had a co-chair for Quality Patient Safety who introduced himself earlier, Dr. Harold Pincus. The Joint Task Force was a sunsetted, I believe, at the end of last year. But again, we had broad US participation, not only in the chair functions, but in some of the member functions and also within some of the topic advisory groups.

The ICD-11 Foundation. That is the principle of how the classification was started as opposed to what was

done with past revisions of the ICD where you sort of looked at a version eight and you crafted a revision nine. This was a different take on how things were developed. It started with a foundation layer, which represents the knowledge base for the reference and derived classifications. It has flexibility built into it.

Somebody mentioned ICD-12. ICD-11 has been built in such a way that there will not be an ICD-12. ICD-11 can be expanded. You will have updates to ICD-11, but highlight doubtful if there will be an "ICD-12". If I am wrong, Dr. Chute can correct me on that, as can Dr. Pincus and others who are in the room that are involved in the process. But the 10-year, 12, 15-year cycle of the past is not intended to be perpetuated going forward.

Consistency. All derived classifications will be consistent with the terms of the knowledge base so that everything will be consistent in terms of its development, its expansion and its understanding and its output.

This is a new slide from what was presented at the June meeting. Many of you asked for more detail about what is the foundation layer. The slide lays out for you the 13 or so concepts that are part of the content model with the ICD concept title, the classification properties, the body structure, the manifestation properties, temporal properties, et cetera. This gives you a thumbnail sketch of

what is included in terms of when a concept is built. What is that foundation? What does it look like?

Basically, a visual of other fundamental foundation elements of ICD-11 with clinical terminology being at basically the core of the work that was done leading to the foundation layer and then you see how the reference classifications are then further subdivided into the derived statistical classifications and tabulations.

Major differences. Again, just some quick thumbnail highlights here. This is not the devil is in the details deep dive. A simplified code structure for your stem codes with a new section for extension codes to add that level of detail that people really want to see for various use cases. And then a new convention for clustering of the codes to show the relationships between the stem code and other codes such as manifestations and how they relate to each other as opposed to just a serial listing of all of the codes that are being assigned for a given patient and their underlying cause and their comorbidities and manifestations, which brings us to the morbidity and mortality statistics classification, which is derived from the foundation component as described earlier.

It does incorporate advances in science and medicine. It has a better representation for public health prevention. And where possible, there was structural

consistency with ICD-10 particularly for those who are looking at the trending of information, which is particularly important for mortality.

And WHO does believe that the migration is expected to be cheaper than previous migrations due to the automation and new tools that have been developed as part of ICD-11.

Another visual to help you understand where things have occurred. New methods. Conventions have been developed for ICD-11. Instead of having many codes that are pre-coordinated, codes really will now be post-coordinated so you will have a stem code with extension codes and other codes to really fully identify the clinical picture of the patient.

Sanctioning rules have been built in so that you cannot create an idiot code, as some of us like to define it. That you cannot do this with that unless it is something that is allowable based on the structure and conventions and the foundation layer of the classification.

Multiple parenting is included; however, in terms of developing a classification, codes are assigned to a particular chapter, as you are familiar with it now. But in the foundation layer, there is multi-parenting.

New chapters. Disorders of the immune system. Blood forming organs. Sleep-wake disorders. A new section

for traditional medicine, which is something that only those interested in using it, will be using it. It is not a mandated required portion of the classification.

Extension codes, which are optional. I do have a slide that describes the extension codes. Some chapters have been restructured obviously based on advances in knowledge and medicine. And some diseases have been relocated. For instance, some that were in mental health chapter may now be in the nervous system chapter.

There is a change in structure. Again, I will not go through all of the details here, but it is part of the materials that you had, as your pre-read.

One of the new sections. The extension codes. Again, the rationale behind the extension codes is to provide more detailed information and not repeat what is already in a stem code. For instance, if you have a concept that does not describe whether the condition is acute, subacute, or chronic, there are extension codes that can provide you that information that would be used an additional code and not pre-coordinated into the primary concept itself. You have type 1 extension codes and you have the list before you and then the type 2 extension codes.

Some examples here for diagnosis timing. You have present on admission, developed after admission, or

uncertain timing of onset relative to admission. These are extension codes in ICD-11, but many of you will know that the present on admission codes are captured a different way currently in the US in our data collection systems. They are not built into the ICD. One of the decision points that would need to be made as part of discussions about ICD-11 is whether you would want to keep the existing system for how POA is gathered or whether there is a need to perhaps move to what is captured with the codes and ICD-11. Again, a key point there in terms of decision making will be if the definitions that are used by WHO in the extension codes in identifying diagnosis timing are consistent with the values and definitions that are currently used in the US for capture of present on admission.

Diagnosis typing is a new feature that has been included in the extension codes and it is to identify for each code that has been assigned whether it is the main condition, whether it is the reason for the encounter, whether it is a main resource condition or is the initial reason for encounter or the admission.

Diagnosis method confirmation. Again, a number of ways of identifying for a given condition how that diagnosis was established.

WHO, on their website, has the number of resources, which includes the coding tool for ease of look

up. There is a browser version of ICD-11 on the website. There are output files and a print version, which some people really do like even though we are moving to a more totally electronic environment. There are still countries that maybe are not as advanced technologically and would still have value in using a print version and that can be printed from the WHO website.

WHO also has for the first time included a number of resources, advocacy materials, training materials, quick guides, maps and a training and test platform. Again, these are new with the advent of ICD-11. None of these tools primarily were available with the implementation of ICD-10.

We have, as I have identified, now have the World Health Assembly's approval and adoption of ICD-11. But WHO has noted that even though the effective date is part of the resolution is January 2022, they do acknowledge that this will not happen overnight. While there may be many early adopters, not many countries are likely to adopt that quickly just because of things that are – resources availability within a given country, how widespread the classification may be used. Some countries only use it for mortality. They may not be using it yet for morbidity applications. And at the other end of the spectrum, you have countries like the US who have a widespread use of the classification and therefore the roll out may take more

time because bodies like this may need to talk about the research questions and the implementation implications, et cetera, before actually moving toward implementation and rule making related to that implementation.

But, again, that is really not quite new. If you look at what happened with the advent of ICD-10, the effective date was January 1993. I just give you morbidity examples here where even though the effective date was 1993, the realization was each country has within their capacity and their resources, they may have a different roll out based on their use and adoption practices and legislative and regulatory authorities.

WHO also has now engineered a new and a robust update of the classification. It replaces the update and reference committee that was in place for the update of ICD-10. Off on the side, you can see there is the CSAC with the morbidity and mortality reference groups, the functioning and disability reference groups and other groups, feeding into the process. As was noted by Dr. Chute earlier, he is co-chair of the overarching group that will be looking at this and that is the MSAC and there is another group that will be participating in the process. There will be annual updates. The update cycle has been laid out in the reference guide that WHO has posted on the website.

With that, I will turn it over to Bob to talk about the mortality implications for the US.

DR. ANDERSON: Thanks Donna. I do want to talk specifically about mortality because the way the sausage is made is substantially different for mortality statistics than it is for morbidity.

Now, Bill mentioned earlier in his remarks that with regard to mortality, it is not about if we implement. It is more about when. And the main reason for that and I put this Article 2 of the WHO Nomenclature Regulations up here as a signatory to these regulations. The United States has agreed to use the most current version of the ICD. And for mortality at least, we are committed to fulfilling our obligations with regard to that.

And the main reason is that WHO collects mortality statistics from all of the WHO member countries and compiles them into a database. They need to be comparable. We need to be using the same revision of the ICD.

We do use the international version of ICD-10 of any version of the ICD for mortality statistics. We do not use the clinical modifications. We do not use ICD-10-CM. We use the international version of ICD-10.

And then we adhere to the standardized coding and selection rules in order, again, to promote international comparability.

We are also involved with some international collaborations, the Mortality Reference Group, which I co-chair, currently is responsible for making decisions and recommending changes to the ICD specifically for mortality and to WHO and also to make recommendations about changes to the coding and selection rules.

And then the Iris Core Group is an international collaboration that is concerned with automated coding. Iris is an automated coding system very similar to what we use in the United States. It is used in many of the European countries currently. Basically, we work with the Iris Core Group to standardize automated coding internationally.

As I mentioned for mortality, the way we get the data is substantially different. I just show this to give you an idea of how the data get into a national data file. With regard to cause of death, it is medical examiners and coroners and physicians that provide the cause of death information. They report that on a death certificate. Once that is registered by the state, it is then sent to us. We code the information and then we compile it into a data file. We send information back to the state as well and then we do a whole lot of stuff with it once it is coded.

This is what the standard death certificate looks like and this is where the information that results in ICD codes is reported. You have two parts of the main cause of death section. Part 1 is the causal sequence leading to death. Part 2 are contributing conditions and then there is this other section down here for injury-related deaths for more detail.

All of this information is used and coded if a code is applicable. And then we go through the process of selecting an underlying cause of death once all of the information is coded.

I will also mention here that the information reported in these fields whether electronic or on paper is free text. The certifier does not report in the form of codes. They do not put encoded information. All of that coding is done by us at NCHS. That is the first bullet here.

We do all of the coding as of January 1, 2011. All of the coding is centralized at NCHS. In the past, some states did their own coding and would pass coding information onto us. But we found because of fluctuating resources at the state level, we were having to take on a lot of the coding for states on short notice. We decided it would be just easier for us to take that on. That is what we did.

The coding is largely automated, using the Mortality Medical Data System software. This reads the free text. It assigns the appropriate codes and selects the underlying cause of death.

About 75 percent of records currently are coded automatically. About 25 percent require some manual intervention. But all records go through the system. Even those that require manual intervention once that is done, it goes back into the system mainly for underlying cause selection.

All information that is reported on the death certificate is coded if a code can be assigned and we code it and we store it. We put it into our data file. All of that information is available. No information is lost.

I will also mention that we do return coded information back to the states. I put this in here. There is a perception very often that coding is a very lengthy process on the mortality side. It takes a very long time to get coded information. And that did use to be the case, but it is no longer the case. For records that can be automatically coded, we typically turn those around in one day. We send it back to the states. It is in our files. It is in our databases. For those that require manual intervention, it may take one to two weeks depending on our

backlog. The mortality data – the coding part of it is really quite timely nowadays.

We did an assessment. We collaborated with the Joint Task Force to do an assessment for mortality statistics. This was done for morbidity statistics largely as well. I am mainly familiar with a mortality assessment so I will only really talk about that.

We did some line coding, which was just coding medical terms reported on the death certificate. We did quite a lot of that in order to assess the content of ICD-11 and also to assess the coding tool to make sure that the entities that are being typically reported on death certificates had a code that we could assign to them. Initially, when we started out, there were some problems, but those have since been corrected and actually ICD-11 seems fit for purpose nowadays for mortality.

We did quite a lot of work with the taskforce as well to make sure that this was the case. We really think at this point that ICD-11 is fit for purpose for mortality. Depending on the morbidity applications, I think many morbidity applications are also fit for purpose. There may be some other issues related to morbidity that will still have to be addressed. But for mortality, I think we could make a transition.

With regard to implementation for mortality, these are the things that have to be done. We have to revise our automated coding system and the decision tables. And really the heavy lift there is the decision tables and I will talk about that in a minute.

We have to retrain our nosologists and medical coders. There is going to be some revision of computer edits and database specifications in order to accommodate the new format.

We have to revise our tabulation lists and table programming. We have to do a bridge coding study. We will do that, similar to what we did for ICD-9 to ICD-10. And of course, we are going to have to promote this to our users so that they understand what it is that they are getting because it will be different.

With regard to timing of implementation, I get asked this question a lot. When are we going to implement this for mortality? We are still not quite sure. But just to give you some history, we did implement ICD-10 in 1999. That was seven years from the publication of the tabular list. I will mention that the index was not published until 1994. We really could not implement ICD-10 until we had the index. That really was a five-year timeframe from the time the index was published. We started the process in 1989. We started planning in 1989. And then we began work on the

revision of the automated coding system. There were some delays associated with that. There were some issues with the contractor, but also many of you will remember that the early '90s was the time when PCs – we were trying to make a transition from mainframe processing to PC processing. But in the early '90s, you had this transition from DOS-based PCs to Windows-based PCs. We ended up having to start over to re-do things for Windows instead of DOS. That is one of the reasons why this took the amount of time that it did.

As I mentioned, most of the time and expense involved revision of MMDS. Our original plan was to implement in 1996. We had to push that to 1998 and then we pushed it to 1999 and then we finally implemented that.

For ICD-11, we are beginning the process, getting the planning process, trying to figure out what it is going to take. As I mentioned, the heavy lift here really is revision of the decision tables. At this point, we are collaborating with the Iris Institute, the Iris Core Group to do this. We are trying to pool resources because it is going to be fairly expensive and take a fair amount of time.

At this point, I think it will probably take us about four years to revise the automated coding systems. The decision tables that are used to select the underlying

cause of death are very complex and it is not a simple matter of just replacing code for code in those tables.

In addition, the ICD-10 tables when they were created were created fairly quickly. We are finding errors in those tables as well. It has to be checked carefully and done thoroughly.

And then we have to complete a bridge coding study and get all that other work. We figure an additional one to two years to do that work. I figure probably six years. I do not want to say six years from now because I do not want to be on the hook if it takes longer than that. But I would say that I do not think that we could implement any earlier than about six years from now. That is, I think, probably the best we can do.

I will turn the time back to Donna to finish up the morbidity part of this.

MS. PICKETT: Implications for ICD-11 for morbidity. Again, as was covered off very nicely in the earlier timeline slide, licensing copyright is an important issue that will be part of the early on discussions.

As was mentioned in the 1990 National Committee Report, there is no single government use of the classification. It is ubiquitous in health care, but not only is it used in federal systems, but it is used in private sector systems. All stakeholders will have interest

in this and the potential impact. Vendor implications, code book publishers, data systems. You all know the list because you are all stakeholders in this endeavor. That will be a very large involved conversation.

Also, WHO has indicated that they would like to limit the development of national modifications. Thinking back to ICD-9-CM, 9-CM at one point was the only clinical modification. Other countries adopted or adapted ICD-9-CM. Canada, Australia, et cetera. With ICD-10, one partially doing to the delays of implementing 10-CM in this country and because there were national needs that were not addressed by a US modification, many countries developed clinical modifications of ICD-10. There is probably about two dozen at this point. France, Germany, Australia. There is quite a long list, but you also have countries that did not necessarily have the wherewithal to create their own national modification and adopted another country's national modification. You have much widespread use of national modifications.

Well, of course, that has created some disconnects in understanding of various diseases because different countries may have handled an expansion differently. They definitely can all map to each other more or less. But if you wanted to take a base classification to try to make sense of the data that is coming from it with

20 or so modifications that becomes quite challenging. And for those of you who have worked in the area of quality and patient safety, there has been a lot of review on how that has impacted understanding of injury prevention and injury surveillance because of the nuanced differences in some of the national modifications.

But, again, we have a regulatory process here that sort of behooves us to update at least twice a year and for national purposes. There will be discussions with WHO further on that issue. There has not been full out discussions with any of the countries that we are aware of that have national modifications with WHO as to how things will proceed in this regard.

Concept coverage following the June meeting. There were questions that came to us about does ICD-11 cover everything. While the initial work by WHO was intended to capture what truly was already in many of the national modifications, as each country including the US has continued to update their national modifications, there may be some gaps in the content coverage. Some of these slides are a little bit older so they likely need to be updated. Thank you, Dr. Chute, for pointing that out.

But, again, as you can see here, there were things that were included in ICD-9-CM that were ultimately rolled into 10-CM that were not in 10 and are maybe only

partially covered now in ICD-11. Definitely discussions will occur as to what needs to happen next. No decisions have been made because we need the input of the stakeholders to advance that work.

The second slide basically shows similar concepts except what we are doing now since we are still actively updating ICD-10-CM, we are getting new proposals from subject matter experts, clinical groups, et cetera, and checking to see if that concept is represented in 11. We are finding some gaps there too. That does not mean they cannot be brought to WHO for an update to ICD-11, but whether their update cycle will really work with the needs of the US and its public health needs is another issue that would need to be worked out.

Implementing ICD-10-CM for morbidity. Again, not only are there discussions that need to be had about content coverage, but also what changes may be necessary to the existing standards, which are used currently to conduct transactions such as X12, NCPDP, et cetera.

The structure, the syntax, the conventions, the addition of extensions for the ICD stem codes. Again, all of this has bearing on what might change in a world of X12 and other standards that transport the ICD codes.

Also, accommodating post coordination and clustering and keeping the codes together that are

meaningful for a patient encounter so that you know which things go with which or which things cause something so that for patient safety and quality purposes, you have an idea that this particular device caused this particular condition in this particular patient and how those work together because currently in our data systems, those are not identified as a cluster. Without sometimes going back and doing audit, you cannot determine what the structure is and what the data is telling them.

This is a cut down version of that lengthy timeline that you had in your pre-reads. But, again, basically, we did an evaluation of 10 to see if it was fit for purpose to replace 9-CM. That took place over a three-year period.

We had the National Committee hearings between 1997 and 2003. And then NPRM Final Rule and Interim Rule. That was the lay of the land for moving toward 10-CM implementation.

Of course, also caught up in the middle of this was HIPAA and the fact that we went through two cycles of adoption, the de facto standards being the initial standards adopted, then moving to 10-CM and 10-PCS. Hopefully, we will not have other challenges in the middle that may delay or prolong discussions related to possible implementation.

Again, lots of to be determined here because I think while we will learn much from what has come before us in terms of history with implementing 10-CM and 10-PCS, I think today's two-day meeting will help us understand some of the research questions and some of the other important issues that need to be laid out perhaps in advance of actually having hearings, but definitely contribute toward letters of recommendation that may go from the committee forward to the secretary regarding adoption of ICD-11.

With that, I will turn it back over to Rich.

MR. LANDEN: Thank you. With an eye on the clock, I think I will ask you to hold your questions for Donna and Bob until after the next presentation, which will be Olivier Bodenreider, who will talk more about the technical. And I believe Dr. Bodenreider is going to have a portion where Dr. Chute will participate here.

DR. BODENREIDER: Thank you. I am essentially going to say everything that I said, again, so it should be easy and quick. The work that I am presenting is essentially Kin Wah Fung's work done in preparation with Julia Xu and Kin Wah, would have presented if he had not been out of town today.

We are looking at two different things here. We are looking at 11 versus 10 and we are looking at 11 versus 10-CM, pointing again that when game changer is going to be

post-coordination, which we did not have before. I am going to try and see whether post-coordination can increase granularity enough that it could make 11 a replacement for 10-CM.

Let us look at 11 versus 10. We use the same data files, the same materials that Donna talked about already. The one thing that we have been using that Donna has not talked about too much are the maps because that is also a new thing. It was not the case before, but WHO provided maps between 10 and 11. And of course, mapping is complicated. There is directionality to mapping. There is a 10 to 11 map. There is an 11 to 10 map. And in the 10 to 11, there are actually two different maps. One is when you want to map to one category only and the other one is when you are allowed to map to several categories. I am pointing this out because we will take advantage of these maps.

We have also taken advantage of the coding tool and the browser that is made available by WHO. And for the comparison to 10-CM, we use the 2019 version that is already available. Because we are from NLM where we developed the Unified Medical Language System, we have also used the UMLS tools for mapping in the 10-CM study where we do not have maps actually. We have maps for 10, but we do not have maps for 10-CM.

Let us look at the size difference between 10 and 11. I am distinguishing between codes that are used essentially for navigation purposes, the intermediary codes versus the codes that are used for coding purposes that are essentially at the bottom of hierarchies if you wish. And what you can see here is that there are about 14,000 codes that can be used for coding purposes in 11 and that is about a 20 percent increase over the codes that were useful for coding purposes in 10. Because these codes are the most important at least for coding purposes, we are only focusing on those codes in subsequent analysis.

It is usually difficult to figure out what has changed between the versions. It is greatly facilitated in this case by the publication of the maps that I have talked about. We really leveraged these maps.

Of course, what has changed is the structure of the codes themselves, but that is rather an important, if you wish, in the sense that it is just the numbers that you use for coding purposes.

For us to understand the mapping between 10 and 11, I think it is easier to start with an example. This is the 10 to 11 map. I take acute bronchitis as an example. And the 10 to 11 maps tells us, for example, that acute bronchitis due to Streptococcus was there in 11 -- is still there under a different code in – was there in 10 – is

still there under a different code in 11. And that is the case for a bunch of others.

What is interesting is that acute bronchitis, the J20, according to the map is mapped to acute bronchitis unspecified and so are acute bronchitis due to other specific organisms and acute bronchitis unspecified all map to acute bronchitis and specified. I am not making this up. This comes out of the maps as surprising as it may look in some cases, especially due to other specified organisms that maps to unspecified.

Also interesting is that mycoplasma and echovirus map also to unspecified rather than maybe other specified acute bronchitis as we could have expected. That is what the map tells us. That is the narration of the map, if you wish.

There is another map from 11 to 10. This was 10 to 11. 11 to 10 is provided in another map. You can see that 11 maps relatively nicely to 10. Acute bronchitis unspecified in 11 maps to the broader code acute bronchitis – other specified acute bronchitis maps due to other specified organisms, which makes sense. This is the map again. This is at is provided.

We leverage these two maps. To derive the notion of an equivalence in the sense that if this code in 10 maps to 11 and this 11 code maps back to the 10 code that we

started with, we consider this an equivalency. That is a round trip mapping. And we consider it an equivalence. That is what we do in this case. That is just saying the same thing.

And based on this round trip equivalence, we were able to identify 48 handwritten codes that are equivalent or supposedly equivalent based on this method between 10 and 11.

This is a sample of these codes. You might be surprised as Donna and I were when we looked at this earlier that acute bronchitis maps to acute bronchitis and specified or is set to be equivalent to the unspecified version. But you understand how it came to be in the previous use of the maps. We need to take this notion of equivalence with a grain of salt and know how it has been provided.

These are other examples of equivalent codes. What we can see is that in some cases, we go from having the very same description to having slightly different descriptions. Sometimes the description in 10 seemed finer grain than the description in 11. In other cases, it is the other way around. In other cases, the two descriptions seemed just slightly different.

When we look at these changes, out of the 12,000 codes in 10 and the 14,000 in 11, restricted dose codes

used for coding purposes. We have 48 handwritten of these codes that are incoming or that represent equivalence defined as we define it earlier. Of course, not being validated manually. But that just gives you the proportion of what remains without direct equivalence, which would be 60 percent of 10 and 67 percent of 11.

Of course, we can look at these things by chapter and we can look at the proportion of equivalent codes by chapter. We will see that pregnancy, the symptoms chapter, factors influencing health status and the perinatal period and also the respiratory system all have over 50 percent of equivalent codes. And the chapters that appear at the bottom including neoplasms, including skin and subcutaneous tissue have much fewer equivalent codes in proportion.

Donna alluded to changes in chapters, which we call chapter shifts. This happens when codes that were in one chapter in 10 move to a different chapter in 11. Of course, this reflects different organizational principles. It is possible to do a precise analysis by looking at the equivalent codes and looking at where they went.

Now, as mentioned before, there are new chapters. And some of these new chapters were split from earlier chapters in 10. We did look very closely at traditional medicine conditions or the extension codes for the purpose of this particular study.

You can create a matrix between the codes that were in 10 in a given chapter and where they went in 11. I have more slides on this, but in the interest of time, I am not getting into the specifics of what has moved where and just the notion that there are new chapters and that some of these chapters were split in some ways or that some of the codes have migrated is probably enough for what we have time for right now.

We are going to switch from 11 to 10 to 11 to 10-CM. And of course, when we do 11 to 10-CM, we do not have because CM is specific to the US. We do not have the nice maps that WHO provided between 11 and 10. We are kind of on our own to do the comparisons in this case.

When we look at the number of codes, there is a huge difference between the 14,000 that I mentioned for 11, and the over 70,000 that we know are in 10-CM. However, when we say for 14,000, we only look at the pre-coordinated codes. We have not explored post-coordination yet. And of course, because of post-coordination, because we can put together, we can build our own codes, if you wish, in many cases, it increases by a large proportion the number of codes that we can – the number of diagnoses that we can express, for example, compared to what is pre-coordinated.

I am not saying that post-coordination is easy and will solve all our problems. It is just a possibility that is going there.

Going back to what was mentioned earlier, it is certainly something that is going to need to be supported by informatics because post-coordination is hard to do. If there is not IT support for post-coordination, we are going to end up with a lot of nonsense. It is not just stitching things together. It is creating codes that follow some pre-specified grammar and this grammar is going to need to be enforced by IT support.

There are two kinds of post-coordination, as Donna mentioned earlier. We can coordinate stem codes with a slash and we can extend stem codes with extension codes so stem code plus extension code connected with an ampersand. That is to add a specific location or a specific laterality, what is covered by the extension codes in general.

Because we are on our own, we do not have these maps to go between 11 and 10-CM. We do what we know best, which is that we use the normalization tools that are provided with the Unified Medical Language System. And these tools help us not only build the UMLS, but they help us compare terms because they abstract a way from language variation that we find in medical terminologies. If we run

the terms from 10-CM and we run the terms from 11, we can find which terms are close enough together based on after normalization, if you wish.

We did this and we found – we run the 32 hand(?) terms. I am going to get into the results a little bit later. That is the kind of things that we found as lexical matches. The terms are different, but after normalization, they normalize the same and there are potentially synonymous, for example.

Again, here, we find cases where a term and the same unspecified terms map together. This is on purpose because unspecified is one of these words that get removed by the normalization process.

We do this when we build the UMLS because the fact that something is unspecified does not really change what the thing is in the first place. It is not an ontological difference. It is an epistemological difference. It is what we know about the thing. It is not what the thing is in the first place. I am not suggesting that they are equivalent for coding. I do not want you to start throwing things at me. I am suggesting that from what they denote, they are equivalent in their meaning.

We also did some manual matching because there is only so much that we could bring together through normalization, through automated lexical processes. We did

some manual matches to see whether the code in 11 could be expressed or the code in 10-CM could be expressed in 11, using all the tricks including post-coordination and including – with multiple stem codes and with extension codes.

The goal was to determine whether the code in 10-CM could be fully represented in 11 by a pre-coordinated code, could be fully represented by post-coordination or could only be partially represented despite all the post-coordination that we can throw at it. We took six examples and I am going to go through these examples quickly as illustration. Of course, that is not an exhaustive study.

We started with tuberculosis. There are 51 codes under tuberculosis. Of these 51, 23 could be represented directly through post-coordination, again, with the caveat that we do not – we consider the unspecified the same thing as the one that is specified, but you get the idea at this point.

We found that 28 required post-coordination for a full representation, for example, tuberculosis enteritis. We can represent with tuberculosis enteritis of the digestive system and post-coordinate the small intestine as the location of the enteritis. We could do the same thing for keratitis. We need to post-coordinate cornea, in this particular case. Tuberculosis. Pretty good.

Skin cancer. Out of the 100 and so codes for skin cancer, we were able to represent five by direct pre-coordination. The majority of them, 92 using post-coordination. And not surprisingly most often what we need to post-coordinate is the location. And four of them, which is for a person, not too bad. There are elements that we are unable to represent because the notion of overlapping sites, for example, was not something that was available through the extensions.

Diabetes mellitus type 2. 86 codes. One could be represented directly by pre-coordination. The majority, 60, could be represented through post-coordination and that is typically with the complications. For example, when you can represent two stem codes, one for the main diabetes, one for the complication. And 25 could be on the partially represented and an example is the oral complications of diabetes.

Hypertension. 17 codes. 5 pre-coordinated can be represented pre-coordination. 9 through post-coordination. And three codes could only be represented partially because there was no notion for renovascular available through the extension codes.

Polyhydramnios. It gets complicated here because 10-CM goes overboard. That is the technical term to say that there are a lot of possibilities in there. They

provide representation for the trimester with four values and which fetus is affected with seven values. Only some of this can be represented in 11 because there is no notion of trimester or multiple fetuses.

Fracture of thumb. It goes well when we want to represent laterality because we can do this through the extension codes. Location. Same thing. Type of fracture. Same thing. The displacements can be represented. The healing can be represented. However, the episode of care whether it is the first visit or a subsequent visit, something like this. There is no such element in the extension codes to represent these things. Not suggesting that there should be. I am just suggesting that it is not there. And that is what gets in the way of representing some – fully representing 10-CM with 11.

When we look at these six cases that we took for illustration, we found that out of 400 codes roughly, 9 percent could be represented with full coordination, fully represented three full pre-coordination. 50 percent could be fully represented through post-coordination and 43 percent could not be fully represented. There was something missing at some point for the presentation.

And now I am going to turn it over to Chris, who is going to provide the broader comparison of the coverage between 9-CM, 10-CM, and 11.

DR. CHUTE: What I am going to present to you is frankly, work we presented here 25 years ago. I did not want to shock you with new information. This is a re-analysis of what we had done. I remember Simon Cohen was with me at that time and we were all presenting this.

The question at that time – this was the famous CPRI. Many of you remember it. Computerized Patient Record Institute. How well do clinical classifications work? These slides – there is something missing. I had 1994 on the bottom. Anyway, these slides were written in 1994. They have fundamentally been changed.

We collected test from multiple organizations, Kaiser, Mayo, other places. We had inpatient notes, outpatient notes and the like. We had about 4000 annotated – 3000 annotated concepts that were from a 14,000-word corpus, edited by the panel members, distributed by the classification.

Then we had a fairly dorky classification system, but it had the advantage of being simple. We scored this content that was coded by the national panels as not classified, vaguely represented, or represented. We either got it, we did not get it, or we sort of got it was the distinction at that time.

Here is a sample text. You see a young woman underwent a biopsy for a mole. It turned out to be a

superficial spreading melanoma and then characteristics of the underlying disease. This is how that particular case was coded at that time in ICD.

We annotated these things with more detail than we perhaps needed, and we collapsed these annotation semantic types into a much more spare number of semantic types, diagnosis, modifiers, findings, procedures, and others. We deleted procedures from most of our reporting because this was about diagnostic concepts, but procedures are included in the overall total for completeness and fairness.

This is the punchline. In 1996, we represented on ICD-9 and a preliminary presentation on ICD-10. We re-did the ICD-10 presentation in 2012. That was our Health Affairs paper. Admittedly, this version of ICD-10 is the 2012 version of ICD-10. This is not the 2019 version of ICD-10.

But I think the point here is at least for diagnoses, there was no statistical difference between 9 and 10 back in the 2012 analysis. And there is a significant advantage to ICD-11. If we look at the overall – and mind you. This was on data collected in the '90s. The tendency would be to bias towards the null, given that these were old cases not representing modern diagnostic concepts. But nevertheless, if we look at the overall – the

modifiers, not surprisingly, significantly increased with ICD-11. And then the overall of course significantly different even though it includes procedures, which are not coded in ICD-11 or 10 for that matter or 9.

Just for fun, this was the analysis that was redone. I hesitate to say. This is preliminary. The 1996 analysis on SNOMED was done on SNOMED III or SNOMED International. It was known at the time. We redid it of course with SNOMED CT recently. But in fairness, this is very preliminary. We have only had one over-read on SNOMED and I think these scores will improve. I think it is a fair statement to say that there is likely a dispassionate observation is there is likely no statistically significant difference in the diagnoses coding between SNOMED and ICD-11 and arguably no difference in the overall. They are pretty close.

This is just a summary that shows SNOMED, ICD-10, and ICD-11 together. Again, I want to emphasize. These data are preliminary. We are doing an over-read revision. But I think the impression that I want to leave you with is that at least with content coverage on a historical data set that was carefully vetted at that time, the content coverage of ICD-11 is visibly better than ICD-10-CM albeit the 2012 version of ICD-10-CM. I do not think is going to

change a whole lot with the 2019 version and that is all I wanted to say. Thanks.

MR. LANDEN: Let us take the next five minutes and go to questions, again, for all four of our presenters. The process is tilt up your tent and we will call.

DR. ANDERSON: Just a comment for Olivier. I think I know why the three-digit codes are mapping to the unspecified. Normally, when we would code acute bronchitis, for example, we would not use that J20. It is not a valid code for coding. We would code it the fourth digit where the fourth digit is valid. But in some countries, they only use the three digits. They do not use the fourth digits in which case that J20 would be comparable to the unspecified in ICD-11. I think that is what is happening.

DR. MAYS: I want to address my comment to the decision making that is going to go on in terms of ICD-11. Can you talk a little bit more about what that decision making is in terms of how it is going to change? Can you talk a little bit about whether or not you can use technology to improve it to use machine learning or some version of that to actually increase your pattern recognition to maybe even be able to get feedback sooner?

And then in that decision making, is there room for changes? It sounds like we cannot make any changes, but

it sounds like if we learn things, why can't we change before it is 10, 12 years or something?

DR. ANDERSON: You are talking about mainly for mortality. Specifically about mortality. With regard to the decision making on how we go about doing this, we are working through the process of planning it at this point and trying to figure out exactly what we are going to do and how we are going to do it. We have not made any decisions yet as to how that is going to work.

That said, we have already begun to implement some things similar to what you are describing. Our automated coding system, for example, we realize is somewhat old. We have updated it from time to time. But it does need to be completely revamped.

As I mentioned, we are only automatically coding about 75 percent of the records. Out of 2.8 million records a year, that is a substantial number that need manual review. We have begun the process to develop a new automated coding system and it does take advantage of natural language processing machine learning techniques.

Our hope is to get that automated coding percentage up to 95 percent or so. That is what we would really like to do. We are working on that.

And the idea is to build in an easy way to make the transition to ICD-11. That was part of the contract

that we let was they had to be able to do this and get up to – it may have been 92 percent throughput plus it had to be able to be converted to ICD-11 without too much additional effort. We are working on that.

One thing I did not mention that had come up here several times is cost of the transition. The ICD-10 transition cost about $7 million including staff time and everything like that. It is nothing compared to the morbidity side of things, but still in real dollars that is a lot of money and especially for NCHS that is a lot of money. We hope that we will be able to minimize the cost by collaborating the Iris Institute to do the decision tables, for example. Part of the work that we will be doing will be collaborative and will be able to spread the cost among – I think right now it will be among eight countries. Hopefully, it will not be that expensive.

DR. MCDONALD: I have a comment and some questions for you. The comment is that what I was startled by when I looked at in the ICD-11 I could find stuff. I could type in words and find stuff, and that was not possible in previous versions. There are no web lookup things that they have. That is a major added value. But to NCHS – firstly, thanks for correcting my rust conclusion, but also have you looked at any commercial systems? I do not know much about the insides of it, but the medical objects claim to do that

kind of thing for physician's type and then diagnoses and whether that is a pathway, or you compared it at all.

DR. ANDERSON: We have looked at those sorts of things. Because the way morbidity coding is done compared to mortality coding, it just has not really suitable. What we are looking at right now is just we are using some standard natural language processing machine learning software to work on that.

DR. MCDONALD: One other question. Are the tables you use available for incorporation like in your --

DR. ANDERSON: The decision tables that I have been talking about are in our instruction manual Part 2C. If you just Google that, it will come up and you can look at it. It is a PDD form. It is a big PDF. It is a huge set of tables, but you can have a look at it if you would like.

DR. BODENREIDER: If I can add a tiny thing to this, there has been a lot of activity in research recently about death certificates that there are a bunch of death certificates that have been made available to the research community with their original coding. That has facilitated work by researchers doing unsupervised machine learning including deep learning these days. And at any natural language processing conference, there are a few papers about coding death certificates. It is a mainstream activity and that is probably going to help you when you

can pick and choose some of these methods and implement them in your system.

One drawback is that most of the systems are supervised machine learning, which means that they do the pattern matching based on prior knowledge. Of course, at this point, there is no death certificates coded with 11. It is going to take a while to adapt the coding of what has been learned from 10 and adapted to 11.

DR. ANDERSON: That is right. There was work being done by NSRN(?) in France, and actually at the University of Udine as well, and actually at the University of Udine, they are helping us. This is in Italy. They are helping us with the decision table transition. We are trying to figure out the best way to do that, using this machine learning approach so that we can make it more efficient and less costly.

DR. ROMANO: A quick question for Chris and then one for Olivier. Chris, do these reflect unique ICD codes or does it reflect the prevalence of the codes?

DR. CHUTE: Prevalence.

DR. ROMANO: Thank you. Olivier, the mappings. I am kind of concerned about the mappings of the not elsewhere classified terms because where you have more specificity in one terminology and less in the other, there is not equivalence between these not elsewhere classified.

And instead the mapping should be from one to a group, a collection of them. Can you comment on that?

DR. BODENREIDER: I was surprised by this also. To be fair, we only looked at one-to-one mappings. The tables that provide one-to-one mappings. The table that provides one too many provide probably more information. It is some kind of a reduction when you choose to point to only one. That might be part of the problem.

MR. LANDEN: A couple more questions in the room and then we will check the phone.

DR. BROWN: I think this is a super interesting graphic. I am not at all surprised by the increase in expressivity between 10-CM although it is bigger and 11 because of post-coordination. That makes a lot of sense.

When you look at these terminologies, there are only two axes you could look at. One is the size and the other is whether there is post-coordination permitted. What I do find surprising is that a larger terminology that allows post-coordination is not doing so much better than a pretty small terminology that kind of has post-coordination in it as well.

Did you allow post-coordination in SNOMED for this? In any event, how do you explain that? There is order of magnitude more things.

DR. CHUTE: This goes back to the '96 paper. Yes, we do allow post-coordination in the SNOMED as well. If you look at the core of diagnosis and findings, proportionally, that is a smaller part of SNOMED than otherwise. As you know, Steve, SNOMED has procedures. It has medications. It has many other things that make up the vast volume. I can see that SNOMED is a hugely, larger terminology. But when you cone down to diagnoses and clinical findings, it is not actually non-comparable to the foundation layer of ICD.

DR. BODENREIDER: It is 100,000 concepts, Chris, in SNOMED, which is sizable nonetheless.

DR. CHUTE: That is about the size of the foundation.

DR. MAYS: One of the things that we have done is we focus a lot on the clinical side. I am good with that, but I am also wanting to say a few things in terms of public health and population health. It may be that I just do not understand why this is not there. But I guess I am not understanding why, for example. Again, this is going to go back to mortality that in the states' death record, we do not have built in with it like a geocoding or some kind of again set of information that allows us to do all the things that Healthy People 2030 is trying to do about evaluation. We have a motor vehicle accident. A person dies. And if you collect it either social determinants data

or additional geographic data, you would be able to say okay. This street corner needs a light. There are these population health things that technology would allow us to do quite easily, I think, that would allow us in terms of the mortality side to move to a bigger picture, a better picture for interventions. I know it seems like we are just trying to do a system, but I think we are also needing to do better health outcomes. I do not want to pick on you, but it is a mortality thing.

DR. ANDERSON: I can comment a little bit on that. There are some states that do fairly extensive geocoding. Currently, those geocodes are not in our contracts. We do not have anything for the national data file. But you can do it.

We undertook a project to geocode. I think we had all but two states in this recent project. It was funded by Robert Wood Johnson. We calculate the set of life expectancy measures by Census track using those data. It was in part to do the life expectancy measures, but also in part proof of concept to show what we could do with the geocoded data.

Geocoding place of injury is a little more complicated because then you either have to go back to – the certifier has to go back to other information that they may not have easy access to. Ideally, systems are

interoperable such that they can just call it up and then enter that information. Currently, we do not have that. Geocoding place of injury is a little more complicated.

Geocoding the place of death or place of residence. That is what we did with RWJ funding. It was geocode place of residence. It is a lot easier to do.

MR. LANDEN: Any questions from those on the phone? Hearing none.

DR. PINCUS: I was fascinated by the right thumb fracture. Why uniquely there and probably other places is there an episode of care, which is not intrinsically a diagnostic issue? It is really a procedure issue. Why is it specifically there and why is it in a diagnostic nomenclature to begin with?

DR. BODENREIDER: It is a rhetorical question, I assume.

DR. PINCUS: Well, the answer may be obvious, but it just seems sort of inconsistent that that would be there.

MS. KLOSS: Very preliminary review. One of our core areas for research is do we need a clinical modification of 11. Do you have any gut feeling or what is the next set of questions that you would have to pursue or you would want to pursue to get at this? It seems to me we are never – ICD-10-CM is not probably the gold standard.

The issue is what is the right level of detail to do a reasonable level of coding given other tools we have because this is not the only tool. It seemed to me that this is – that we cannot make that judgment based on how well it compares to ICD-10-CM because that makes an assumption that that is the gold standard and it may not be.

DR. BODENREIDER: I think that there are a couple of things that we can say about this. One question is are all the details that we find in 10-CM meaningful and do we want to be able to express these kinds of things that are currently not expressed. If we want to do this, do we want to do this through pre-coordination of throughput coordination. The first visit versus subsequent visits is something that could easily be post-coordinated or that could be part of something completely taken out of the classification. Could be a checkbox somewhere else. And we have the same issue here as we have between terminology and information model. Should we have a pre-coordinated term for history of heart disease in the grandfather? Maybe not, except that it is convenient so we keep having these kinds of things because not all EHR systems allow you to express that through the information model that they have.

Another thing is what is a reasonable level of detail, clinically speaking. One thing that – I have not

checked in 11, but one difference between 10 and 10-CM is that 10 had only one code for bitten or struck by crocodile or alligator. I am not making this up. I swear. And 10-CM thought it was actually important to distinguish between bit and striking and between crocodile and alligator. It really depends on the level of clinical detail that we want to record. Of course, I do not have a good answer for this.

I think more seriously it is also important to take into account the number of cases, the number of actual cases being coded and not just the number of codes that we have. And if we can have evidence-based terminology, if you wish, and if we can focus on those cases that are really most prevalent, I think we might be able to avoid some of the tail of the distribution. That might account for a very large number of codes, but very few cases in the end.

MR. LANDEN: Eye on the clock. I regret. We will have to cut off the questions with apologies to you guys who have tents up. I urge you to continue your conversations over lunch. We will resume back here at 1 o'clock as per the schedule. The cafeteria is up on the penthouse level. Thank you very much. Productive conversation. Great presentations. We will resume at 1 o'clock.

(Lunch Break)

AFTERNOON SESSION

Agenda Item: Research Questions – Breakouts 1 & 2

MR. LANDEN: I hope you all are refreshed and ready to take what you learned this morning and start digesting it and discussing it.

This afternoon the focus are the roundtable breakouts, and we will get more into what is expected of that in our sessions. Right now, let us just take a step back and look at the overall purpose. And purpose number one for why we are together these two days are to look at the important or to frame up the important research questions for adoption of ICD-11 for morbidity and mortality. Health terminology and vocabulary standards should be supported by research confirming the benefits and estimates of cost, burden of use, adoption and recommended criteria for adoption of health terminology and vocabulary standards that you saw in your pre-work package. That is number one.

What that is about is it is to inform NCVHS for the adoption pathway planning. NCVHS is obligated to map out an adoption pathway. And part of this is to know the questions to ask.

Now, in formulating these questions for time management purposes, it is important to understand that we are just looking for the questions. We do not need the

answers today. We will find who will give us those answers and how later. And the thought is that it will be a commissioned study, not necessarily identical to the RAND, but along that concept. Some well-equipped group will be chartered or authorized or contracted to actually then go out and do the research based on the questions that this group collectively comes up with as vetted by NCVHS.

Then secondly, after we have accomplished that task, the breakout sessions will then tomorrow continue into important communication messaging to go out to the industry stakeholders about ICD-11 for both morbidity and mortality.

Coming out of this meeting for NCVHS, first off, we will do a meeting summary to a written report. We expect that NCVHS will issue a letter. We will send a letter to the secretary of HHS recommending that HHS fund the research and then the third, the aha's guiding moment thing is we realize in our planning, we cannot anticipate all the nuggets that this group will shovel on to us. There may be other actions that we have not conceived up yet that we will want to take. That is what we are looking to do. Come out with a meeting report. Send some recommendations to the secretary, which we presume will include a recommendation to commission a study.

You have been divided into different tables. The labels on the tables are generally closed, but they are not to be a limit to the breadth of your discussion like the clinical scope and use tables. We have two of those. Looking into representation of current medical, behavioral, health, health care, public health, impact on productivity, including documentation, clinical decision support, but it is broader than that. We are calling it clinical, but that is a label of convenience. We are actually looking at pretty much anything that falls to any primary user or downstream relating to the health, wellness, public health, population health, wellness, including hospital, physician, dentist, pharmacist, psychologist, counselor, social worker, home health therapist and then on to stakeholders like registries, databases, whether they be state, multi-payer, what have you. And then importantly, the computer tools to allow us to harness the information gathered based on the ICD coding, the clinical decision support quality metrics and so on.

For the training and implementation tables, impact on productivity, cost of access and dissemination, support for automatic updates.

The technical and opportunities table. System changes for implementation, opportunity for AI or computer-assisted coding and other computational products or ideas

or possibilities and opportunity for automated classification and mapping.

Then each of the tables will also look at the benefits in supporting the major purposes, classification disease, quality metrics research, payment pricing and of course important category, other.

They will also talk about adoption pathways and time tables, stakeholder engagement, vetting processes, lead times for adoption, rulemaking and adoption on the morbidity side, window of implementation opportunity, how long the implementation period should last, and impact on related standards. Under HIPAA, we have administrative transaction standards, X12, NCPDP, Health Level 7, CAQH CORE, NACHA, the National Automated Clearing House for the banking side, and then we have a lot of other terminologies and vocabularies and again the all-important other because there are always things that we miss.

The roundtable focus areas. We have talked about these before. Mortality. Because it is a path different from morbidity, they are pretty much everything unto themselves. There is only one table that will cover all the topics. The morbidity tables will break out their main topics and then collectively discuss the others. And, again, the concept of clinical as we are using, it needs to be broad sweep. Anyone and anything and anywhere along the

spectrum of health care, all those professions that I mentioned earlier.

Major uses for morbidity, classification of diseases, reimbursement, quality metrics, research. For mortality, similar, but different cause of death codings, surveillance research.

The common area of focus here. These are the topics that all the groups will address. Impact on related standards, pathway and time table. Mortality obviously is different than morbidity.

This afternoon's roundtable. The first breakout will have the three tables: clinical scope and use, training and implementation, technology issues and opportunities, looking at the major purposes.

Breakout number two then will move on to look at adoption pathways. Breakout number two means the second session of this afternoon. Same tables. Adoption pathways and timetable, impact on related standards, other research issues.

I think that in a nutshell is the task for this afternoon. We are going to pause and get your reaction to feedback. Make sure the charge is clear. The tables will spend some time self-organizing to get together. Also because we ran a little bit late this morning, instead of the hour and 15 minutes the agenda had for us, we are going

to reduce the discussion time for both of the sessions this afternoon from an hour and 15 minutes to one hour. That should make up the time. We will still get out of here at 5:30.

Bill or Rebecca, is there anything you want to add?

MS. HINES: Logistically, how are you going to capture all of your good work? Linda invented a process last year that worked really well so we are going to do it again. At each table, you are going to have one for breakout one yellow sheet. This is what one of you is going to report out to the full group in an hour or so. That is your final product.

But we learned last year that it is really helpful if all of you start. I do not know if you still have that slide. Take five minutes and you will have a white sheet for each of you to fill out on your own to inform your discussion. Each table, you will have a series of white work sheets that we will want to collect. Somehow they all got stapled together. Behind your number one is for the second breakout and behind that is the one for the third breakout. But just so you know where it says number one, it is just for the breakout we are in now. All of the tables now coming around is your yellow sheet that one of you is going to report out with and then the white sheet is

for all of you to work on. I actually, if your handwriting is good enough, will try to make sure they get typed up for us and we even use them in the meeting summary. Optional whether you put your name on them, but it helps me follow up with you if there is a transcription or an interpretation there of what you wrote. Really do not be shy. It is very helpful to have all of your ideas.

Again, you have one sheet for this breakout and then stapled to that is number two for later this afternoon and number three for tomorrow. Does that all make sense?

MR. LANDEN: Let us see if there are any questions from the group about the charge. Are we all good? It is 1:18. We will wrap this up and come back for our report out at 2:15. Ready, set, go.

(Breakout: Roundtable Session 1

Agenda Item: Report Outs to Full Group

MR. LANDEN: We have arrived at the magic minute from what we have been able to observe from our seats here in the front of the room or the back of the room wherever we are. It seems like everyone was well engaged. We are expecting the superlative outcomes that we all knew you would come up with.

The next step is reporting out of the workgroup discussions. We have an hour for that. And what we will do – we will have each group have their designated

spokesperson stand up and present out their ten questions and an explanation. Rebecca will be capturing the themes. We will go through and take a look and have a group conversation around the themes at the end.

Kicking off are people from the mortality table.

DR. ANDERSON: We had a long and interesting discussion about this. Some key research questions on the focus area. Making some real determinations about the differences between ICD-10 and ICD-11 in terms of – and particularly in terms of the level of detail that is available.

A good example of one of the gaps in ICD-10 is the drug detail. We do not have good drug detail in ICD-10. For example, if you want to know how many deaths due to oxycodone or due to fentanyl, you cannot get that from the ICD-10. At NCHS, we had to create a work around in order to be able to do that. We have an extra data set that is based on the literal text that is reported on the death certificate in order to get at that.

ICD-11. It does have a drug extension code. But the question that still remains is how good is that set of extension codes. Is it adequate for our purposes? It may very well not be. We need to know before we implement ICD-11 before we implement an extension code, a drug extension code, a set of drug extension codes.

Another research question that needs to be addressed is the comparability study and how that is to be carried out. I think we will do it in a very similar way to how we did it in ICD-10, but it would be nice to have some folks look at that process and see if it could be done in a more efficient way.

We need to look carefully at the mapping between versions. As Olivier pointed out, there are some mappings in what WHO has done that are not going to be useful for us. We need to identify those to make sure that we are doing it right.

This is particularly important both for the comparability study and when we are creating new cause of death of lists. We will have to create new standardized lists for ICD-11 and the mapping between the two revisions is really important in doing that to make sure that we are creating comparable categories.

We have impact on data quality with a question mark. I do not think that this is really going to impact data quality, but that could be looked at.

Since the certifiers do not report in the form of codes, they are reporting in free text and were coding after the fact. Probably not an issue, but it could not hurt to take a look.

We need to look at the costs to switch. We talked a little bit here about what the consequences of not switching are. I think those are pretty serious. I do not think that that really is an issue of whether – again, whether we will switch, but when we will switch and what it will cost to do that.

And then I think we could look at what – I guess this goes – this is sort of a sub-category, I think, from the first one, but sort of a specific research question looking at the percent, unspecified or other specified in ICD-10 versus what you get in ICD-11. This, I think, will tell us how much additional specificity we get in ICD-11. That is going to be, I think, fairly substantial with regard to the drugs, but there are other categories, I think, that are important from a public health standpoint that we cannot really get at using ICD-10.

One of those that I can just think of off the top of my head is ALS mortality. ICD-10 does not have a specific category for ALS. At least the international version does not. The CM version does have one, but the international version does not. Without going back to the literal test, we cannot count ALS deaths.

And then some key research questions on major uses. We do not think that the uses will change much, but perhaps if some more detail is available, that might open

up avenues of research to some people who might not have otherwise used the data. It is a possibility. I think it is worth exploring.

And then we wanted to bring up one other issue. Going back to the – this is a morbidity issue, not a mortality issue, but we thought we would bring it up anyway under other ideas. With regard to comparability studies, Denise was talking about how it would have been really great to have been able to do a comparability study on the morbidity side. We have been doing this on the mortality side since we implemented the fifth revision. But on the morbidity side, it really has not been done. Although I think there was something done between 8 and 9, but it was not done between 9 and 10.

We talked a little bit about this and the challenges that would be to create a dual coded data set and just to get the data that could be coded. We thought perhaps the development of a synthetic data set might be useful for that purpose and then you could code it both ways and see how it was different. You could get around issues of representativeness and make sure that a very broad set of clinical conditions could be looked at and you would avoid any of the privacy concerns.

Anything else from the group that we need to add?

MR. LANDEN: Thank you. Training and implementation.

MS. BOWMAN: I am going to report out on that one. We mostly focused on the first area, the research questions and the focus area. First off, we thought an early decision on clinical modification or not is really needed because that really impacts the training needs and the assessment of coding accuracy and productivity if we know whether it is going to be the WHO's ICD-11 or an ICD-CM and what that ICD-11-CM if so would look like and also the need to make an early decision on which categories of the extension codes the US is going to decide to use because they are optional and they are pretty extensive so that also would really affect the training and implementation to have that decision.

Also, we think this is going to be a great opportunity to really look at innovative ways to train coders so no more manual workbooks and sitting in a room with giant books and that sort of thing. We thought that we should research some innovative ways to use electronic tools, virtual tools and tools that are economic and scalable in order to train coders across the country.

We also thought that we need to really evaluate the systems changes that need to be made including the need for improved convergence of clinical and administrative

systems to accommodate ICD-11. This really goes into the pre-coordination versus post-coordination. We hear a lot that one reason we have so many pre-coordinated terms in ICD-10-CM like the laterality is because we just do not do a great job in our claims and in our systems particularly with the separation between the clinical and administrative systems in linking pieces of data to say that this modifies that. We do it in a few cases such as the Present on Admission Indicator or CPT modifiers, but in a lot of cases, we just do not really link data very well and that is why we end up with so many pre-coordinated terms where we are trying to put everything into the code.

There is going to be a big need for more sophisticated tools and this is a great opportunity as we saw with the move to ICD-10 to use more computer-assisted coding, natural language processing, artificial intelligence. But one of the problems is sometimes the tools are not developed early enough. What ways can we come up with to incentivize vendors to develop such tools as early as possible?

Also, we need research that should include controlled field testing across all health care settings. And one model we discussed to look at is the University of Calgary actually did a great ICD-11 field testing project where they looked at the coding accuracy compared to ICD-

10-CA, which is the Canadian modification of ICD-10 compared to ICD-11. Their process of how they conducted that would be perhaps a great model for a similar sort of testing project in the US.

The key research questions on major uses. The major point we came up with there is we thought the list of the major uses was way too limited. The research really needed to be what are all of the uses that ICD-11 could be used for, the ones that were often cited for ICD-10 as well as we thought because of many of the new concepts, the new structure of ICD-11. There might be some additional uses beyond the long list we saw with ICD-10, which could bring up some benefits to some groups of users that had not really been considered before.

Under other ideas, we talked about looking at how the role of the coder might change going forward under ICD-11, given that we see a lot of opportunities for much more increased automation of the coding and the coder perhaps being more of an auditor kind of role instead of the current process of manually assigning the code.

And as Donna had alluded to during her presentation right now by law, the US has to consider any codes for new diseases for implementation twice a year. It has not really happened the second time, but they have to bring them forward and present it. If we decide not to have

a clinical modification in the US, we may actually have to pursue a change in that law. That was under our other ideas category.

Anything else from my group that I forgot to mention?

MR. LANDEN: Thank you. Technology issues and opportunities.

MS. DUPEE: For technical issues and opportunities, we spent a significant amount of time on three topics. The first one is can we use an interoperable representation of research and clinical terminology classification to simplify distribution and deployment.

The second was can a post-coordination model support complete and safe retrieval of encoded data with respect to recognizing concept equivalence. It is very technical. I am sorry. Go back to the first one.

Can we use an interoperable representation of research and clinical terminology classification to simplify distribution and deployment?

The second. Can a post-coordination model support complete and safe retrieval of encoded data with respect to recognizing concept equivalence?

Three. Can ICD coding for X be implemented as a computable service on top of statements captured –

standardized clinical statements captured by EHR from process of clinical care?

PARTICIPANT: (off mic)

MS. DUPEE: Key research questions on major uses. We came up with three points: intellectual property, maintenance updates, and extension sharing.

Any input from the group?

PARTICIPANT: Are these research questions?

DR. CHUTE: They are really axes. The first three were research questions and we incorporated some axes like content coverage and the like into them. But then frankly, we had a bunch of axes dangling. We threw them into the next category and --

MR. CAMPBELL: As an example, we have ICD coding for X. There is going to be IP issues on it. How do you keep the coding for X up to date? There are going to be maintenance issues. There may be local extensions. I think part of it is that these axes, as Chris described them, need to lead to sub-questions. Can we have an interoperable representation of research classifications? What are the intellectual property things about being able to share that interoperable representation? Can we use that interoperable representation for maintenance updates? Can that interoperable representation be used for extension sharing? You create matrices of the research questions and then some

of the major uses – I think was kind of the intent. Is that fair, Chris?

MS. HINES: If that is on your sheet, we would like your sheet.

MR. LANDEN: Is that it? Thank you for that. Anymore conversation? Thank you. Next table. Clinical.

DR. ROMANO: We worked on five research questions on the focus area. The first is really about what would the impact of ICD-11 be on provider effort, burden and workflow across the entire health care system, basically, all levels of care, all care settings and environment so really trying to get a better understanding of that impact, the burden and workflow.

Second would be then what tools are needed to support more effective implementation and clinical practice. These tools could include improved interface terminologies, computer-assisted coding, natural language processing tools and so forth, but tools intended to reduce that burden and impact and allow providers to incorporate into their workflow better.

Then the third is really –

MR. LANDEN: Can you pause one second so our scribe can catch up?

DR. ROMANO: Then the third would be about what the benefits are that would accrue to stakeholders within

the health care system, really assessing the potential improved ways of measuring quality, outcomes, and value in the health care system and then of course being able to communicate that those benefits effectively back to providers.

And our fourth question was really about drilling down to better understand the implications of the reliance on post-coordination and especially what is currently described as optional post-coordination and the use of extension codes, which in some cases, a base code might require many extension codes. That has important implications for the precision, the accuracy and the reliability of data as it is collected within health care organizations and providers so the implications of post-coordination basically on the data quality.

And then finally, we think there needs to be some research around what clinicians and other stakeholders think is missing in ICD-11. Perhaps exploring the questions of content coverage that were discussed a little bit this morning, the meaningfulness of the categories in ICD-11. And that relates to the question of do we need a clinical modification and what about linkages to DSM-5, for example, for behavioral health. What do we need to do to make the code set more meaningful and to provide complete content coverage from clinician's perspective?

In terms of major uses, the first was about really the use of ICD-11 to design classification and binning algorithms and these algorithms obviously are very important for payment, MS-DRGs being an example for risk adjustment, HCCs being an example for quality measurement or quality indicators and CMS quality indicators are an example there. How well will ICD-11 support the design of classification algorithms that are at least as good if not better than what we have today with ICD-10-CM?

The second question is about the impact of the changes from, for example, pre-coordinating concepts to post-coordinating and then maybe later deciding that it did not work to post-coordinate them. We need to go back and subsume them in the pre-coordinated terminologies. There is additional level of complexity as Donna described where codes may have multiple parents. There may be alternative approaches to the coordination of these clinical concepts. We need a better understanding of the impact of these changes on the use cases.

The third category of research questions is around how will ICD-11 support a generation of real-world evidence to inform, for example, pharmacovigilance, device surveillance, and other applications that include features of research and quality improvement that really goes beyond what is on that table.

And then finally, we had some discussion about the issues of stability and maintenance over time. This is obviously a huge change. We do expect that bridge studies will be necessary and so forth to understand the impact of that change. But then if there will be no ICD-12 then how will ICD-11 be maintained and updated over time and what are the implications of that model of maintenance and update for the various uses of the code set?

MR. LANDEN: Thank you. Next table.

MR. CAMPBELL: I just want to make a question or comment. I think at least as I am understanding it, extension is overloaded and I think it has been used in at least two census that there is a specific extension thing within ICD-11 and there is also the notion that if something does not meet your needs in your local environment, you may choose to have "extensions".

The sense in which we were using extension in this group has at least part of the – a little difference than as you were using it in that group. I just wanted to point that out.

DR. BROWN: We were the second clinical group. I think I will be able to reflect everything. I would invite my group members to jump on in if I do not get it exactly right.

Another thing I would like to note is I think we scared Clem off.

PARTICIPANT: He said he would be back in the morning. He had an afternoon commitment.

DR. BROWN: We addressed three general areas, each with three or four kind of – it was suggestions or proto questions. And the first is how can ICD-11 be used to bridge the gap between fine-grained data that is useful and needed for clinical and research uses with large categories of data needed for administrative purposes.

The second and specifically was is it possible to use SNOMED and EHR problem lists to be able to code a sign or symptom in order to preserve the clinical dimensions of a problem at hand, but in front of the doctor at the time. It is noted that this practice is clinically happening, but those dimensions of the problem say anxiety and schizophrenia I think was the example may get lost in the administrative translation and how to preserve that on an individual patient level.

DR. HINES: More generically possible to use SNOMED and EHR problem is to do what?

DR. BROWN: To be able to code a sign or symptom in order to preserve the clinical dimensions or the context of an actual patient problem without losing that in the administrative translation to a billing code for a visit.

In general, we noted across several specialties sort of tension about what is appropriate evidence of care at a specialty level and at a patient in front of you level versus being rolled up into a classification and not losing utility. It was seen in both dental and in the instance of psychiatry. I think it is pretty easy to imagine that there are others as well.

Then we looked at impact on productivity, including documentation. One question was are there methods or incentives to generate coded clinical observations about patients that may not relate to the current episode of care, but maybe related to preventive screening and potentially modifiable risk factors with downstream health benefits, things such as cognitive function, visual impairment or gum disease. How do we get people to make these observations and put them in the record in a coded way that is useful in a downstream way?

And then is it possible to enhance productivity by generating administrative codes from clinical data in a reliable, accurate, and useful manner?

We discussed decision support. There are two statements regarding that. Is ICD sufficiently expressive and rapidly updated to be used for cohort and intervention definition in a way that is safe and effective? To be used for cohort and intervention definition.

Then the next was can ICD be used to integrate things such as external and environment factors or social determinants to improve the utility of decision support. I think that gets it.

MS. NARCISI: We also had a conversation about that ICD-11 or whatever code system is going to be used should be used in all specialties, sub-specialties that are part of the body in medicine because there are some groups that do not use it. Dentistry does not use ICD codes. Very small percentages use it. Oral surgeons use it and some of the Medicaid plans.

MR. LANDEN: Thank you. That was a lot to capture. Thank you, Rebecca. Just so we do not lose track, I think you will need to keep your yellow worksheets today, possibly tomorrow, but just – because we do not want to use them, please give them to Rebecca at the end of the day tonight and then Greg or Rebecca and then we will have them available again for you tomorrow if you need them when we get in tomorrow's questions.

Now, we do have time for some clarifying interaction between across and among the groups. Are there questions you would like to ask of other groups or elucidations of what your group has discussed relative to what you heard from other groups? Have we drained you all?

MR. CAMPBELL: I will just comment that I heard in more than one group a desire to go from data that is not coded to take care of the patient clinically to automatically get the administrative burden out and that impacts multiple areas, usability, acceptability, training reliability because it becomes out of an automated and highly reliable way. There are massive implications to that question.

DR. CHUTE: To extend that, in the early slides around the creation of ICD-11, we aspire to what we call an aggregation logic or to put it metaphorically, effectively a clinical grouper to go as groupers today go from ICD codes to DRGs. The vision back in 2007 was to have clinical data either coded or otherwise be aggregated to create the ICD code and that the whole notion of a human being having to assign an ICD code would be as bizarre as a human being assigning a DRG.

DR. STEAD: What I am struggling with a bit, I get both of these concepts, is how we would actually go about the research question because the difference between now and some years ago is that we have ICD-11. It exists.

The question in front of us is how we could actually I think construct a research protocol. I am still trying to keep it at the level of the question, but a way we could actually construct the protocol that would get at

that answer because I think – I do not think anybody is – one approach to answering the two things you have suggested is to what degree with ICD-11 be fit for the purpose of direct clinical capture of the things that clinicians want to do. I guess we could pose that as a hypothetical question. It seems to me given the – at least in this country, given the standards that in place and underdevelopment, under promoting interoperability that would require a complete flip of thinking, which is unlikely to occur as we try to provide an ICD-11 path forward in some reasonable period of time.

You are probably thinking about – you would probably want a protocol that could test the feasibility of using the standards we are dealing with today in some form and the foundation and various tools that ICD-11 produces to let us in essence compute what we need for ICD-11 for classification purposes for any number of uses and produce what is needed. You would in essence be asking the question, what is the feasibility of stopping direct entry of ICD because we are calculating it. If that is the basic use scenario, what is the research protocol that would address that or the approach that might address it?

MR. LANDEN: A response to that. Let's do those first and then there are a couple of other questions I saw.

MR. CAMPBELL: Framing out a research protocol is going to take more time. But the general framework, I think, you hit on it, which is that – and it also is synergistic with other efforts going on in US health care today and that is having truly "semantic interoperable data" because if the data that is available at one site is very different than the data that is available at the other site and your algorithms, in fact, cannot work from site to site because of local variation. I think focusing on to what extent the interoperability efforts are sufficient to enable this and where the gaps are is one of the – and that way it is synergistic. It is not something separate.

DR. PINCUS: I believe one of the tables alluded to a study at University of Calgary, which actually was an offshoot of something that the quality and patient safety tag for ICD-11 developed as part of the workflow that we did.

It is just worth pointing out that actually one of the members of our tag, Hude Quan, received a substantial grant from the Canadian Institutes for Health Research, actually address a number of the questions that we have been raising here today and it may be worthwhile actually either contact him or bringing him in to describe some of the work that they are doing in terms of the way Canada has begun to approach some of the same questions.

MS. HINES: I have heard several people say there is research already going on. Wouldn't a research question be to identify all the current research so we already know what is in play?

DR. PINCUS: Yes. His research actually has been funded and now it has been initiated.

MS. HINES: That is my point. It is like we need to know what the actual current state in the research is before we --

DR. PINCUS: There may be other countries that have done similar things and specifically funded by their equivalent of NIH.

MR. LANDEN: We have had, I think, three referenced to Canada already. Do you need more detail, Rebecca?

MS. HINES: No. I just think that we ought to mine all the knowledge in the room for research that is already underway so we can say we already know this is underway.

DR. BROWN: One comment. I hope it is constructive. You could also ask a general class of research questions and then let investigators give you their questions that they believe are answerable that you may not anticipate their exact answer. You might say we are interested in the topic of X and Y and then we send letters of intent in three months and describe a one pager on what

you want to do. You might find that you get some unique responses that you did not anticipate by asking a very specific question.

MR. LANDEN: Other questions, comments? I think we can adjourn for our break and we will resume at 3:15. See you in 17 minutes.

(Break)

MR. LANDEN: Let’s get back into Round 2. For a reminder, start the same as we did last time. In the first few minutes, just individual reflection. Decide on who is going to report out. This time around we are discussing the implementation pathway and time table. That is the first set of three or four questions on your purple sheet. And the second set of questions is the impact on related standards.

For each topic, what issues would you like to see studied in advance of an adoption decision? Again, like your purple sheet has three or four per topic area. Wide ranging discussion and then have the group synthesize and agree on a report out. We will plan on doing another hour, but we have gained back a bit of time. If we need to run a bit longer, we can. Any questions now that you are all total expert at this process and format? One question.

MR. MCLAUGHLIN: Are we still doing this from the viewpoint of our topic area?

MR. LANDEN: Yes, from your topic area, but these – understand these cross all the different tables. Again, a little bit different path from mortality, but primarily from your own focus. But all groups are going to be working on these same questions. Another question.

DR. PINCUS: Could you clarify – maybe put the slide back up that provides a more complete definition for implementation pathways and related standards.

MR. LANDEN: I do not think we have a slide like that. Did we? It does not add much clarification. Again, for mortality, that is a separate pathway for the morbidity side. This is a HIPAA code set. That is why this is a team effort. Adoption, pathways, and time tables and impact on related standards. Can everybody see those? Stakeholder engagement, vetting process, lead times, windows of implementation, opportunity, dual pathway, retirement of the previous standards, impact on related standards, X12, NCPDP, HL7, CAQH CORE, NACHA to name the key ones under HIPAA, other terminologies and vocabularies and updates.

MR. CAMPBELL: It may just be me, but can someone define implementation pathways for me?

MR. LANDEN: On the clinical side, implementation pathway is the soup to nuts from where we go at this point in time where we know that WHO has adopted 11. Adopted, I think, is the word. Donna? WHO has adopted so 11 is

official now. For implementation in this country, there is a pathway that we have to follow that starts with NCVHS making a recommendation to the secretary to adopt or not adopt ICD-11 with or without a clinical modification as a HIPAA-mandated code set. HHS then reacts to that. There would be a proposed rule, public comment, final rule, and included in the final rule would be specify the process for how long of a lead time there is between the issuance of the final rule and by which time industry would have to implement. That is the pathway. I have been told Linda can add on.

MS. KLOSS: I just had a comment on that. Just a reminder that we did send a letter to the secretary suggesting that adoption of ICD-11 need not be put through the regulatory channels because it should be viewed as a version update. We do not know whether any action will be taken on that recommendation.

I think when we think about pathways, there is the regulatory pathway and then there is the idealized pathway, if you will. If this were something that could go forward after all the necessary research has been completed, what is the right timing, assuming that we are good by World Health Organization perspectives to begin after 2022? But just thinking this out with other things going on in our environment. One path is the regulatory and

the other is let's say our recommendation gets adopted and the requirement that this be a regulatory change gets adopted.

MR. LANDEN: Those are two alternative pathways. As we have been talking about the previous breakout group, we are pretty sure we want to do some research. How long is that going to take? It is just a sense of timing from now to the endpoint and your group's vision of what are the steps in between here and there.

MS. KLOSS: It is not hopefully another 30 years.

MR. LANDEN: Okay. Seeing no more questions, please go have some more fun.

(Breakouts: Roundtable Session 2)

Agenda Item: Report Outs to Full Group

MR. LANDEN: We will start with reverse order if that is all right.

MS. NARCISI: Some of the things that we discussed. What is needed to keep the stakeholders to a five-year process for implementation? Just putting it out there. Can we identify related stakeholders such as physicians, coders, professional or national organizations to assess readiness for change, resources for change, barriers to change and how to develop a diverse implementation strategy to meet all of the needs? Resources

for change, barriers to change, and how to develop a diverse implementation strategy to meet all the needs.

Study different models of care especially value-based care and the impact and the windows of opportunity. It may not be fit for purpose. How will outcomes be tied to payment models? And will ICD-11 be able to support this approach?

MR. LANDEN: Rebecca, the first word on that last bullet was "may" just so we can figure it out tonight.

MS. NARCISI: Is the vetting process of ICD-9 or 10 appropriate for ICD-11? Are the current costs that have been identified – are they just for the implementation of the code set or does it include system upgrades, training, et cetera? Identified for just the implementation of the code set or does it include system upgrades, training, et cetera.

Two more. How will current standards handle post-coordination? How will it affect electronic transactions as well as paper forms?

DR. BROWN: I would like to make a friendly addition in terms of other standards – mentioned transaction standards and the like for pain, but it does not mention content standards, terminologies, other standards for things like decision support and ECA rules, cohort definition, quality and the like and anything that

is a potential consumer of a patient's specific data is going to have to be looked at.

MS. HINES: You said terminologies, decision support.

PARTICIPANT: Any content-related standard.

MS. HINES: Consumers of patient data.

DR. BROWN: Like interrelation with other terminologies, cohort definitions that build upon coded data. Event condition action rules. Report definitions all need to be examined.

DR. CIMINO: One, actually, I did not get to mention to you guys, but -- how are the lessons learned in pilots going to be generalized for implementation, more widespread implementation?

What does it take to build the tools for implementation in terms of time, cost, and the stakeholders that need to be involved?

How do we transform coders into auditors?

What are the changes up or down to clinician burden versus changes up or down in quality and value of data?

Will a CM be needed? And if so, can 11 be adopted as the CM is being developed?

What will be needed by each stakeholder group to achieve implementation?

What dual coding studies should be done to understand impact?

Last in this section is what are implications of technical changes such as file structures, code lengths, et cetera?

PARTICIPANT: I lost that last one.

DR. CIMINO: What are the implications of technical changes such as file structures and code lengths?

Under related standards, what will be the role of SNOMED? Should we code in SNOMED and translate or will SNOMED be obsolete?

What are the overlaps with other code sets and can ICD-11 be coordinated with others for post-coordination?

PARTICIPANT: Can you read that second one? What are overlaps?

DR. CIMINO: What are overlaps with other code sets and can ICD-11 be coordinated with others for post-coordination?

MR. LANDEN: Was it critical back on your SNOMED bullet to say whether --

DR. CIMINO: Do we code in SNOMED and translate to 11 or is SNOMED obsolete?

One more. How does 11 coordinate with detailed clinical documentation? For example, the 20,000 terms in

the echocardiography dictionary. That is it. Did I miss something?

MR. LANDEN: Are we good? Okay. Next table. Technical issues and opportunities.

MS. DUPEE: Technical issues and opportunities. We came up with PET, pilots, evaluation, testing. Integration into the EHR and terminology service vendors. Systematically evaluating consequences of mapping on quality and safety. And then key research questions on related standards. FHIR. Leveraging-related terminologies for domain-specific concepts such as medications, toxins, and devices.

And lastly, evaluate methods to accommodate regional and urgent codes without compromising consistency.

MS. HINES: Can you say more about those first bullet points? You said pilot evaluation testing. What is the question? Integration into EHR and terminology service vendors. Can you help us understand so we will capture a research question?

PARTICIPANT: (off mic)

MS. HINES: If you all will bear with me, I am going to attempt to log in. If WebEx were an airline, it would be out of business. They have kicked us off so many times today. We are going to be Zoom tomorrow. Our

contractors got us on Zoom. Tomorrow we will be Zoom and we will see if we get kicked off so sorry. I apologize.

Rich, are you good with these bullet points? They are not as clear to me, but then I am not the main audience here.

MR. LANDEN: Yes with the caveat that we know where they live. Training.

MS. LEON-CHISEN: Okay. No matter where we started, we kept coming back to the same basic question that pretty much influences everything that there is an urgency to do the research we talked about in the previous breakout session. Number one is CM needed a clinical modification. Do we need extensions, post-coordination? What are we really talking about implementing? That research has to be done first before we can even figure out a timeline for anything else?

And then one of the questions is would it be feasible --

MR. LANDEN: Just pause one second.

MS. LEON-CHISEN: Would it be feasible to implement by 2025 if we do the implementation without a clinical modification and the need for regulations? Or if we do need regulations in a clinical modification, would 2027 be feasible? And just so you do not think that we picked 2025 randomly out of a hat is that that would be ten

years post-ICD-10-CM/PCS and we really do not think that it could be done earlier.

We think that there is a need for stakeholder engagement in all the research that we are talking about today. How do we make people aware of the results? How do we engage them to disseminate the results?

And lessons learned. We think that there should be early engagement of physicians at every level.

We need to evaluate methods of comparing longitudinal data that does not involve mapping. I think we were concerned that from the get go, we thought mapping was over relied on that people should be coding with the native codes. But we realized that mapping was used in lots of different places with not so great results.

We also think that with regards to implementation pathways, people are in a different place today than they were when they had to implement ICD-10. With that, we think that ICD-11 should be implemented soon before we lose the knowledge that was gained during the transition.

PARTICIPANT: During the transition to 10?

MS. LEON-CHISEN: Yes, to 10. We think that we need to take a look at efficiencies that are different because last time we had to implement ICD-10-PCS, which was the most difficult part of implementation so moving to ICD-11 should be relatively easier.

We are also concerned about the quality of the coded data. In fact, it is of great concern specifically when it comes to physician data.

As far as the questions on related standards, we said everything needs to be looked at. Starting out with X12 and we kept coming back again. Once we know what we are transmitting, can it be done? X12. All the billing data, insurance processes.

We were also concerned over organizations that are not currently part of the HIPAA standards.

PARTICIPANT: So not covered entities?

MS. LEON-CHISEN: Right.

PARTICIPANT: What about them?

MS. LEON-CHISEN: Number one, I do not know that I know who they all are, but we do know that some of them are using diagnosis information. If ICD-11 is part of a HIPAA transaction update of some sort, if they are not covered by HIPAA, what happens to them? I know that some of this came up in the transition to ICD-10 with workman's comp.

Did I miss anything else?

MR. LANDEN: Mortality.

DR. ANDERSON: We do not have too much here. But there are two issues under the implementation pathways and time tables that need to be address, I think. In terms of stakeholders in the implementation phase, there is really

only one other set of stakeholders and those are the states. They will have to modify their systems to accept the new codes and there will be new edits and specifications that we will provide to them. I guess if there is a question in there, it would be what is the cost to the states to do this and to prepare for the transition.

The other issue has to do with time table. Of course, our screen of opportunity, our window of opportunity, we kind of look at it as sort of a screen rather than a window. That window of opportunity is flexible, we think. I do not think it matters that much whether we implement in 2025 or 2027, for example.

However, we believe that there are some benefits to earlier implementation, some benefits that ICD-11 has over ICD-10 that we could enjoy if we implemented sooner. I think it would be good to explore what are the benefits, some sort of comprehensive list of the benefits. What are the benefits of earlier implementation versus later implementation?

Obviously, increased resources will help us to implement earlier. If there are substantial benefits that others can see, perhaps that could turn into additional resources for implementation.

And then on related standards, we do not think that for mortality that there is an impact on other

standards; however, I think it ought to be looked at just to make sure. We do have some projects currently with regard to interoperability between electronic registration, death registration systems and medical records and coroner and medical examiner systems. Those generally concern HL7 and FHIR. I do not think that ICD-11 factors in there, but somebody ought to take a look and see.

That is all we have. Anything else from the group?

MR. LANDEN: Okay. You have heard the report outs. Let's see if there is any discussion on what we have heard. Linda.

MS. KLOSS: I was just curious, Bob, Donna, others, who have worked with WHO. What are you hearing from other countries as they now begin to get their arms around what their implementation goals are? Are there any insights that are beginning to accumulate?

DR. ANDERSON: I can talk in terms of mortality. Many of the countries that we are talking to are using automated coding systems. The Iris system, for example, which is used by most of the European countries and Australia at this point. They share a set of decision tables with us. Our implementation timelines will be very similar. I expect that we will implement within one or two years of all of those other countries. That would probably

include Japan and Korea as well even though they are not using the same exact tables. They are very similar, but not the same. But we are collaborating to make them consistent.

MS. KLOSS: And I could imagine that there are some benefits to having these systems come up across countries at about the same time for comparability.

DR. ANDERSON: Yes. It is important that our data be comparable that we are using the same systems.

MS. KLOSS: So that 2025-27 timeframe is what others are striving for?

DR. ANDERSON: We have not put a number on it yet at this point, but we generally agree that – we are looking at probably four years for the revision of the decision tables unless we get an influx of resources and then a couple of years, probably two years to complete the work.

MS. HINES: Are you saying decision tables?

DR. ANDERSON: Yes, decision tables. Those are the tables that are used to make decisions on the underlying cause of death.

MS. HINES: Say it again the last thing you said about decision tables. Something about they are issuing decision tables or developing.

DR. ANDERSON: We share a common set of decision tables. With the Iris system, the decision tables are the same as the ones we use. It is essentially the same. Iris

has updated the decision tables to the most recent version of the ICD and we have not, but it is essentially the same set of decision tables. It will be certainly in the future.

And then there are a few other countries that use something similar, but it is not exactly the same. It is consistent, but not exactly the same.

MS. PICKETT: It is a little different on the morbidity side because for those countries that have national modifications, again, they are going to be bound by their regulatory legislative authorities. Some countries when they implement actually it is sort of more of a voluntary process or a negotiation process. A number of countries are now beginning to talk to their stakeholders. Some have been talking to them all along about what was happening with the status of ICD-11, its development. Now that it has been formally adopted by the World Health Assembly, those discussions will now continue in earnest. But I think pretty much all of the countries are in a slightly different place, but they are all in the place of evaluating what this will mean, what it means in terms of changes to their national statistics and then also looking at the changes that they mean for their case mix and reimbursement schema. And, again, it depends on how widely ICD is used in other various aspects of their country were outside of just acute care, inpatient hospital work.

And then of course, there are – not of course, but I think I mentioned previously. There are some countries that are still quite concerned about their ability to have their own national modification and some of those discussions will likely need to be concluded before a lot of work and/or effort go into actually overhauling their systems, but certainly people are looking at it for the potential impact.

But, again, for the countries that do not have a national modification and would be looking to implement ICD-11 for morbidity purposes, again, that work too will be ongoing. WHO has been going out to various countries that have expressed either an interest in being an early adopter or that have expressed the need for outreach or other assistance to generate discussions and to help talk to the policymakers. There has been an effort there. Again, using some of the tools that they have already developed to show that the countries are not having to go this totally alone as they may have when they implemented 10, when some of the tools were not available because actually almost none of the tools were available or came afterwards. Some of the training material related to the use of ICD-10 came well after the implementation of ICD-10 in some countries so kind of variable.

I think now that the World Health Assembly has adopted is taking a more earnest look because there was a concern that they would do all of this and maybe it was not going to be adopted.

MR. CAMPBELL: Thank you. I wanted to emphasize one point and then there was another point. In listening to the discussion, I realized sort of an oversight. The point I wanted to emphasize is how much the pathway to the previous implementation depended on mapping essentially. Interoperability by mapping. That is also prevalent as that is kind of the default approach that people look for interoperability between health records.

I think spending some time looking at the patient safety and the data quality issues as it relates to mapping is very prudent, not just with respect – I think there is definitely a case to be made with regard to ICDs that data that is going to persist in the patient record that has been derived by mapping. I am aware of an organization that has had some problem list data that was entered in ICD-9 and then that was mapped to SNOMED and then it was mapped to a third source and then it has the potential to be imported into – I think those are kind of issues that we really need to surface and make sure that policymakers are aware.

The oversight part was that I have heard talk about post-coordination. That is a topic that I thought died a while ago. It is not because I wanted it to, but essentially there is no electronic health record that I am aware of that really supports post-coordination in a meaningful way. And I can point to both VA and Kaiser experiences there.

One of the things that happens with SNOMED is that they get a lot of codes that are being proposed by Kaiser and part of it is because they can only enter a single code into their problem list in their system. You end up with pressure in order to meet the clinical needs to get actually contradictory codes that no presence of this or presence of this and the absence of something else and get quite complex expressions that they want added to the terminologies, which actually have a potentially adverse impact on data quality.

One of the things that that has led to as some people have talked about is why can't we share "post-coordination libraries" instead of having to create support for post-coordination and the electronic health record in the first place. You just start to share the problem list and VA has a problem list like this. Kaiser has it. It is available through the UMLS – problem with subset that you can get to from the UMLS that represents the things.

I think that there are some issues here that need to be explored. One is can the EHRs support post-coordination. If they cannot, how do we mitigate some of these challenges that are currently in place with regard to their support? Thank you.

DR. ROMANO: I just want to articulate a little bit more a theme that I think we heard across a couple of the groups, which was the idea for a really systematic and conscientious needs assessment with all of the different stakeholders. Clearly, we were focused at this table on providers as stakeholders. But of course, we have many other stakeholders, insurance companies, the states, regulators and so forth. Each of the stakeholders needs to be engaged to better understand where are they now with ICD-10-CM. What is the desired state of where they would want to be with ICD-11? What do they need to get from here to there? That kind of exercise will then lead to some of the things we talked about earlier this morning in terms of developing tools, testing tools, and doing additional field testing work, for example, to assess whether we are actually addressing the needs of the stakeholder community adequately.

DR. STEAD: Given your comment, Keith, I cannot avoid the temptation to point out that there was at least one EHR that supported post-coordination quite nicely in

the late '70s. There is absolutely nothing about the capability, about the technology particularly today's technology. There are examples in today's predominant EHRs. They are just in a different space. If you look at the way that Epic has implemented the PROMIS, Patient-Reported Outcomes Measures, for example. It is a post-coordinated adaptive process. It is not like they don't know how to do it.

How we build the case that it needs to be done is a very valid point. But it certainly is not a technical limitation. In fact, it enhances workflow and cognitive support when you do it that way provided you do it on top of the right kind of grammar rules.

MS. AULD: You might want to add on to what Bill just said. If technology is not an issue then you are going to have people saying that it is not cost effective. You need research that looks into the cost to show whether or not it can be done in an effective manner to get to an end product that is more useful than one that does not use post-coordination.

MS. HINES: We need research to show that it is cost effective.

DR. CHUTE: The biggest obstacle to post-coordination has not been technical. It has been human. Clinicians despise post-coordinated phrases. We do not

think in post-coordinated context. We think in sentences and paragraphs. And clinicians like pre-coordinated expressions that exhibit a full concept.

The dissidence I think really from a research point of view is natural language processing. To the extent that we can have clinicians say what they believe and think in a voice to speech to text transformation and then do natural language processing to extract from that text and other relevant sources in the record the appropriate coding. This gets back to some of the earlier morning issues of algorithmic coding.

Many people have articulated and I happen to agree with them that no human being should ever do ICD coding. It is just unnatural. And to the extent that we can make tools and resources or framed in the context of a body of research pursue bodies of research that support algorithmic coding that can be reviewed by a clinician, I am a great fan of clinicians correcting and modifying and refining what is done by machine, but having people do – as a clinician, I can say clinicians are the very worst coders ever born and to have clinicians unable to have the data generated algorithmically through a body of research that would obviate the need for them to do complex coding post-coordinated or otherwise would be a huge step forward.

DR. ANDERSON: I agree completely with Chris that the automated coding is the way to go. With that said, I did want to add a word of caution that we do not want to get to a situation where all we have is this black box and nobody knows how it works or how it does what it does. We still have to have, I think, trained coders, expert coders, but maybe we need less of them and to be in charge of making sure that the automated coding systems do what they are supposed to do.

MR. CAMPBELL: I will just emphasize the point I think the table behind me brought up, which was turning coders into auditors, getting to the point where we are actually able to audit data quality is a very valuable place to be and I think that is going to be a better place than where we are right now.

MR. LANDEN: I think we are ready to move on to the next aspect, which is a challenge that I am going to turn over to Bill Stead and that is to the extent that we can on such short notice. Let us recap what we have heard and we will start with the outcomes from the first round of break outs.

Agenda Item: Recap of Insights from the Day and Discussion

DR. STEAD: Just so you know how we plan to do this. I have done my best on the fly to synthesize what I

heard and we captured in the first round. To the degree, I was lucky. It will also cover some of the part of the second round, but there was no attempt to go back and fit any of this in as you went through it. Rich will make a few points probably about it to build on to show where it builds on what I have already done. We will have group conversation. Then we are all going to go eat dinner probably and sleep.

In the morning, we will have had lots of thoughts. We will have also caucused and captured what we have today plus what we hear now and what was in the stuff we just did that we missed in both. We will start with a recap of that. Again, we will get your input from that. It builds as we go along.

And then we will do the Round 3 breakout and then we will synthesize it. If you want to, you will be able to leave at lunch. If not, you are welcome obviously to join us for what will be a Subcommittee round of work on actually trying to begin to turn this into what we are going to say, which would be the next crank, as we go through this and would bring in those pieces so that we are hoping that we walk out of here tomorrow afternoon not with something that is wordsmithed and so forth, but something that has the key things we are trying to do. This is an iterative process, iterative journey that we are on. It

will sound familiar to those of you that were with us a year ago.

These are my thoughts. I am probably going to step on everybody's toes because in large part, I have brought a way to think about mortality and morbidity together although I have pieces along the way where I split them out. I have tried to use the concept of key use cases to let us come up a level of detail from many of the things that people talked about.

The first research question we need to pose is what are the key use cases for ICD-11 for mortality and for morbidity. If you took the 80/20 rule, what would in fact be a fresh look at all the use cases? The uses that we gave you with were a very small starter set of use cases, if you will. We have many rich examples in the things that people suggested as we went through the day that would be other use cases.

Then I like the generalized, this idea, as Bob mentioned, about alternative approaches to comparability studies. How do we support ongoing comparability studies and comparability studies across use cases? And comparability to let us compare ICD-11 versus ICD-10. Let us compare various post-coordinated extensions to cover content gaps. And then the idea of comparing computer-generated classifications to support the use case from the

promoting interoperability clinical standards and to support ongoing comparability of each iterative release of an update to ICD-11. Even though they are going to be incremental, we need an evaluation engine that lets us learn of potential consequences and adapt to them as we go along. This probably could be expanded a bit.

Then compare the quality cost elapsed time for implementing commercial NLP tools plus the ICD-11 foundation to auto code death certificates to developing new decision logic for NCVHS' mortality coding system.

Then we want to basically – I am not saying one or the other. I said it would be very useful to have a comparison. What would the result look like?

We should be able to use this infrastructure to evaluate the quality of the World Health Organization mapping for each of the use cases that meet the 80/20 rule.

What tools are needed to reduce workflow burden and improve documentation quality by use case by stakeholder in each use case?

Evaluate alternative approaches to training and ongoing support for using ICD-11 costs and benefits by use cases. Innovative training approaches, computer-assisted coding, workforce role changes such as its auditors instead of coders.

I think all of that is largely independent of whether we are talking about morbidity or mortality. I think its infrastructure approaches, comparisons that actually would be relevant to both. We might get some good reuse of the methodology. Obviously, the specific use cases would be different, but that is how it generalizes. I hope it might generalize.

Then now you have to get specific. What are costs and benefits of alternative timelines for switching from ICD-10 to ICD-11 for mortality? What are the costs? What would it cost NCHS to do the back end part of the coding changes if we wanted to do it in three years versus six years versus nine years? What would the cost differences be?

And then for each mortality use case, what are the costs related to not the NCHS cost, but the system and longitudinal database conversions for the various people that use the data? We may need to build something for the states into this that is different from the users, but really thinking of the statistical research quality improvement people that use all of the data. What are their costs?

And then what are the benefits of switching from ICD-10 to ICD-11 for mortality by use case? And then compare the cost-benefit ratio of switching in three years,

six years, or nine years coming on top of that. That could give us some way of figuring out what makes sense.

Then switching to morbidity, evaluate the fitness of ICD-11 to support convergence of clinical and administrative standards for morbidity. And then I just plumped in the three questions from the technical table, but substituted use cases for X, which achieves the same basic purpose.

And then what are the costs of supporting these by use case because in essence, this would be some sort of an ongoing platform that would allow us to do this? What are the benefits by use case?

That was an attempt to get up above the detail and provide a general framework of the research questions we might want to pursue.

Open that up for discussion or do you want to first insert thoughts from Round 2. Rich, what is your preference?

MR. LANDEN: Obviously, it leads us on the fly. I will start off by apologizing. There were a ton of issues that were brought up that I wanted to include, but mental processes, short-term memory did not support that. I have a list here that I think are some of the key – as Bob correctly stated up there, there is some degree of overlap.

Some of the nuggets that I pulled out are to CM or not to CM. One of the major questions that needs to be asked and the decision on the clinical modification for morbidity needs to be made before we can have any final determination about timelines on the morbidity side.

Next nugget was regulatory or non-regulatory. As you have heard a couple of times here, NCVHS has recommended that the adoption not be run through the NPRM final rule process, but in order to do that, HHS would have to have rules and regulations in place to change that. That is a key question that needs to be addressed here.

The next set of nuggets. Updating the transport standards, X12, NCPDP, Health Level Seven and the two operating rules, authorizing entities, bullets. Make sure they can all – make sure they can support the extensions and number three, make sure there are guardrails (operating rules) around how the extensions are used within the transactions.

Next nugget. State back end systems particularly with mortality, but parallels on the morbidity side, state Medicaid systems and in fact all insurance processing, Medicare systems.

HIPAA-covered HIPAA realm. The non-covered entities are not included in the HIPAA mandates. That is

workers comp and no fault are the two big ones in that category, but there are others as well.

For mortality, we heard an optimistic minimum four years' maximum seven years from today. For morbidity, it was minimum five years, optimistically without the NPRN final rule process, seven years if we go through the NPRN and final.

Can 11 be implemented? Interesting question. Can ICD-11 be implemented separately and apart before any US clinical modification?

Patient safety and data quality issues related to mapping. Can EHRs and associated software support post-coordination? Will or can ICD-11 support natural language processing or vice versa?

Then the last nugget that I was able to grab was EHRs and software. How much of the coding burden can they take on? What is the cost? What are the incentives that have developed? What is the timeframe? How are we going to test and prove it? And then the coding profession – as a former accountant, this boggles me why anybody would see becoming an auditor is an upgrade. Coders and skinny ties and green eye shades just do not compute for me. Thank you. Codes will become auditors of computed codes and guardians of the code data quality.

That is what I captured. As I apologized already, I know there is a lot more in there that Rebecca's notes have more detail on and will be added. But I think at a point in time, I would be happy if anybody wants to suggest any other key nuggets that should be on the short list for group consideration before they depart tonight. Think about this overnight. I will take that as a sign that you are all exhausted.

DR. STEAD: I want to know whether – flip back. I would love to know what is totally wrong or what people would want to expand on this to the degree you had time to make a first ponder of it; otherwise, we can do that as we have another chance in the morning.

DR. BROWN: A friendly amendment on 2B. You say it is post-coordinated extension. You are implying that making molecules will improve content gaps and that is true. But you also sometimes need new atoms. And you might want to look at the extent to which just making a molecule of existing atoms is not enough and you need a new atom or two.

DR. STEAD: Could somebody turn that into English away from physics?

DR. BROWN: Post-coordinated expression. You link a couple of concepts together to make a new one. Let's say you wanted to link three concepts together to make a new

one, but only two of them were present in the base terminology. You might have to add that third thing and without that third thing, no amount of post-coordination in the universe is going to get you where you want to be. It is another type of content that you would be assessing.

MS. HINES: Does that do it to call it base concepts rather than atoms? What is the ICD-11 term for the base? Stem. Does that capture what Steve just said?

DR. STEAD: Do we need to keep the molecules or new atom or is there a better way to say that? Do you like it that way? If it works for Rebecca, it works. Thanks Steve.

Other comments or suggestions? Keith, you have your card up.

MR. CAMPBELL: I just wanted to clarify what 2C means. Is it trying to say that we are going to use a computer to generate the codes or are we using it to generate ICD? So computer-generated encoding of a classification?

DR. STEAD: I am really trying to stick with the concept of ICD as a classifier because I think that is one of the places people get in trouble. I may be trying to be too precise.

MR. CAMPBELL: I think if we just make -- computer generation or computer extraction of ICD codes. Does that

work better for others? Maybe I am the only one confused. Generation to me means you are creating a new stem code.

DR. STEAD: Computer assignment.

MR. CAMPBELL: That is fine.

MS. HINES: Is it to support use cases from or for promoting interoperable --

DR. STEAD: The kind of things that will confuse the innocent if we are not careful is that there is a difference, I believe, from this using the foundation than mapping. That distinction may be lost on people that just have lived in mapping land.

MR. CAMPBELL: This is the realization of what I think it is. It was originally saying that can we use the same data efforts that they are going to try to get interoperable data to then extract. It is not to promote interoperable.

DR. STEAD: Down at the end, you are going to find the bullets you gave us earlier. Down here, you have the research question of how do we evaluate the answers to these questions. That is work that needs to be done.

Up here, what I was trying to get at – it is worth teasing out. What I am really talking about here is what is the method and infrastructure that could support the comparability studies. We need comparability studies. We need to do not only as we are evaluating different

approaches to implementing ICD-11, but in an ongoing fashion. I think that this is one part of that infrastructure. Am I computing or am I in left field?

PARTICIPANT: I get it now.

DR. STEAD: You did not answer my question.

(Laughter)

PARTICIPANT: You are computing.

DR. ANDERSON: On number three, I think it is worth noting that we already have embarked on a project to do that. It is supposed to be implemented in January 2020. I actually do not think that that it is going to happen. It will probably be 2021. The implementation of this product using NLP and machine learning will be implemented during ICD-10 and the goal is to extend that system to ICD-11 when ICD-11 is implemented.

DR. STEAD: You are already switching to –

DR. ANDERSON: We are already moving and the goal is to move in that direction because we really need to boost the throughput. The manual review for the 25 percent of death certificates that we cannot code automatically is killing us. It is expensive.

DR. STEAD: I get the reason that you want the platform to be more powerful and effective. Does that mean that you have in fact – you are, in fact, implementing something that sits on top of what Clem, for example,

because he was the one that raised the question that led to that bullet, would recognize as a market leading way to get this done in 2020.

DR. ANDERSON: I think so. I have some results from the initial set of testing that I have not looked at yet, but the initial indication is that it is coding about 95 percent of the records. The question is whether it is doing it correctly or not and that is what we have to figure out.

DR. CHUTE: I am not fully informed with this particular experiment, Bob, and I do not presume to question its relevance. But I think we have to be cautious when comparing prototypes that are built on an ICD-10 environment in terms of their generalizability or even contribution to a solution in the ICD-11 space. And the reason I make that statement in the context of natural language processing is that ICD-11 has the advantage of having a large ontological underpinning through the foundation component that from an NLP perspective is a huge resource in terms of enhancing the reliability and consistency of NLP algorithms. You may have a similar resource historically built up around ICD-10. I do not know. But I am making the distinction that we have to be careful not to use what we learn on ICD-10 generalizable to an ICD-11 approach.

DR. ANDERSON: I understand what you are saying and you are right. What we are doing really is more supervised machine learning. We have 17 – more than that – almost 20 years of ICD-10 data. We have the death certificate terminology stored as well. It is really being driven by what we have.

The trick will be in the conversion to ICD-11. The trick will be that we will not have any coded data when we make that transition to ICD-11 other than what we do with the bridge coding study. The question is then how do we transition to ICD-11 using machine learning, given that we do not have all that. We think we have a strategy, but we have a few years to –

PARTICIPANT: And I would submit the distinction is going from a historical machine learning approach, which is valid to the extent that you are leveraging your data. But ICD-11 has the distinction of having that ontological underpinning that ICD-10 did not.

DR. STEAD: What you would do today, I think, and we have a great advantage. Our job is not to answer. Our job is to try to understand how to pose the question. With the foundation, it might be very interesting to just simply compare what do humans do versus a modern NLP engine without your decision logic and the foundation. How comparable is it? It may be that it is not comparable at

all, but we ought to ask that question. Because if it turns out to be comparable because of the power of the underlying foundation, we have suddenly reduced significantly the amount of work you and the other countries need to do to develop decision logic. It could really change the game.

What you might noodle on because none of us know what you have actually been doing – what you might noodle on is what is the right way to word the question that would actually get at that nugget.

DR. ANDERSON: There are actually two questions and one is how do we go about making conversion of the decision tables. That is one question. And that is something that the University of Udine is working on.

The other question is how do we implement then because the decision tables really handle the selection of the underlying cause. We still have to have our automated coding system recognize the terms that are reported and assign the proper codes to them. Then the decision logic can determine how to select an appropriate underlying cause from among those codes.

I guess one of the ways I would think that the research question could be worded is something to the effect that how do we use the natural language process and machine learning to make this transition to ICD-11 from

ICD-10 from an ICD-10 system using an NLP machine learning to assist in using ICD-11, using the same tools.

The problem is, as Chris correctly pointed out, is that we do not have the history of ICD-11. We do have some advantage with ICD-11. We are hoping to leverage what is in the coding tool, for example, to do that work. But it would be good to have somebody looking closely at that. How do we efficiently make that transition without coding a million records to teach the system how to code?

DR. STEAD: We will keep working on it. I think we understand the challenges of coming to the right wording. Linda and then Steve.

MS. KLOSS: Because we have been hearing all day that driving toward automating the coding process is such an important opportunity, I would just like to broaden that the research challenge to be thinking about it not only in the application of mortality, but what lessons might be learned as we think about going forward to morbidity. Is there a way to jumpstart that process for morbidity as soon as possible because that just is going to be a really – we cannot have that technology lag the implementation the way it has been lagging now even the transition from 9 to 10.

That technology is just moving pretty slowly in the morbidity coding world. I think one of the questions is what can be done to stimulate the advances there.

DR. BROWN: One of the items was CM versus not CM stuff. One of the things I took away from today was with the data that Oliveria and Chris showed was how much better 11 with post-coordination is than 10 for expressivity and that is not a great surprise. It is of course.

It impresses me that you have this new technology. It is not just a question of CM or not CM. It is like why did you need it in the past. What is the use case based gap and what is the analysis of alternatives for getting across that gap?

Especially in light of what I also heard today was there seems to be some disincentive for national-based clinical modifications and they are trying to rein that in basically I think to prevent fragmentation and splintering. Are there alternatives that do not splinter across international boundaries – trying to reduce complexity and reduce fragmentation while still crossing the gaps?

MS. HINES: Are there methods that do not splinter across international boundaries?

DR. BROWN: Are there methods that meet the gaps that CM would seem to be required for without getting the folks who did not want there to be national-based CMs to be made at you?

DR. STEAD: Rich, I do not see any more tents. Do you want to bring us to closure?

MR. LANDEN: As you all have heard, it has been a very productive day. We thank you a lot. The process from here on, you will have a night to relax, refresh and I am sure deeply contemplate everything you have heard today.

The first thing we will do tomorrow is give the opportunity for everybody, including the committee members to do another stab at the review of what we accomplish today in our thinking. Then we will go into the breakout groups, the roundtable session number three, where we will work on the drafting of some key communication topics and messaging, followed by the report out to the group and the synthesis.

That will bring us to lunch at which time you are free to leave or if you want to stay and join the Standard Subcommittee members, it will work to again synthesize everything we have been hearing plus everything else we have learned in our institutional knowledge and try and outline a draft just to quantify the – reduce the writing, what we have come up with, a draft outline of a letter of recommendation, assuming recommendations to the secretary and then define the next step for the NCVHS purposes. And what we are hoping to do is have something that the Full NCVHS can address and sign off on at its October meeting.

After that, we will have the obligatory public comment for anybody that has been listening in today or

present today or any of you for that matter who wishes to do it and after that we will adjourn. The target time for that is 3 p.m. tomorrow afternoon.

With that, if there are no further questions or business brought before the group, we are adjourned for the evening. Thank you all very much. Enjoy your evening.

(Whereupon the meeting was adjourned at 5:30 p.m.)