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In conjunction with the National Library of Medicine

Expert Roundtable Meeting on

Health Terminologies and Vocabularies

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Agenda Item: Review Morning Work Plan

DR. STEAD: Colleagues, can we come to order? As usual, we will start – first of all, come back, but then we want to start by the committee members reading themselves in and mentioning their conflicts as appropriate. I will start. I am Bill Stead. I am from Vanderbilt University. I am chair of the Full Committee. No conflicts.

MS. KLOSS: Linda Kloss, member of the Full Committee, co-chair of Privacy, Confidentiality, and Security Subcommittee, member of the Standards Subcommittee, no conflicts.

MS. GOSS: Alix Goss, DynaVet Solutions. I am a member of the Full Committee and the co-chair of the Standards Subcommittee and I have no conflicts.

MR. ROSS: Hi. I am Dave Ross, member of the Full Committee, member of the Population Health Subcommittee. I am affiliated with Emory University and I am with the Task Force for Global Health. No conflicts.

DR. MAYS: Vickie Mays, University of California Los Angeles. I am a member of the Full Committee, Pop and Privacy. No conflicts here at this moment.

DR. CORNELIUS: Lee Cornelius, University of Georgia, member of the Full Committee, Population Health Subcommittee. I am just Zen, so conflicts do not exist.

MR. LANDEN: Rich Landen, member of the Full Committee, member of the Standards Subcommittee, and no conflicts that have been revealed to me yet by my therapist.

DR. STEAD: Debra, are you on the phone? Are any members on the phone? Rebecca, do you want to lead off for staff?

MS. HINES: Good morning. Rebecca Hines with NCHS. I am the executive secretary and thank you for coming back. Do we have any other staff?

DR. STEAD: Deb, did you just join us on the phone?

MS. JACKSON: Debbie Jackson, Health Statistics, CDC, committee staff.

DR. BRETT: Kate Brett, committee staff and CHS.

DR. STEAD: I wanted out invited participants who joined us to do what we did yesterday, which is to introduce yourself and let us know in addition to who you are and your affiliation and what you hope to see happen over the course of the rest of this meeting.

Do you want to kick off, Bill?

DR. RILEY: Sure. I am Bill Riley, associate director of Behavioral and Social Sciences at the NIH. Sorry to miss yesterday. I do not know how much I would have contributed, but I certainly missed the fun given what

I heard in the last hour on WebEx and what I could have learned from all of you in the process.

The one thing I would just mention as a start here is that for all the difficulties that we see in electronic health records and other kinds of medical terminology, when you look at behavioral and social terminology, we are in even much worse shape. There is a lot of work we need to do to catch up and a great more. That is what I hope to be able to help with today.

DR. STEAD: Thank you. Bob.

DR. ANDERSON: Hi. I am Bob Anderson. I am chief of the Mortality Statistics Branch at NCHS. I am here with Donna to talk about IC-11. I hope that there are lots of questions.

DR. STEAD: Good. Linda, do you want to take us away?

MS. KLOSS: I just wanted to add that we are not doing any breakout groups this morning. If you want to rearrange where you are sitting so you do not have to turn around, you are welcome to do that because there are empty seats facing forward. Feel free to rearrange yourselves. We just did not have enough table space to go back to our customary and formal hollow square. We are keeping this set up but feel free to make yourself comfortable.

Just to reset where we are at, first of all, you would not believe what wonderful notes we already have compiled from yesterday, pages and pages that Rebecca took. I know Vivian was busy taking notes. We have your table reports and we have flip charts. Compiling all of this will be our next task that we really relish.

But just to review what we went through at the close of yesterday, we teed up near-term priorities. As Bill said, we are not saying what near term means. It is just that it looks like we have consensus and could proceed to crafting some recommendations that would have meaning and impact in the short term.

DR. STEAD: Not to dive in depth, but the key principles to drive adoption surrounding clear definition of scope, purpose, when to use something, and evaluation mechanism that lets us know how it is being used, its usability, currency, and cost benefit and then this adoption process that is suitable for terminology and vocabulary, very different from what you need for messaging standards where things actually have to plug and play, getting at this concept of the difference of an iterative evolution and curation.

Principles for update including clear principles for curation that, in particular, deal with backward

compatibility and transparency. It is easy to see by humans and electronics what has been added or changed.

And then a publish cadence that is cost benefit based for the purpose of updates. Why do we need to update something and when does the benefit justify an increase in pace and to have that be predictable?

And then a dissemination mechanism, moving to electronic with appropriate implementation and mapping tools, minimizing cost and licensing. Those are sort of the initial things that we seem to have really pretty clear consensus around.

MS. KLOSS: Upon reflection over the evening, anything you would suggest be clarified or really a highlight that needs to be considered for addition. Are we still good with this set? I see not.

DR. STEAD: With the level of nodding, our next step will be to begin to frame draft approaches to recommendations around this so that we can work at the Full Committee meeting in September because this is the part that really seems maybe ready for prime time.

MS. KLOSS: Then we put forth this area where we need to do some of the things that the committee does pretty well, which is to noodle on big issues. What is the pathway toward convergence? We said there was a need to

consider how to bridge more deliberately, more effectively the clinical and administrative domains.

This convergence theme has been part of the NCVHS. It has been a driver for discussion for several years, but I think it needs now to kind of be applied in this place.

Distinguish purposeful overlap and redundant effort.

DR. STEAD: I think that is a place just to remind people of the commentary. If two different terminologies that cover a similar biological or psychosocial space, but the purpose that they are used for is different then that is actually purposeful overlap and it is a richness, not redundant effort where the redundant effort is when we are actually having competing efforts working in the same space for the same purpose and so clarifying and distinguishing between those.

MS. KLOSS: We had a little discussion and confusion maybe around Bullet 3 and we probably need to do a little sharpening of the terminology. But what we meant there was that while we can have a fairly limited flexibility, if you will, around what standards need to be embedded in our technologies, which can be combined with some greater flexibility of the on-ramp versioning.

DR. STEAD: Do people think we should say change limited optionality to parsimony of name standards? Is that a better term based on yesterday?

PARTICIPANT: Can I ask a question? Patrick and I were discussing last night the flexibility and versioning. Would that mean that you would have conceptually some organizations on ICD-9, some on ICD-10 and some on ICD-11 at some point?

DR. STEAD: Probably not. What we are really thinking of is if you take – this would make no sense if you have decades between updates. We are basically – I think really one of the key concepts that have come out of the predictability roadmap work with the Standards Subcommittee is that we need to have a common floor or what is the oldest version that is in fact allowed. That has to be regularly moved forward. Right now, that is all we do. Therefore, we do not have a way of meeting business need and therefore the people that are dealing with business needs, which are most of the industry, are doing one thing or another in essence alongside or whatever with the standards.

All we are suggesting is you ought to be able to have a limited, but definite window where you have the version everybody has gotten to. Ahead of that, you have a little bit like the glide path that the USCDI has proposed

and some of the suggestions of the HITECH committees. You would have versions that are increasingly able to meet the definitions we had on the previous slide for an option.

And then in front of that, you actually have drafts that are being worked on much more the way FHIR works today where people are actually working from real use cases and testing out things.

What you actually want to do is make all of those transparent, visible where people can be playing in which part of that spectrum works for them and constant moving the floor forward as we move. That is, I think, the difference that has come out of the discussions with predictability. I am looking at Alix. Nick is not here yet. Am I saying that correctly at all?

MS. KLOSS: Rich has a question.

MR. LANDEN: On that same bullet, I actually have two comments. I am not sure that limited optionality or parsimony really describes the complexity of what we are wrestling with because there are two senses. One is the total number of name standards. If we say limited or parsimony would make that absolute number smaller. But I think part of what we are talking about here is allowing users' choice between multiple standards that essentially accomplish the same thing. We need to look at that a little bit and I am not --

DR. STEAD: I think when we are talking parsimony, we are actually talking about not allowing you to have a choice between two terminologies in the same space that have the same purpose.

MR. LANDEN: That I am comfortable with.

My other concern is flexibility in versioning. I wonder if we should also add extensibility because it is not just different versions, but with the 8020 rule. if the base standard does 80 percent, but there is 20 percent that is specific to the market niche that could be done with extensibility, not with versioning.

DR. STEAD: Good point. That extension may turn into a next version. It may evolve. Good point.

MS. KLOSS: The last bullet was research and evaluation of T and V models, biomedical and health concepts and based on the discussion at the end of the day yesterday, we added and machine learning.

DR. MAYS: A question and a comment on the last bullet. Do we want since we have been talking about social determinants of health to either put in psychosocial or social determinants or something in there to make sure that that stays in?

DR. STEAD: Let's look at the slide after next and then see whether it needs to be here.

DR. MAYS: Behavioral maybe?

MS. KLOSS: She is biomedical, and health is too narrow.

DR. STEAD: If you feel that is not covered in health then yes.

DR. MAYS: Definitely it is not because I think that that is what we are trying to expand here. I think we do well in terms of our terminology that fits in biomedical and health, but we are trying to do more that was not fitting as well in terms of terms is either behavioral or social determinants or something like that.

MS. KLOSS: So noted. We will wrestle with that. I think when we put it down, we intended health to be very broad and certainly to include –

DR. STEAD: We want a broad definition and we have the details of that as we get into the gaps discussion, but you are right. We need to get whatever is right at this higher level.

DR. MAYS: Can I ask a question about the first bullet. Again, I am not sure if I am on the right page with this or not. When you are looking at the bridge between clinical and administrative domains, do we also need to at all think about the bridge in terms of research? And the first thing that comes to mind is life, the difference between using RDoC and using DSM. If we do not find some way to make sure that those are connected back, we end up

again kind of with fragmentation. Should research be in there at all?

MS. KLOSS: I think we were thinking domains in terms of terminologies and vocabulary domains.

DR. BLAKE: I think you bring up a really good point, Vickie, in that there is a – we captured the data in health care delivery and we have lots of secondary and tertiary uses as Dave and I were just discussing. If what you bring up is something that resonates with the group, I would like to see it be a separate kind of bullet because I have a very specific objective behind what I think is the goal behind bridge of clinical and administrative domains, which is more about the overarching efficiency of how we do the delivery and the capturing of data for downstream purposes beyond that just well-being of a citizen and that we have some very big challenges around that as we want to merge what I affectionately refer to as the HIPAA and the HITECH world.

But I think you bring up a good point. If it resonates, I would suggest we maybe add something related to not losing that research learning health system aspect.

DR. STEAD: I think one of the – there is one example I have been working through in my day job of how you have to think differently about patient-reported outcomes. At least in my world, patient-reported outcomes

have been a prominent part of our research world for a long time, but they are rarely appropriately used or addressed within the clinical environment. As I looked around the country, I actually found nobody that is doing this well as a system. There are examples where people are doing well, but they are not as a system.

The flip that has begun to go off in our head is we have actually got to work out the right interaction in the patient's world, the right interaction in the clinical encounter to capture the patient's reports of outcome in a way that is meaningful to the patient and meaningful to the clinician and in particular meaningful to the shared discussion between the patient and the clinician. If we can work that out then you can extract from it what you need for quality improvement. Then you go next to extract from it what you need for research and then you also get pop value. You get to where you can do pop value and research at the same time.

Flipping that around, we may want to draw some pictures that actually show how that could work that might be like our 21st century health statistics picture. We may want to add a bullet. I think it is really important to be explicitly clear that we want to take on the – we have to take on the current divide between, if you will, the HIPAA

name standards and the standards that are in the USCDI, et cetera.

DR. MAYS: I would like to then make sure that we leave a blank bullet or something because I think this notion of how we operationalize research, how we then translate it clinically, and then how it is that the patient can understand all these things. We need some kind of standard by which we are operating; otherwise, what happens is the research world is over there. People cannot find it. Clinicians are not making use of it. But we have the perfect terminology, the perfect everything, but it does not get meshed in a way in which it becomes useful.

DR. STEAD: Can you work on drafting what that additional bullet might be and feed it back into us later as we move through the morning so that we can come back and edit? I think adding that point is a good idea.

DR. ROSS: The conversation just confuses me a little bit. I see research as a function and that is separate from – it is what you do with using the data, but it is not per se related I do not think to standards. It informs the change of standards over time. I am not sure. Maybe that is an offline longer conversation. I am trying to understand what you are trying to get at, Vickie. I am a bit confused.

MR. LANDEN: When I think of clinical data, what is in my mind is the stuff, things, items that directly impact the patient/physician or patient/provider relationship and everything else is administrative. Administrative is actually kind of a HIPAA legislative term that really shows to put the boundaries around the administrative transactions as opposed to the rest of the electronic business that is going on. Maybe we need to think in terminology of bridge clinical and nonclinical because I would see research as another nonclinical use of the data. We may need to tease that out some more.

MS. KLOSS: Vickie will work on that. We will replay it at the end of the morning and see if we come closer. Thank you.

We added several bullets based on the closing discussion and your feedback on coordination and governance. It seemed like there was an overarching suggestion that we need a strategic plan for T and V that also includes the business case and as reflected in the last bullet, John White's suggestion that that business case be non-wonky and speak to the larger public about why these arcane topics are really very important to them as individuals and to all of our institutions.

We also heard back on near-term focus on areas in highest need of coordination. There were some areas that

were targeted that really could use some short-term attention and that we would be advised to deliberately take a look at public-private collaborative models, what has worked, what has not worked, including internationally. As I said earlier, there are probably six pages of very rich information in addition to this, but those were four high-level take-a-ways that we heard.

Anything else that is urgent? Yes, George.

MR. ARGES: I just wonder whether it would be important to identify and maybe this is part of strategic planning, any impediments that have been a part of the past that have stood in the way of migration towards new terminologies that are out there. If you look at ICD-10 adoption, there was a lot of pushback. But at the same time, we knew its importance. But I think just cataloging what those impediments are and seeing how perhaps we can overcome them I think would be helpful to move it forward.

MS. KLOSS: The longer-term opportunities that we discussed began with thinking about some permanent dissemination, resource center with tools, resources that are needed to support the whole industry.

Bill, do you want to take the second?

DR. STEAD: The key point around dissemination resource center and having a single point at which you go for support, quite different from the idea that one center

would manage all this stuff. The word dissemination is very important there.

It plays back a little bit to the conversation we have just had. The fact that in the electronic health records, we should be using terminologies that are clinically useful and that makes sense to the people engaged in the interactions that are being recorded in those records and supported by those records. We listed some of the current examples, but to make clear that we were not being exclusive.

Then another suggestion is to decouple the intervention and procedure codes from the facility type. If you just look at the rapid transfer of surgeries from inpatient to outpatient and of other interventions from inpatient, outpatient and now to home and to have a common way of talking about what the intervention is and a separate way of talking about the setting or the facility or whatever in a way that allows them to be linked, but not tightly coupled.

And then ways of calculating or computing payment classes, if you will, from the clinical content. Imagine that we had a data science algorithm that in essence, produced an acuity index or a utilization intensity index, or an intensity of the interaction index, whatever things people are trying to calculate without somebody having to

record that separately. Similarly, robust ways to calculate quality metrics and --

MS. KLOSS: We were going to change that.

DR. STEAD: We were going to keep quality, but we were going to add another – clinical decision support or what were –

MS. KLOSS: Decision support.

DR. STEAD: And then the subject – we are going to morph into shortly. Expanding the scope of named terminology and vocabulary standards to include vitals in public health, pop health, social and behavioral determinants, mental health. Obviously, the list is longer than that. But those are some genomics that is in there in some way although it is sort of interesting to the degree the way genomic science is done in a way that is natively computable, but that is another – but we could make it a named – it exists. We can make it a named standard.

MS. KLOSS: That leads us into our first discussion of the morning.

DR. STEAD: Any other comments about this before we – Steve.

PARTICIPANT: The decision support is great and I think we ought to maybe extend that to decision support – the decision support is a great addition and if we could

make it decision support using data across sites that would make it an even better long-term opportunity.

DR. CHUTE: To generalize on the point that you made about genomics, I think if you add basic science ontologies, which covers a broad waterfront. I think it should be on the screen somewhere if only to maintain that point.

DR. STEAD: That is a good add. Basic science ontology.

MS. KLOSS: We are going to proceed to discuss gaps.

DR. STEAD: I will be good and get out of the way.

MS. KLOSS: You met Susan Roy yesterday. She is going to lead the discussion and we are all going to help.

Agenda Item: Discuss Gaps in Named Standards

MS. ROY: I have two slides and then you guys are talking for the last 45 minutes. And then my colleague, Vivian, over there. She is actually – and I will explain as we go ahead. She will help us on the timing aspect.

Really, we are bringing it back to the original environmental scan that you all have read, and we have been discussing since yesterday. For this environmental scan, we wanted to provide obviously a summary of the current landscape of the health terminologies as they currently

are. But we also wanted to ensure that we included some of the perceived gaps.

I want to be upfront. We did not do a complete gap analysis. What we really wanted to do was just bring to light some of the current known gaps, some of the areas of health care that we see as key emerging areas that really need better representation in the terminology standards.

As we all know, the more that terminology standards are adopted and used, the more we find that the current terminologies might not actually meet all use cases and really that the recognition of health-related domains outside of what has traditionally been covered as health care. That is really starting to broaden. That has come up this morning. This came up yesterday. We are going to see that this is going to continue. As more areas beyond what is traditional, clinical, and laboratory medicine continues to expand. We also need to figure out ways to provide coverage on ways of describing and coding and really exchanging those data as well.

What we wanted to do today was to cover some of the gaps that we already mentioned. In the report, we identified eight gaps. These are content gaps. These are US regulation or recommendation gaps or again these are gaps that have been noted as important in the I am going to call it the next generation of health care. This is a reminder

to scan. We identified the gaps and we provided some information about what and how some of the gap is currently described conceptually in standard terminologies. But what we have not done and what is actually out of scope for this environmental scan is identify the specific solutions on how to cover those gaps.

Instead what we would like today is to actually go over those eight gaps. We will have approximately five minutes for each of them. But what we would like is to hear feedback from you. Is this really a gap? Are we missing anything within the environmental scan right now? Current coverage for the gap. Any specific use cases that were not mentioned. Any other current relevant work that is being done that could influence or could impact this particular gap.

As we go through these, we want to make sure that you keep in mind the potential solutions that we provided that could be used to move forward. Those were expanding a current standard, name an additional standard, and three was develop a new standard. Keep those in mind.

We will finally wrap up this session with looking at those potential solutions to get your thoughts on that and the potential use of the USCDI.

We are just going to jump right in because we do not have a lot of time and I want to make sure that –

because I know some people have keen interests in particular areas. I want to make sure that all the gaps get enough time and coverage.

Vivian will – you are going to put your arm up. If it gets really bad, just waving your arm. And then we have a couple of people recording. Thank you.

I would like to just open up the floor and hear your thoughts on – first, we are going to start with medical devices. If anyone has any questions, comments, concerns, or additions that we should include within the medical device perceived gaps.

MR. HAMLIN: I have one question because I do not know this territory. When we talk about medical devices, are we talking about the entire range from home based to facility based, everything?

MS. ROY: Who defines medical device is to mean any instrument apparatus, implementation machine, appliance, implant, in vitro region or caliber software material or other similar or related article intended by the manufacturer to be used alone or in combination for human beings for a specific purpose.

MR. MOSCOVITCH: The UDI is associated with those other standards. Once the UDI is captured, you can identify the GMDN, for example, using FDA's database and also the G10 is a type of UDI. With this one, I would argue that UDI

is the standard that should be used and that where there is gap on and UDI is increasingly being captured including being referenced in the common clinical data set from ONC. The adoption into EHR is another data set that is happening with the UDI, not those other aspects.

Where there is a gap with medical devices is the data that they create. There is, for example, a medical device that is feeding information into the EHR. There is a lack of standardization there.

MR. MACNEIL: It is not classically considered a device, but you are seeing an increasing amount of software applications on generic devices, cell phones and the like that can in fact collect and manage a lot of – well, that is actually a device, but it is communicating to – my point is the app phenomenon constitutes a category that is a quasi-device environment, yet it is really software focused, not so much a mechanical device per se. And where you put that I think is a component of this gap.

MS. ROY: I do think that the WHO's definition does include software, but that is definitely an area that I do not think a lot have focused on for this. That is good to note. Everyone is all set on that one. We will move ahead to functioning.

MS. MORRIS: If we just go back. I was just flipping back to see if I could find the actual detail on

this. The Canadian government has been talking about the UNSPSC as the standard to use, but that has been delayed is what I am saying. People are very interested in just knowing what is going to be used for medical devices.

We do a lot of tracking of implants like hip and knee implants and that kind of stuff and people are so interested in getting the supply chain piece of that straightened out. There is a whole lot of interest beyond even just pure health system in terms of getting a standard on that. Why don't I just send that to you so you have it?

DR. BLAKE: I wrote down UNSPSC.

MS. MORRIS: Correct, which stands for the United Nations Standard Products and Services Code.

MS. ROY: Just to give an update for SNOMED International, we do have a group formed for devices. It is not an official work plan project item, but we met last April and our meeting in October as well to see if we can create a new path forward for the concept model.

PARTICIPANT: We will make sure that is captured as well.

DR. BLAKE: Maybe just briefly, there is also in this country, there is an FDA-sponsored learning UDI committee or really a community and it is tackling all the issues that relate to describing a device like you open a package and it has ten packets of suture. You only use one

of those packets in a given patient. You use the others in other patients. This is proving to be a multi-year challenge of how do you then track those different items that have the same UDI, but are received by multiple patients.

I am co-chairing a high-risk medical device implant group. We are finding discrepancies across multiple coding systems. Some devices, for example, are called implantable, but actually are not. They are tools associated with implanted devices. And the patient never goes home with the tools or instruments.

There is also discrepancy of what really is implantable. Some would say it is anything an individual leaves the implanting facility with, meaning it is in their body. But actually FDA and ONC say it is anything that is still in your body 30 days later. Happy to provide more information.

MS. ROY: We can make sure that we circle back so that we capture that. Thank you.

Moving along to functioning. It is described in detail in the scan and again any additional comments.

DR. BROWN: We have been almost solely focused on LOINC for functioning. We have been either requesting new for standardized instruments for functional status assessments. We have also been successful in requests for

single question standardized questions for functional status and have been using that in almost all of our measures. That is our preferred vocabulary.

PARTICIPANT: The Department of Veterans Affairs, I think, is another important use case for disability. It uses different standards than Social Security. I would hope that that could be included. Ideally, we would be able to collect fine-grained clinical data and roll that up into the kinds of things that are necessary for disability assessments at the VA in order to try to obviate additional examinations. I would hope you would include that.

MS. ROY: Absolutely. Actually, I am embarrassed, and I apologize for not including that in the original draft. Yes, that will definitely be included.

MR. VREEMAN: I think one thing to be mindful of as we go through all of these things is some of the domains are easier to circumscribe than others. We will have to at some point wrestle with some of these issues that Chris mentioned briefly in this idea of the information model versus the terminology model, but specifically around functioning.

I come from a profession that is quite interested in this particular area. It is useful to think about the distinctions between assessments and conditions, problems, diagnoses, et cetera that might relate to challenges with

functioning. And then there is also the space that ICF covers, which is an interesting not tangential, but different level of granularity in some ways.

What I specifically want to say a use case was also for CMS and the US is the general reporting to CMS, not just on outpatient, but it is kind of the whole post-acute spectrum. And CMS has been actively engaged in all of their required instruments, in Canada, we heard yesterday the interRAI instruments are used in the US. We have a tweak on one of those called MDS and then other instruments across the other settings and they have been engaged in creating LOINC-related codes for all of those and to SNOMED as well. That is a separate issue.

I guess I just wanted to highlight. It is harder to get your mind around the structures that are used to capture information in functioning. You might be zeroed in on one particular aspect without kind of taking a bigger picture.

DR. STEAD: I think just from my perch and partly I am doing a little bit of attempted agenda management – I think these two examples have – then the conversation has brought out nicely the complexity that is involved in each of the areas of gaps.

If I can suggest, we may want to pick up the cadence quite a lot and work through to see if we have in

fact gotten the key gaps on the list. In many ways, that is what we are trying to do here. And then let us close with this discussion of how we tackle this.

Because I think one of the things that has come out is we need each of these areas is going to have to have a well-defined community of practice that can work out the choices in how we define scope and look at, if you will, both what things exist and what kind of glide path we could conceivably get on and how could then some piece of that turn into something that is named. I am guessing it is that complex. If it is – if we can capture that concept in a way that could become a process slide that would really move us if we just sort of made sure we got the right high-level gaps.

MR. HAMLIN: I was going to build on what Dan was saying. The gap that I do see though is the way we are doing functional status assessments now is more prospective so looking at goal setting and goal achievement. I think that is where there probably is a little more grayness, or perhaps not well defined terminologies or vocabularies for how you actually would track those and report those and record those.

PARTICIPANT: I am wondering as part of the analysis whether you had an opportunity to look back to some of the other work that had been done previously by the

committee, the consolidated health informatics groups, because they had done environmental scans as well. And the reports are still available. There may be some lessons learned or some additional information that we could glean from those earlier works.

The CHI report on disability and functioning is still up on the NCVH website and it was published in 2006. But when you look at the content, it still resonates in terms of the work that we are attempting to do now. There are other reports as well that maybe we need to look at if they have not already been considered.

MS. ROY: Thank you, Donna. There are clearly a lot of things that we missed in the current scan. If you do not mind sending us your questions, comments, and concerns and things that we need to include for the next draft. What we should probably start to discuss instead is are there other domains outside of these eight that we have currently identified that we should probably include in this. Chris.

DR. CHUTE: I think that this goes back to my previous comments. Genetics and genomics are two things. One, it has a much broader scope because it is proteomics and metabolomics and other kinds of molecular level considerations that are increasingly relevant in precision medicine and the like.

And furthermore, I would argue. It is not really a gap. They actually have very sophisticated and mature ontologies in those spaces. It is just that this is what I called previously that semantic chasm of despair where the clinical world is simply unaware of what is prevalent and ongoing in the basic science world.

DR. ROMANO: I guess I might challenge a little bit also whether rare diseases is actually a gap. I think that between ICD-10-CM, ICD-11, and SNOMED, it seems like that gap is pretty well covered. Conceptually, there should be a code in ICD-10 and ICD-11 for every disease. In the clinical modification, those are broken out more to cover rare diseases. SNOMED also covers rare disease concepts. I am not sure there is a need for a different terminology. There may be a need for perhaps some clarification or expansion within existing terminologies, but I would be careful about proposing an additional named terminology in a space that should already be covered.

DR. MAYS: There is one that I am less sure of, but if it is a gap, given what we are dealing with with the opioid crisis, I suggest putting it in and that is whether we should have mental health and substance use disorder in there. Again, I do not know how well matched it is. If it is not, then it would be good for us to plug that gap.

DR. CLARKE: I was actually answering Donna's question, but she was actually just asking when we have the term mental health, is it just a broad category that also incorporates substance use disorder. But when we do speak about it and write about it, we do have mental health and substance use disorders. I would like to have it there as well.

MR. VREEMAN: I think we need a little more clarity on the last one, public health. Certainly, many existing public health activities rely on and use quite extensively clinical terminologies, but that is a very broad term and I think maybe we could be more precise in trying to zero in on what parts of that spectrum there are perceived gaps. Disease surveillance, for example, seems like it is okay there. Other aspects are less so.

DR. STEAD: One of the ideas we have been working our way through is whether we can use the measurement framework for community health and well-being, which in essence ended up with 10 domains and 30 sub-domains and only one of those domains is health because we tried to get at the other pieces. We think that could in fact be a useful starting point in trying to identify what exists and what gaps are.

Again, as we talk about this, we are thinking of one challenge is identifying whether we have terminologies.

Another is whether they are or should be named. Those relate but are slightly different.

DR. BROWN: I have two comments. First, from the perspective of semantic interoperability, we have done a good job at providing terminologies for the marquis actors. You say labs. Labs are done. Right? But when you want to use lab data, it is not done. You have the great ways to name lab tests. But they are not great ways to share non-numeric results necessarily like three plus white cells in the urine. What do you do with that? We should not deceive ourselves into thinking that domains are done. I think that we just got the name actors and the supporting cast is just not there to contribute.

Then the second thing I would say is regarding process interoperability, I know that is bubbling up. But one of the real problems we face is sharing patients across sites and I keep harping on that and how do we coordinate care in meaningful ways without re-duplication. I do not know that we have any agreed upon terms or anything. Analysis needs to be done on the actual process of health care that we need to be able to track to defragment what we do.

MS. ROY: Definitely. With biomedicine constantly evolving and getting better and changing, the continued maintenance, the curation of what we currently have is

definitely never done. That needs to progress. But also with the changing of some of how we actually describe health that that is opening up some other domains that are either not currently covered in some of the standard terminologies. As we start to define these perceived gaps, we definitely need to make sure that some of these other domains that have been traditionally covered are not also left unintended.

Vickie, did you have something?

DR. MAYS: I just want to follow up because there was a comment I was going to make about what Bill was saying about well-being because I think we have to think about that also in the sense that it is very much used and in connection with a lot of the mHealth apps and all this other stuff. Its vocabulary needs to get more into what we are looking at. I know that NIH is attempting particularly through NIA to develop more around well-being as people age. I think we should think clearly about it connects to several of the things that we have here.

MS. HINES: Susan, we have a comment following up on the substance abuse over the phone. Kate Brett with the Subcommittee on Population Health would like to add that the other gap that is related to substance use disorder is that RxNorm is only for prescription medications and now we have a need for coding illicit drugs and something that

gets to the most detailed drugs and then categorizes them. It is a huge issue that we are working on at NCHS, but it is lacking.

MS. ROY: We are going to move ahead because I also would love to hear your comments about the potential solutions to the gaps. And, again, this environmental scan was just to introduce some of the current perceived gaps and start to introduce this so that NCVHS could look into this for going forward. We did not actually provide any solutions to these gaps. But what we wanted to do was start to lay some of the groundwork on what could move this forward.

We had suggested three potential solutions including expanding a current standard, naming an additional standard, or developing a new standard. In the past, these have all been used in different situations with success. All of them have pros and cons. It really depends on the situation if one of these particular solutions will actually assist.

One of the potential new game changers has been the USCDI or the US Core Data for Interoperability and the potential use of this in identifying those gaps as well as potential solutions forward. I just wanted to hear your thoughts on this section.

MS. MORRIS: The one standard that we use in Canada quite extensively is interRAI, which can be applied throughout care settings, largely non-acute so home care, long-term care, mental health. It occurs to me that it addresses a couple of the gaps, the functional status, but also cognitive status, which you flagged did not make your list, but it was addressed somewhere else in the environmental scan.

One of the things that we do with that, which is newish, is we are using FHIR to do sort of a direct link. The assessment is done clinically. It is kind of fed in and the quality or the clinical decision support is kind of built into that too. Your cognitive status might influence your falls risk or other things that kind of trigger a care pathway. That is just one standard that it seems that it might pick off a few of the things that are on your list.

MS. LIPON: Just with regards to the three. If I think about some of the discussions we had yesterday, it sounded like there is a lot of standards. If I think of the user level, there is a lot of different standards in making them all work together and interoperate together is always a challenge. I would suggest that developing new standards or new terminologies should be the last choice.

MS. ROY: Absolutely. That is actually something that we have always said, but also just to reiterate, that

has been used in the past. We had a gap with drug terminology. Actually, that is how RxNorm was developed. Yes, absolutely. There are particular use cases where it might be.

MR. VREEMAN: Two comments from the perspective of a standards developer. One is for LOINC, and for SNOMED in particular, content gets added because of a community of practice who is requesting it, meaning we are not out prospecting for new things to do. We are responding to the needs of the community. Sometimes that is the change in the structure or the format or the way that people are sending or capturing information changes. You think about genomics. There is like this rich computerization that has already been done, but what is being sent across is a PDF. You just get the report, right?

Gradually, people build in additional substructures and moving in that direction, which requires different kinds of identifiers to go along with it, but it is driven from that community of practice.

Part of this work is activating and connecting that community of practice with SDOs. I think it is in Bullet 1, expanding current standard. But I just wanted to make that point of there is an element of the users contributing to a process.

The second is there might be cases, which fall in between, which might be what we really need about our connections between existing standards, which is in order to solve the entire puzzle, sometimes you need a little bit here, a little bit here and then additional connections between them.

MS. ROY: And that is something that was brought up yesterday a number of times, so that is a good point to take.

MS. KLOSS: We will let Bill have the last question here.

DR. RILEY: Following up on the earlier point because especially in areas with weak terminologies right now, public health, social determinants of health, those sorts of things, I think my position has always been that we should be looking at integrating within existing standards and existing terminologies, not creating yet new sets. That developing new terminologies I think it is at a critical point that we are integrating, connecting to, not creating yet another set of standards that people have to figure out how to follow.

MS. ROY: That is actually good to hear because that is an area that sometimes gives us heartburn. It is good to hear that there is some consensus.

As we go through today and as you leave for the week, if you could send us any additional questions, comments, and concerns around this topic, that would be great and really anything on the environmental scan. We are going to be drafting the final draft that will go to the Full Committee. This is kind of the last go around before that. We really appreciated your comments in the first round so thank you. By the 26th of July, if you could get that to us that would be great. Thank you.

MS. LIPON: Can I just quickly say just thank you so much for putting that report together? I know that having come into this world like four years ago from Infoway, I had some knowledge of standards obviously, but no knowledge of all of the standards or lots that existed. That was a really good read. I think when it is final, we will definitely be sharing it with our community and use it as an onboarding tool. Thank you.

MS. KLOSS: That is excellent. Thank you. Well-deserved Susan and Vivian again. Thank you for this good discussion. We know you will provide us more valuable input when you re-read it over the next couple of days.

We are going to turn our attention now to ICD-11. We are running ten minutes late. This did not happen to us yesterday, but that is okay. Bill and I are committed to be back on schedule. We have just eaten a little bit into our

ICD-11 time, but we had an hour and I think we will have plenty of time to both hear about it and ask questions. Bob and Donna are going to – they will allow time for discussion as well as bring us up to date.

Agenda Item: Review Status of ICD-11

MS. PICKETT: Good morning everyone. Thank you for the invite to come back and once again present on ICD-11. This time I think we are both excited because there is actually some new information about ICD-11 and the WHO launch that occurred a couple of weeks ago.

Given the time constraints and the fact that we do want to make sure that we have time for discussion, we have a lot of slides in the slide deck, but we are not going to try to cover them all, but they are there. When they are posted, you will have the information available to you, but more information as we move forward with the understanding of what the launch may mean for US implications and applications. We will be happy to come back. And some of that information will also be covered at other regular meetings like the ICD-10 coordination and maintenance committee.

With that, I am going to turn it over to Bob, who will start us out. And the reason we are both here today just so you understand, is as Bob introduced himself earlier, he is the branch chief for the Division of Vital

Statistics, which handles the mortality side. And of course, ICD-10-CM is for the morbidity side. We are actually flip sides of the coin. And the pathways have been different, but it is important, I think, for everyone to understand what those differences are, but also where some of the common elements are, but there are differences. In this presentation, we will be covering more on the mortality aspects than we have in previous presentations to the subcommittee and to the Full Committee. With that, Bob, I will turn it over to you.

DR. ANDERSON: Thanks Donna. I used to always say that I only really cared if you were dead. But participating in the ICD-11 activities has given me a lot more appreciation for the morbidity side of things. I am going to talk mainly about the mortality stuff, a little bit about morbidity and then I will turn it back to Donna and then we will back and forth at the end.

Let me just give you an idea of the revision history here. We have been using the ICD for mortality at least all the way back to 1900 when we implemented the first revision of the ICD. In each of the subsequent revisions, we have implemented something close to when the WHO adopted – the World Health Assembly adopted the ICD.

For mortality, we have only used typically the international version of the ICD except for the eighth

revision when we used the version adapted for use in the United States. Obviously, for morbidity, we have had clinical modifications or their equivalence starting in the eighth revision.

The tenth revision. We have been using for mortality since 1999. And obviously for morbidity, we just recently did that in 2015.

For mortality statistics, the ICD is really important, and the primary importance is for international comparability of cause of death statistics. And of course, this goes into things like sustainable development goals, but also is used for national statistics as well.

This gives you an idea of the timing of implementation internationally for the last few revisions of the ICD. You can see that there are always late adopters. As I mentioned, we implemented ICD-10 in 1999. This is a little bit difficult to interpret. You can see here this drops off. It is not that people are going away from ICD-10. It just means that there are countries that are delayed in reporting to WHO. This has to do with reporting to WHO.

For morbidity statistics, obviously we are talking about things incidence and prevalence and that sort of thing. It is also really important for public health. Morbidity statistics are much less widely applied

internationally. Comparability is a real problem, which is something that we are trying to address with ICD-11.

And of course, there are other needs and uses of the ICD. There are administrative uses, clinical uses, and then uses for monitoring specific topic areas.

Going back to ICD-10, this was approved by the World Health Assembly in 1989. It is kind of old. The tabular list was published in 1992, the index in '94. Implementation really began internationally in 1994. At that point, it is already five years old. As I mentioned before, we implemented this for mortality in the United States in 1999.

ICD-10 is updated periodically. There are minor updates every year, major updates every three years. For mortality, we found that this is probably a little too frequent. For morbidity, obviously, it is not frequent enough. That is an issue that has to be addressed.

It was thought at one time that ICD-10 that we would need another revision of ICD-10 because of the updating process and of course that did not turn out to be the case.

ICD-10 is translated into 43 languages, used in over 100 countries, and it is currently the basis for global cause of death statistics. But it is now more than 25 years old. There was a need for a revision.

This occurred because of substantial advancements in medicine and science over the last 30 years. ICD-10 is really outdated. There were some substantial structural changes that needed to be made to some of the chapters. And these changes it was determined could not be handled under the normal ICD-10 updating mechanism.

In addition to that, there was an increasing need to operate in an electronic environment and a need to capture more information especially for the morbidity use case. A decision was made in 2007 to begin work on an 11th revision of the ICD.

Now, in order to make this happen, in order to get something that was useful, there were some things that needed to be considered. We needed to capture advances in health and science and medical practice, make better use of digital technologies, and better address topics such as quality and safety. And traditional medicine had not been addressed adequately before. Address persistent major gaps in the basic use for mortality and morbidity statistics. We needed it to be easier to use particularly in the electronic environment. To manage national clinical modifications more effectively and make them consistently. One thing that was really determined to be important was the integration interoperability of classifications. We

needed these to be consistent and then also comparability of translations.

Ultimately, the goals were to ensure that ICD-11 would function in an electronic environment and that it would be multi-purpose and coherent, interoperable between different derived and reference classifications.

I wanted to just show this slide here. I will not spend any time on it really other than just to say that this idea of integration and interoperability between classifications was a major driving force of the development of ICD-11.

The revision process was the largest revision process ever undertaken for ICD-10. The revision process involved mainly one person, but did not take nearly as long as ICD-11, but was not nearly as complicated.

There was an internet platform for collaborative authoring that was developed. Hundreds of scientists and clinicians were involved in contributing to the process and also more than 90 countries have been involved in the production, reviews, testing and commenting. To date, there have been more than 10,000 proposals received on the platform. All of these have been processed. I am not sure exactly how effectively they have been processed, but they have been processed and they have been looked at and considered.

Just to give you an idea of how the revision process was structured, again, I will not spend a lot of time on this. I just wanted to say that there were quite a few topic advisory groups that were formed to look at specific chapters of the ICD and specific topic areas. In addition, we had these cross-cutting topic advisory groups that were intended to make sure that there was consistency across the specific topic areas, in particular, to make sure that the classification would be fit for purpose for these various subjects.

What is new? We mentioned tabular lists. One of the things that is new is that ICD-11 is capable of generating multiple tabular lists that are consistent across lists. With ICD-10, you have a singular tabular list. You have some short lists for statistical tabulations. In ICD-11, the idea is that you can drive multiple tabular lists.

This slide mentions the foundation. I have not really told you what that is. Maybe you have heard that in previous presentations. I will mention it briefly again a little bit later.

There are some new methods. I am not going to talk about the pre-coordination and post-coordination. I think Donna is going to mention that briefly. But these are just new methods for using the classification.

There is new content, some new chapters, and then also some new electronic tools that are used for browsing and for coding, for translation, for mapping between classifications and then the proposal tool has also been developed to handle the proposals that come in.

This process. Donna is going to talk about this in a little bit more detail. The Phase 1 was getting the input from the clinical tags and putting something together, pulling together all of the information and getting it into some form that resembled the classification.

Phase 2, which started in 2015, was really to focus on refining that classification to make it fit for purpose for mortality and morbidity statistics.

Phase 3 is currently underway and that will go until this is presented to the World Health Assembly in May 2019. We are basically preparing an implementation version. A version was released last month. That is sort of a pre-implementation version, I think. And then implementation activities will then begin once this is approved.

And then Phase 4 would be a maintenance.

Ultimately, what we are trying to get at is not just a classification, but a system with an underlying foundation from which reference classifications can be derived. And also then additional classifications or

tabular lists could be derived from those reference classifications. That is really what we are trying to get at here.

I did want to mention that once – one of the drawbacks to having so many people involved was that you had a lot of disparate ideas, a lot of different things coming into the classification. It really did need some refinement so that it could be fit for purpose for mortality classification or morbidity classification. A joint taskforce was put together to go through the classification for mortality and morbidity statistics, chapter by chapter to make sure that it was fit for purpose. Some changes were made as a result of those reviews.

In addition, there was a statistical review where many of us who used the classification for statistical purposes were brought together to look at the classification from a statistical standpoint to make sure again that it was fit for purpose.

We also spent a fair amount of time updating the mortality coding rules as well to make sure that they worked with the classification. They are pretty much the same as what we had in ICD-10 from the rule standpoint, but we had to make sure that these could be used with a new classification as well.

Before I turn it back to Donna, I wanted to say something about the foundation. If you want to know a lot about the foundation, you ask Chris. Chris is really the architect of the foundation component of ICD-11. I know I will not do it justice here, but I just wanted to talk just a little bit about this because I think it is really important.

The foundation is the knowledge base for the reference and to drive classification. What we use for mortality statistics and for morbidity statistics will be contained in this foundation. The foundation is much more detailed than what we have in the reference classifications.

This is intended to be constantly changing in responses to advances in science and medicine and then periodically the reference classifications will then be updated with that new content.

It is intended to be very flexible so that you can have multiple classifications and tabulation lists. One of the most important things, I think, is consistency and interoperability between the classifications and this foundation component provides that basis.

There is a content model associated with the foundation. You can see that it is fairly detailed and quite ambitious. The goal, I think, is that as the ICD-11

matures that this content model will flesh out across all of the different concepts and categories in terms that are included in the foundation.

Let me turn it over to Donna than.

DR. CIMINO: Very quickly, two things. Crosswalk and ICD-11-CM.

DR. ANDERSON: There is a crosswalk between ICD-10 and the foundation that exists. That will be used of course in the transition from ICD-10 to ICD-11.

For ICD-11-CM, I think Donna is going to say something about that later. That is her thing, not my thing.

MS. PICKETT: Thanks Bob. Pardon for those of you who I have my back too, but I am not going to be able to stand. I am going to do it from the chair here.

As Bob indicated, ICD-11 is morbidity and mortality statistics. And, again, the history of the ICD. It had its foundation in mortality and then as countries developed greater needs for more specificity, more detail, morbidity was introduced, but this time it is with a focused set of work to increase the amount of information related to morbidity again with the WHO intent to really look around at all of the clinical modifications, national modifications that have been developed by other countries. There are many. It is not just the US with a CM version. As

was indicated yesterday, Canada has a CA version. Australia has an AM version. France has one. Germany has one. As the classification has become used more widely for different use cases, there are about 25 different national modifications that have been developed or adopted by other countries that did not have the wherewithal. Again, ICD-11 was a way of trying to embrace all of that and make it useful for multiple business case purposes.

Content. There are things that have changed. This slide just highlights some of those changes. We are not going to do a deep dive, but there is a lot more information on where those changes have occurred.

Again, major differences. One of the things on this slide that is important is the code structure. In ICD-10, 10-CM, and other modifications, we have gone to a model of pre-coordinated codes. You have diabetes with renal complications and that is sort of for morbidity purposes morphed into having additional codes to identify exactly what those clinical details are.

Rather than have these concepts coordinated at a pre-coordinated code in ICD-11, we will be using extension codes. There are additional codes that are identified in a separate chapter to identify temporality, severity, anatomic site, laterality. Instead of having all of that bundled in a pre-coordinated code, an ICD-11, you will be

using additional codes to identify that level of detail. That may have implications for mortality in some degree, but to a much larger degree for morbidity.

A new concept also that has been incorporated into ICD-11 is the clustering of codes so that you can identify the codes that should logically group together because they are related to one another. When you have a string of codes, you now will have a way of understanding how those codes relate to one another.

Some diseases did change chapters and there are new chapters.

ICD-11 is intended to be IT friendly. There are web services. There are online services. There are output files in various formats and of course there still will be a print version. They still have the look and the feel of the past. For those who just want to grab a book and not do an online tool, there is a way to still do that.

And, again, since this is from an international perspective, understand that while we all embrace technology and ways of doing things, not all countries are there.

Also, included with ICD-11 are additional materials that are intended to facilitate implementation, advocacy materials, training materials, quick guides, maps

and transition tables as Jim was asking about earlier and then training and test platform.

The process for agreeing and adopting, Bob kind of covered this earlier. These slides have a little bit more detail about how that was accomplished. You can read those at a later date after the slides are posted.

As Bob also mentioned, in Step 4, summary reports that will go to the World Health Assembly Executive Board and then ultimately Step 5, which is to actually have the World Health Assembly adopt ICD-11. It would become effective January 1, 2022.

Now, again, that is sort of the starting point for the work that countries would have to do to actually start the implementation process. The release that occurred last month really is to give everyone a chance to actually look at it, see what things have changed, how it affects their data systems, how it affects data capture, their formats for data capture. A lot of things that do have to go into it. An early release was designed to facilitate people beginning to look at it and not wait until the World Health Assembly's approval.

In terms of the way forward, ICD-10, as Bob mentioned, did have an update process, but it was not robust. It was difficult to deal with new science, new medical knowledge coming down the pike. There are new

systems that have been set up for maintenance and update in terms of governance and the WHO-FIC Network as a whole. Development of new tools and then more country support at least we hope because there were many countries who participated, but clearly it was not the entire international community that is represented in the WHO-FIC Network.

We have new groups. Under ICD-10, you have the update and revision committee that was responsible overall for updating ICD-10. With ICD-11, we now have the medical and scientific advisory committee. We also will have a classification and statistics advisory committee working together to try to make sure as things are considered for inclusion in ICD-11, that we have the medical view, the scientific view, and that is well understood and there hopefully is consensus among the clinical groups internationally, and then a view of if that is accepted by the MSAC how that will work in incorporating the information into the classification itself.

List of the countries that have participated. Again, with the curation with ICD-9 and ICD-10, it has been stated that it was at the decibel level. Whoever shouted the loudest maybe got their codes in. This participation was brought with invited stakeholders from a variety of

perspectives and their ability to use electronic tools, but also knowing that everyone is not quite there yet.

A launch occurred June 18. The information about that if you are interested. There are slides that cover that on the WHO website.

Now, I am going to turn it back over to Bob who will pick up on the possible implementation issues related to mortality.

DR. ANDERSON: One of the advantages that we have in mortality is that to implement – I do not want to say it is not difficult. It is, but it is not that complicated. We just have to decide that we are ready to implement a new revision of the ICD and then of course we have to have the resources to do it.

But there is a lot that goes into it. We have to revise our automated coding system and decision tables. And the decision table part of this is really quite an extensive effort.

We have to retrain our nosologists and medical coders although our automated coding systems do a lot of the work for us. It cannot do all at this point. We have some rejects from those automated coding systems. We still do need medical coders to do part of the work. Also, it is really important to have human beings that know what go into the automated coding system so that we do not end up

with a black box. We do have a fairly extensive retraining of our human coders to do.

We have to revise our computer edits and database specifications to accommodate new formats. There is a revision of our tabulation lists and table programming. By tabulation lists here, I am referring to our short list, the ones that we typically present. They will need to reflect the new categories, the new classification.

We will need to do a comparable study and bridge between ICD-10 and ICD-11 so that we know what changes were due to the revision and what changes are actually due to changing health and mortality.

And then we will need to develop educational promotional materials. For mortality, we work with state vital records offices. A lot of our training and promotion will be with the states because they send us mortality data. We send them back codes. At some point, we are going to all of a sudden be sending back ICD-11 codes rather than ICD-10 codes. They are going to need to understand what is going on.

When might this happen? ICD-10 took seven years to implement. That is from the publication of the tabular list. Seven years from 1992. We actually implemented in 1999. It took us seven years total once we started work for implementation to get that done.

Assuming that we have sufficient resources in terms of personnel and monetary resources for changes to IT systems and stuff. Assuming that we have international collaboration on the revision of the decision table, which I think we will have, the decision tables that are used for our automated coding system are common to the other major automated coding system that is used internationally, Iris. We hope that we will be able to collaborate with the Iris Institute to be able to revise those decision tables. We will not have to spend quite as many resources as we might have to otherwise. Assuming that we can do that, I think it will take a minimum of five years to implement. I do not think that we will be seeing ICD-11 data for mortality before 2023.

Given the scarcity of resources these days, it is likely to be a little bit later than that. But I do not think it can happen sooner than that. Maybe if somebody gets really excited and dumps a bunch of personnel and money in our laps, maybe we can do it, but otherwise no.

DR. STEAD: Just a point of clarification, that implies the 2022 adoption by the World Health Assembly is not the starting point for your five years.

DR. ANDERSON: 2019 is actually when the World Health Assembly will consider and approve. 2022 would be the effective date given time for revision.

I was counting actually from now from 2018 originally because the implementation version was supposed to come out then. 2023 I think would be very ambitious.

Donna is going to talk about the morbidity considerations, which are much more complicated.

MS. PICKETT: They are much more complicated. And, again, some of these issues are likely to resonate with many of you who have now gone through the ICD-10 transition. But there was a 1999 report published by the National Committee that looked at the issues as they related to the possible transition to ICD-10. Very interestingly, nothing new under the sun that some of the issues are still the same as we move forward to looking at the transition to ICD-11.

There are licensing implications for ICD-10 implementations, for morbidity. It was defined as for US government purposes and because ICD is used for morbidity across the board for everything. It is much more complicated than how Bob described it in terms of the mortality implementation. Again, what is the US government purposes? Is that for statistics only, coming out of NCHS for statistical purposes or other agencies that also produce health data? But does that also apply to payers who use the codes for reimbursement and coverage decisions?

Will they be required to have a license agreement with WHO in order to use the codes?

Again for 9-CM and 10-CM, they are available without copyright. Anyone can use them. As many of you know who use ICD-9-CM and now 10-CM, there is a lot of effort that goes into publishing books with value added things that have been provided by the publisher and again no copyright limitations or restrictions at all in terms of the use of the classification.

One of the discussion points and this would be with WHO is what will US government purposes be defined as. That would be part of negotiation.

Vendor implications. Again, the book publishers, the data systems, all of the touch points where the classification is currently used. What are the possible implications for copyright and other possible uses that go beyond what may be defined as government use?

It was mentioned yesterday. It is the WHO intent to limit the development of national modifications.

MS. KLOSS: Could I just ask a point of clarification? Are you saying that the licensing and copyright issues are new to 11 and they have not been there in past versions?

MS. PICKETT: That would be correct to an extent. We have an agreement. All the countries that develop

clinical modifications had an agreement with WHO. But, again, for the US specifically, I cannot speak to the agreements that WHO had with other countries, it was for government use and government use was defined quite broadly. But as we all know, government use for the code sets is not a single use. It is used for quality bench marking, for reimbursement, for coverage determination, for case mix systems. The list becomes quite long. Is that going to be included under a definition of US government purposes?

And an extension of that also would be if a publisher wants to publish a code book that has new features that are not part of the official coding classification. What are the licensing implications for the publishers? What about data systems that include the code sets so that billing can occur, and other data exchange can occur? Would that be included? There are a number of questions there. I do not have them all listed out. Obviously, the way the classification is used and the way we use ICD-10-CM in the US is very different from other countries as well.

As was mentioned yesterday, many countries use it just for inpatient acute care or hospital discharges. Some countries have migrated to using it for physicians' offices. However, in the US, ICD-10-CM is used for

inpatient, outpatient, home health, rehab, any place that the diagnosis is needed in the health care setting. ICD-10-CM is the adopted standard for that. Again, different issues will arise in terms of discussion about what is government use and what are the inferences in terms of that use. Again, those decisions and discussions would be very focused with WHO because of the unique way that the classification is used in the US.

Back to the second bullet point about limiting the development of national modifications, WHO did a huge scan to look at all the different modifications that were used in other countries to try to bring in the best of the best into the classification. However, I think countries that have their own national modifications with legal authority to do so and mandated requirements in terms of what an update cycle should be, how frequently something should be reviewed, how many times a year meetings need to occur. That is something that will also need to be fleshed out as we move forward because all of the countries that had national modifications had their own set ups for reviewing proposals to modify.

We did in many instances work with WHO through their ICD-10 revision process, but that process was not always quick enough to do the considerations that needed to happen at a country-specific level.

But, again, the WHO intent is valid in that for diabetes, for instance, even though there was a new classification that diabetes put out by the World Health Organization separately, right around the time of the roll out of ICD-10, it was never incorporated into ICD-10 itself. What happened in many countries is based on clinician input in their respective systems, each country pretty much set up their own way of classifying diabetes and having more detail in their classification. When you look at nine different ways of having done that when you roll up to do comparability at an international level, you do not have much. Again, the reason to limit how much the countries can actually modify the classification.

For here in the US specifically, of course it will include revisions to the HIPAA standard and it was mentioned yesterday. Maybe a specific named version should not be included in the regulation. Maybe it is to say the next version or the next iteration without naming it specifically. But it also will entail looking at changes in structure and conventions as it relates to the 837 and the paper forms that are still used for administrative data.

We have already started some very early discussions with X12 to figure out what might need to change in the environment to accommodate the ICD-11 codes given the change in structure.

Post-coordination again. There is a whole new chapter with extension codes, which is good. However, the problem becomes with our way of reporting things, how do you accommodate the addition of all these new codes that did not exist before or were actually part of a pre-coordinated code in ICD-10-CM? And then there is the issue of clustering and how do you report that.

Without losing the ability to report, more diagnoses because that was one of the major changes between the 410 and the 510 was to increase the number of diagnosis fields that hospitals and others could report because it was a way of showing how many diagnoses a patient had, which helped explain the severity of the patient's case. A lot of things that will be play and part of the discussion.

Some of you have seen this slide before and it still has validity. This is the 10-CM implementation timeline. Starting back in 1994 where once the tabular list and the alphabet index were made available, NCHS undertook an evaluation of 10 to see if it was fit for purpose to replace 9-CM, which had an annual update process. That took roughly three years. Documents still do exist on the National Committee website.

Hearings were held by the National Committee between 1997 and 2003. Summary of all that information is again available on the NCVHS website. An NPRM was published

in 2008 with a final rule. Another NPRM was published in 2012 with another final rule. We had an interim final rule in 2014. Finally, implementation October 1, 2015.

For a possibility of what might happen in evaluating ICD-11, I will just give you the first bullet line because we do not know what the implications are. But a question would be when would the US start the evaluation. Would it be 2019 after the World Health Assembly approval? Would it be 2020 or sometime after as WHO has indicated that they will release an update? Approximately 2020-2021. Do you wait a year until things settle and then do an evaluation? Even the starting point is somewhat up in the air in terms of possible implementation pathways. Again, question marks for everything else that would follow.

With that, we will stop. We can entertain questions.

DR. STEAD: It sounds to me like one thing we should consider in this set of near-term that could be turned into recommendations would be that given that we have outlined the principles for an option, we could suggest that we apply those principles to an evaluation of the preliminary version to do a risk benefit of using the international version and not developing a US modification. Would that be a valid thing to consider?

MS. PICKETT: I think that is a valid thing to consider and very much in keeping with what was done with the evaluation for 10 and whether a clinical modification of 10 was going to be necessary. The process will be similar. It just may be more detailed this time around that it was in the past. A few more things that have been introduced that will likely steer where we head with that evaluation. It is just not a code-to-code type of evaluation, but in 10-10 and scope.

MR. LANDEN: Donna, on your previous slide, the first bullet, who is responsible for initiating that step? Is that us at NCVHS?

MS. PICKETT: I am trying to remember.

MR. LANDEN: Let me append. Is there a trigger that will start NCVHS rolling this or is that completely up to us?

MS. PICKETT: I think it would be up to NCVHS. Again, timeframes are important because you want to make sure that what you are evaluating is stable. That was one of the issues that I think I mentioned in previous presentations to the committee. Things were not stable so we could not tell you what some of the implementation issues were going to be because we were not sure at various points what the code structure would look like, how much post-coordination was going to be involved. There were a

lot of things that we could not answer then that certainly we can answer now.

But, again, when you start to look at the full landscape of what the codes touch and how they are used that too has to factor into the evaluation, I believe. Probably more widespread than was done back in 1997.

Rich, did I get everything?

MR. LANDEN: Yes, thank you.

DR. BROWN: It is me again. I would love to hear a little bit from Chris about the intersection of SNOMED and ICD. There was just mayhem at the clinical administrative border boundary, which honestly, we are still feeling. I would like to know a little bit about that point of intersection from different perspectives and what we might do to reduce pain and mayhem in this age of pain-induced from EHRs anyhow.

DR. CHUTE: Heavens. The foundation component is a semantic network of meanings with multiple inheritances. It violates every rule that a classification is supposed to follow, which is why we have the derivatives from that classification, something like the MMS, which is a linearization as I call it, a tabulation as some people call it.

To answer your question though, the semantic network of ICD-11 was built from historical index terms,

from new content from the revision steering committee and all of its topic advisory groups, and created this mess of meanings and concepts that were crudely hierarchical, somewhat ontological, but there was no attempt whatsoever to – in fact, we explicitly avoided using a description logic to characterize the relationships between and among. And the reason for that is that a description logic is at least in the view of many of us inappropriate for health concepts because they are too rigid. Medicine is a probabilistic, almost an imperfect process and ISA relationships are too rigid to represent those relationships. We used a SKOS relationship, Simple Knowledge Organization System, broader than/narrower than relationships, exclusively in the semantic network, exclusively in the foundation.

That being said, we recognize the advantage of anchoring that semantic network against a well-formed ontology and SNOMED was the obvious candidate. We had an exquisitely positive relationship in the first many years of that exercise with the chair of the board at that time, with Ken Spackman, with others and had a memorandum of agreement in 2010 to define what we called a common ontology, which would be a subset of SNOMED that would form the semantic backbone of the foundation to which we would

link not using description's logics, but rather using query logics.

The example of that was if you take a concept like hypertension, you who know ICD, hypertension explicitly excludes hypertension associated with pregnancy or preeclampsia. You have this logical subsetting function. It is a negation function, not preeclampsia. That is difficult to represent in description logics. ELL plus plus, which is the SNOMED description logic, does not represent it.

We were using query logics instead, which are essential SQL style relationship logics that were alternative type of subsetting logic, a set logic theory that could accommodate that kind of association.

We were going great guns. We completed the chapter as a demonstration and proof of concept on cardiovascular. We had a subset of SNOMED that semantically anchored the foundation in that category.

How do I phrase this? New leadership arrived at SNOMED and made statements that led effectively to the withdrawal of SNOMED from that partnership and relationship. This was unfortunate.

We are in the position now where the foundation layer is basically building its own semantic anchoring. That was not our intention, but it is the reality. I will

stop because I will get emotional and say things I should not say.

DR. BROWN: If I could just follow up. This may be the exact kind of opportunity or thing that needs to be fixed in the longer term to reduce mayhem and chaos over a ten-year period. Lots of opportunities for integration. Because it does not appear to have happened and Chris did not get into the real interesting part where he would start crying. We now face this dichotomy and we deal with it day in and day out for every encounter and every clinic.

DR. STEAD: It would be useful to know if text could be developed that could go into the path forward, not the end game, but the path forward that would be useful. If we could get such a draft for the committee to think about that was put together by people that know what they are talking about, which as generalists the committee is not the right to put it together. I think that would be extremely helpful.

If in fact you had a way to a common anchor that anchored the parts of ICD and SNOMED that were redundant whether purposeful or not then you would have a semantic anchor to do interoperable computations of relationships. That would probably be okay. If we cannot do that then it seems to me the alternative is to think through. Can you say that there are certain parts of – certain things of

SNOMED we should not – certain parts of SNOMED that should not be included in a name standard because for parsimony, we should use ICD for those parts or vice versa. There are two ways that you could conceivably get out of this if I am hearing you right.

DR. CHUTE: There is an important implication to the concept of a common ontology philosophically. We are all aware of efforts to map SNOMED to ICD and vice versa. They have categorically and uniformly failed. This is known. This is well established. It was proven again in December last year with ICD-11. The whole premise of a common ontology is that it makes a mapping mute because you characterized it perfectly, Bill, in that one can computationally engineer the association given the linkage framework of a common ontology.

Furthermore, the whole notion of ICD-10 to ICD-11 becomes computational if you think of it that way. The original plan had been to make an ersatz copy of ICD-10-CM and ICD-10 as a linearization from the foundation and then use those computational linkage capabilities because you can then logically walk not only from SNOMED to ICD, but you can walk from any linearization to any other linearization using the same computational machinery. This is a crucial piece of the architecture that was never completed.

MS. KLOSS: It looks like we are ready for a break.

DR. STEAD: Donna and Bob, thank you. That was extraordinarily helpful.

(Break)

Agenda Item: Road-Mapping Standards including Health T/V

MS. KLOSS: I am calling us back to order times three. We are going to shortly talk about predictability roadmap for standards and explore its applicability to what we have done here. Alix Goss, co-chair of the Standard Subcommittee, is going to take us through that.

Before Alix begins, Vivian has a comment.

MS. AULD: I just want to make a comment about Chris' comment about WHO and SNOMED. This is not to negate what Chris said because that is his perspective and he totally has every right to that perspective because it is what he thought, but it is not the whole story and it is not the whole perspective. I do not want SNOMED to have a horrible reaction from all of you due to that.

More importantly, I think we need to look at this. It is the type of challenges that are in front of us for all of these things. There are issues between SNOMED and LOINC. There are issues between all the different pieces and how you fit them together and there are

different communities that have to fit together and get their perspectives to mesh and there are ways of working to mesh. It is a huge challenge across the board.

Like I said, everyone's perspective is different, but there you have it.

MS. GOSS: I am going to attempt to not block anybody's important view of these awesome slides. I am going to stand over here and I am going to present today on behalf of myself and Nick. He will chime in as he needs to round out my commentary.

My primary objective is to make you aware of an effort that we are undertaking with the transactions portion of standards. I am talking about the EDI transactions for medical and pharmacy when I am going to talk about predictability roadmap for standards because all of the Standards Subcommittee has a broader scope including vocabularies, et cetera. This presentation is only specific to transactions. And what I hope to do is make you aware of our effort and then get some input about how you see predictability in vocabularies evolving. That will help our overall learning as a Full Committee.

Show of hands. Who is aware of the fact that we have been doing a predictability roadmap for standards? That is awesome. Good.

From a historical perspective, let me kind of frame this up for those of you who have not been going through somewhat a painful journey with us over the last couple of decades. The HIPAA legislation was passed in 1996. It is of legal drinking age at this point. It still needs to grow up a bit as far as how the system advances itself to new versions to keep pace with business.

One of the dynamics that we have been experiencing is industry feedback to NCVHS saying that we need to have a better way of evolving upgrades to adopted standards so that we can keep pace with technological and business changes. Just for example, value-based care is a good one to look at.

Because of the volume of feedback that we have received from the industry over the last 15 years if not a little bit longer, we decided to step back, create a very specific project around scoping out what does predictability look like.

A lot of the components that we have been considering have evolved from specific hearings or review committee efforts, the testimony that we have received. It has also been influenced by our annual reports to Congress on HIPAA, which is a responsibility of the National Committee.

We have also had the opportunity to review those standards that were adopted under our Review Committee responsibilities, but also to consider what we wanted to propose for new additions and modifications, moving forward as a part of our Standards Subcommittee work and being the gate for the industry to take their development work and have it be funneled into the secretary of HHS' processes for formal rule making.

When I talk about standards, I am referring to, as I said, the EDI transactions. I should have also included operating rules. Think about X12 and NCPDP as the medical and pharmacy EDI transaction standards. We have NACHA that supports us with the EFT functionality for the payment through the automated clearinghouses' infrastructure from payers and providers. And then we have the constraining of business rules within the functionality of the adopted standards and the operating rule authoring entity or CAQH CORE has brought together a coalition of businesses used to say we know we can do a huge amount of things within the adopted standards, but we really want to constrain it down to garner more efficiencies and how we function together as an ecosystem so the standards that we have been looking at or that scope.

What have we accomplished so far? We wanted to make sure that although we thought we understood what the

landscape looked like that we validated that. We undertook a series of steps in interviewing the SDOs. I am using that term globally because not all SDOs are ANSI accredited, but the tally that we are looking at does include the operating rules, X12 and NCPDP.

We wanted to make sure we understood how they functioned, how they were composed, and their structures. We have produced an artifact that is available on our website that summarizes all that information. Lorraine Doo gets a really big shout out for all of her tremendous work in helping us to produce these artifacts.

We did a daylong visioning exercise. It happened to have been ironically scheduled not only on the day of the solar eclipse, but also on HIPAA's 21st birthday. We gathered to have an appreciative inquiry. We have been kicking the tires on what is working and not working on HIPAA since we adopted it. We decided to step back from what was wrong and look at what could be and that created a variety of thoughts. I can distill those down into five core themes: governance, standards adoption, regulatory process, data harmonization, and third-party entities. That report of the appreciative inquiry is also available on the website.

We also met with our federal rulemaking partners. I have intentionally neglected them in the body of

participants at this point because we have tried to figure out how the industry works together, but then we also have to figure out how do we adopt all of this and how do we advance the nation on using the standards that we have been collaboratively developing.

We have known for a long time that there are barriers and challenges within the federal rulemaking process, which is intended to help and support and protect us, but at the same time have really slow down our ability to do more than one massive upgrade to the adopted framework for EDI transactions. For instance, in X12 versions, we adopted 4010 initially. We are now sitting at 5010. One version major upgrade in 20 years is not really keeping pace. We needed to also understand the opportunities with HHS about what they might be able to do.

An additional consideration related to that is how can we learn from ONC and others who have been able to use some really effective tools like sub-regulatory guidance that we might be able to adopt within the HIPAA framework.

In all of this, we knew we needed to meet with the end users, the people that have to live with this stuff day in and day out. We saved that best for last with the CIO forum that we held this past May. In a day from now we will have the posting of that meeting summary. It was a

really phenomenal event. The recap is just that. It really gives you a global view of all the tremendous input that we have had.

We are looking to move into a set of formal recommendations or draft recommendations that we will present to the Full Committee in September. We will then set those out to the wilds so that industry can review them, discuss them with their own memberships and prepare their testimony for an upcoming hearing. We have not set the date on the hearing. We anticipate doing some coordination with our SDO partners at the end of August and likely to start to coordinate a little bit more closely on what will need to be happening this fall.

We do believe that the industry is going to need several months to discuss the draft recommendations so that they can prepare their consensus-based views to bring forward to the hearing that will then enable us to finalize our recommendations and then complete the NCVHS process of bringing it to the Full Committee, having discussions, truly finalizing them, and then sending them off to the secretary and likely recommendations targeted towards specific SDO's leadership.

As we have been going through this journey, we have been having parallel work within the Full Committee and also the Standards Subcommittee as you are a part of

that in this terminology and vocabulary effort. There has been a sense of mutual learning and evolving our thinking as we continue down the path.

One of the things that we anticipate is that we need a predictability roadmap for terminologies and vocabularies. With that said, do you have any thoughts on that or do you have any questions on what I have just given you an overview on? I may have just gotten you time back on the agenda.

Rebecca is suggesting that I might provide some additional commentary on the convergence of administrative and clinical world. We believe that the foundational information that comes out of the patient-clinician interaction is really the core of the data capture. And the CIO forum made it extremely clear to all of us that there really is an artificial distinction.

We have to figure out how to overcome that. I think that you are asking me to tackle that from the perspective of as we are looking at terminologies and vocabularies and how that impacts our use of code sets within the transactions, there is a very clear linkage and there is a lot of work going on within the ONC and the USCDI to advance the – how do we look at data classes, how do we get people to adopt a base version and then know that there is something coming down the pike through the

interoperability standards advisory. These are tools in the toolbox we may be able to use to advance us towards convergence.

I think for this conversation today, I am very curious about your sense of how do we think about terminologies and vocabularies keeping pace with business needs and medical needs, technical needs, and how that fits in with the data information exchange and how we might want to further link those in our thinking on building roadmaps.

MR. COUSSOULE: Let me just interject for one second. I think one of the challenges that we had and we purposefully tried to restrict the discussion throughout a lot of this process to the administrative standards and transactional standards. And every time we went down that path, we had to purposely push out some of those interaction challenges between the distinction between the clinical and operational side.

We recognized pretty early on that the distinction is somewhat arbitrary and necessary. And the further along we get, the more complicated it becomes to do it that way. Part of the process in the CIO forum was to get the feedback from people who are – part of the challenge with that was not just to get – it was not just CIOs, but we framed it as people that actually use this every day in their operation. It was from all different

parts of the ecosystem. It was software companies. It was payer organizations, provider organizations, intermediaries, et cetera. The feedback we got was it is necessary to advance that process of administrative standard simplification. At the same time, you cannot ignore the challenges of that clinical integration having to happen over time. We recognize that.

It is a little bit almost for us even a parallel path of saying we definitely want to be able to advance the administrative side recognizing at the same time that you cannot ignore the clinical side because they are very intertwined.

MS. KLOSS: One of the discussions was data harmonization, one of the five themes that Alix mentioned and the issues that came up there. Of course, it was much more compressed discussion. They were all of the things that came out yesterday. These are integrated, and we need to look to at least the predictability roadmap model in a way that takes in both.

MR. HAMLIN: You said something that actually triggered my comments/question. The nature of the clinician-patient interaction is massively changing from a physical presence, even if you extend that to telehealth to a synchronous communications using APIs to mHealth applications to a whole host of other things and how the

standards, the terminologies interact from that clinical data from the EHR to all of these other applications that includes some really interesting FHIR apps that work for the providers in documenting some of these transactions. I do not think that they are in the realm of consideration because I think people are still too traditional in thinking about that in those transactions.

MS. GOSS: I think you bring up a really good point, which is that we have had this. I am going to send you a claim, but claims are really part of the old world and alternate payment models and value-based care methodologies. We are really focused on outcomes.

We know we need to address some of the current day short-term predictability because you cannot throw the baby out with the bath water in the install because not everybody has gone to value-based care nor is it going to happen in one fell swoop overnight with everybody going there. We are going to have to figure out how to straddle some of these issues.

What we also need as we look to the convergence issue of administrative and clinical, how do we then start to provide a longer-term glide path for recognizing things like FHIR and Da Vinci and Argonaut, the use cases that take FHIR and enable us to get that information flowing. I think we have some deep philosophical discussions that we

need to tackle here as we move forward. That is something the committee will be grappling with especially as we look to our 13th report to Congress.

MR. HAMLIN: I am actually less worried about FHIR than I am about the mHealth apps that are expanding what we are calling clinical data. The information is being collected in the nontraditional sources, but it is being incorporated into the EHR or it should be because it is very informative. FHIR is doing that in a very nice standard way through transmission formats and things like that. They are really trying to constrain to that idea. But I think there is a whole host of other work out there that could use a lot of guidance. As some convergence happens, there are some other things that are going to really affect that.

MS. GOSS: I am hearing the idea that we almost need to have a brainstorming day around what does this mean to frame it up much more concretely.

DR. BLAKE: One word I do not think we have explicitly stated yet, but the use of all of the apps prompted me to think about it is cybersecurity. As we think about all of this content coming from many different sources, I know certainly on the health IT policy committee, there was a huge discussion and a difficult one about the fact that clinicians are required to allow

patient data to go wherever the patient wants it to go. Yet at the same time, we do not have a system in place for in any way knowing with rare exception how trustworthy those sites are or those instruments are. I could envision the same thing happening where that poorly vetted or we could say maybe even poorly performing app is sending information into an electronic health record upon the request of the individual and it is not reliable data. It therefore is wasteful of time, memory, et cetera and has to be vetted. Just a thought for your group.

MS. KLOSS: We have not discussed at this meeting, but the committee is working on another initiative, which we are calling Beyond HIPAA of privacy and security issues that are outside the traditional control of covered entities and business associates and of course that world of privacy and security beyond HIPAA is just exploding.

We have put out an environmental scan as Bill mentioned on that. I do recommend that scan. It was just very well done and it just kind of gives you a broad perspective on how many of these concerns are very real and what protective mechanisms we have and the Privacy, Confidentiality and Security Subcommittee is working on examples of what kind of control mechanisms are possible either in the private or public domain across three of these spaces beyond HIPAA, the big data space, the app

space and the device space just as a beginning to put some stake in the ground. We are certainly not ready to be making recommendations, but we are pressing forward on that path for all the reasons that you mentioned, Kathleen.

Have you done all you care to do today for the cause, for the good of the cause? Not quite because those of you who are staying for the afternoon, we are really going to go into a deep dive and do some work.

Before we adjourn, I think we just really want to thank you once again. I would like to just flash through where we think we are going next with this although we have had some new ideas about putting some meat on the bones – where we are going next and get your wisdom on how we might modify this.

We will have completed the roundtable. We actually have a writer who has been on the phone listening and we have a report outline of this meeting. We are going to move rapidly to prepare a report that we will share with you. You can look at it, review it. We will get it then locked down as Vivian and Susan said. We have until the 26th of July to get any comments or suggestions on the environmental scan and then we are going to prepare that for action by the committee in September.

We are going to immediately kind of go to – we will update our project scoping document. In an iterative

project like this, we kind of go back and revisit that and see what we have learned and incorporate change in insights into how to proceed.

Draft project report and letter to the secretary and our chief here is already whispering in my ear is I think what we need to do in August. We are going to move forward lest we forget and lose any momentum.

We want to have committee action on a letter and then importantly start incorporating the key themes in non-wonky language in the next report to Congress and start building the case, if you will, as to why all of these initiatives are really critical to moving our health care system forward.

I think we have explored some really important longer-term initiatives. The communities of interest were a new theme that emerged this morning and how to convene those communities of interest and begin to leverage all of those who are interested in contributing. That is our plan.

DR. STEAD: I have just been slowly trying to get the take-homes from this morning. I am not all done, but let me start with where I am and see whether this computes or not. Let me go back to the gaps' piece. It seems to me in terms of content areas, we said we needed to add substance abuse to mental health, add basic science ontologies, parens, exist, need to connect to the clinical

world, add illicit drugs, add process of health care or content areas.

Then under process, clear statement. We need to integrate new concepts into existing terminologies of practical. We needed to recognize the importance of a community of practice to define scope of a content area and perspectives to include. And we needed to recognize that as we considered gaps, the curation process would be a continuous process with promotion of a concept to named status as evaluation shows it is ready for a purpose.

And the next steps under gaps were please email gaps' use cases to us by 7/26 for inclusion in the final version of the environmental scan. Is that a fair summary of what we came out of gaps with?

PARTICIPANT: (off mic) – include veterans disability –

DR. STEAD: As a use case under function.

PARTICIPANT: There probably are different concepts just because some of it is pretty –

DR. STEAD: But that was a use case – include the VA as a use case for function. Thank you.

DR. BLAKE: Not for addition, but for deletion. It seemed there was discussion suggesting that there is no need to consider rare disease as a gap to be addressed. I

do not know if that is the consensus of the room, but make the list shorter in some ways.

DR. STEAD: We are really talking about using ICD for rare diseases or ICD and SNOMED.

MS. ROY: We might want to also pull in some researchers in the rare disease realm because we have heard otherwise, which is why SNOMED has continued to work with Orphanet and others.

DR. STEAD: And that again plays to the idea we need – in essence, I think where we are headed is we are going to need to make explicit the idea of a community of practice around each key content area, which will support continuous curation of things that need to be added to. And then the key question is which areas are not covered by named standards at all and how do we try to include them. I think that is where this is headed.

MS. PICKETT: I want to support what Susie and Bill have just said in regard to rare diseases because I think you need to have the subject matter experts around the table because as Patrick Romano mentioned earlier, yes, the ICD captures it; however, is at what level of detail. We have already been in discussions with the rare disease program at NIH to talk about are there 6000 rare diseases. Are there 8000 rare diseases? If you are looking at a global perspective that number can be higher because many

countries have their own definitions of what a rare disease is and what that number actually is.

From a US-centric ICD perspective, we are actually having a discussion about that at our 10-CM maintenance meeting in September because we have received a lot of proposals to have unique codes. But can a classification readily accommodate 6000 new codes to accommodate 6000 rare diseases is part of the discussion that would need to occur?

DR. ROMANO: I think more generically to second Dr. Stead's point is there should be a process for considering the gaps, to start with identifying the gaps as has been done in the report, but then to characterize those gaps further. What do we mean by a gap? What aspect is really the gap? How can we define what the scope of that gap is and what the purpose of filling that gap would be? Knowing that then you can move forward with the choices, the choice set that you have outlined. I think the development of new terminologies would be the lowest choice on that choice set. The higher choices would be adapting or refining existing terminologies. There, I would encourage people to look carefully at opportunities for international harmonization because from the research perspective, obviously tools are more useful if they have been adopted internationally. We have the ability to develop

international collaborations and to do international benchmarking. To the extent that we can borrow from ICF or other international standards, I think that opens up additional opportunities for research application.

MS. KLOSS: Is there anything else on your list?

DR. STEAD: Then I was going to move beyond gaps and there I ran out of typing so I will just talk. Around ICD-11, it seems to me NCVHS needs to review the process we used to comment on ICD-10 some period of time ago.

It sounds to me like we should develop a – that one of the things we should do in 2019 after we get the recommendations of the short-term list out and follow up to this hearing, it seems to me that we should scope a project which would in essence begin to hold the hearings and do the analysis of the fitness of the ICD-11 for both – I guess really for mortality, morbidity, and interventions because Lord knows where we would land. We ought to begin that process.

Even though the terminologies may get updated or will get updated, it would probably behoove us to do a walk through the process so we in essence learn how to do the fitness analysis with the drafts we got, get some idea of whether it looks like it could be conceivable that we would be able at the end of that process to recommend avoiding creation of US versions or not because the earlier we know

which direction that is going to go, the better off we will be. It seems to me that that probably needs to come into this radar screen.

It seems to me the other thing we have to figure out a simple way of capturing as part of probably both the principled roadmap toward convergence and the long-term opportunity. It would be different in those two slides, if you will. It would be to capture this concept of how we get to what was a computationally engineered relationship amongst reference terminologies so that we get out of the business of having to develop mappings as an additional labor-intensive process that is not ever going to be precise. We might try to capture those two concepts as part of the path. I did not get to type that down to where I could read it to you, but then we have lunch still before we regroup to do the Subcommittee work. We will try to work on it.

Is that directionally the right take-homes or not?

MS. KLOSS: I see nodding. Any comments? Any additions, clarifications?

MS. MORRIS: Just on the path to ICD-11, the one thing and this may be super clear in the US –

(Laughter)

MS. MORRIS: Some of the points that you are listing are all steps that we have in terms of thinking about it.

We also have a big piece about who needs to weigh in on this and how their views get aggregated. For us, we do not regulate adoption. We recommend adoption and people have to be willing. We need a critical mass of people who are willing and persuaded by the value or the business case to move forward. I am just not sure whether that is out of your scope or whether that is part of the plan that needs to be noted.

MS. KLOSS: Very good. I think that did come up in our discussion yesterday that we need to be keener in terms of describing what the benefits are and why to do this.

I think we wanted to conclude today with revisiting what we said we wanted to get out of this meeting and see if we at least touched on or if there are any gaps. I cannot ascribe to any person, but let me just review these and let's see.

We wanted to focus on promoting increased use and value of terminologies. I certainly think that has been discussed. Identify solid opportunities for increased interoperability and that we explore that as much as we can. Tighter integration of models. We have not done it, but it is part of the longer-term plan.

Promise of translational medicine. Dependent on semantics. Has that been explored sufficiently for the time? Developing a framework for integration in systemic update methods. We are not going to lose these bits of wisdom.

MS. HINES: What is the second --

MS. KLOSS: Steps to identify gaps. Expand to code sets in thinking with that. I am not sure I remember. I probably have other notes. Anybody ring a bell.

MR. VREEMAN: The idea that we might want to also consider syntaxes such as HGVS, for example, rather than just enumerated list codes in this conversation.

MS. KLOSS: More efficient transitions. We talked about that. Tighter integration. Less duplication. We have certainly explored that. Voice of the clinician included. We have certainly explored it and agreed that we need new mechanisms. Streamlined update process. Steer a path to improved patient care. Closer link between the work associated with capture and value to patient care. Too many standards. We have explored that. Clear lines of sight between groups for collaboration. We certainly have explored that and the difficulties therein. Communicate the understanding of where we want to arrive. Common understanding.

Opportunities to streamline and great simplicity. Come away with tangible action items. We hope we focus on short-term. Preferred set of vocabularies for our patient phenotypes, tangible opportunities to coordinate. Exchange trusted framework. Modernization of ICD maintenance process. A lot of good recommendations across that. Don't lose sight of value of standard terminology. Worth the investment. Going back to making the case.

I do not think there is anything here that we have not explored at some level. We have a few minutes. Can we get your responses to the values, the take-a-ways of this from you? Anybody at this table want to comment? I will not call on you individually, but let’s just go around the room by table. Observations?

DR. CIMINO: I am particularly interested to see a draft of the short-term actions. I feel like there was a good set in there. I think probably that when we get to see them, I am sure there is going to be some loss of information between what we said or what we were thinking, what we said, what gotten written down. We will have an opportunity to beef that up a bit, put back more of the information if we did not convey it clearly when we were saying it initially. I am particularly interested in that. I think that is going to be a very useful compilation.

MS. KLOSS: I have sometimes used a technique in complex means like this where we have actually attached to that summary report the typed notes in their raw, not very pretty form. But it is often enough for you to trigger. I said that and you could not read my writing, but I can fill in the blanks. I do not know if that would be useful, but it may be useful for this.

DR. STEAD: We will, I believe, have a typed transcript of everything, but the breakouts. That will be posted on the web as part of our meeting material. We will not lose that. One of our principles is that we – our summary, the meeting summary will go to all of you and be vetted for errors and omissions.

MS. KLOSS: I am suggesting that attached to that is an appendix with the table reports and the typed flip charts. Later on when we are agreed that we have captured things correctly, we can rip off the appendices and the report will stand.

Anybody else at this table?

DR. BROWN: I have just a couple of things. First of all, I think it was really helpful for me to learn from so many other really smart people and about things that I did not really have a lot of insight on. That was real helpful.

I think a lot of the themes that have come out have been excellent. You might want to just read up on usability, especially usability at the clinical point of care. I did not see that up there, but there is tighter integration and the impacts of the point of care I think are very important.

We did mention tighter integration of models a couple of times. We did not really hop down the bunny trail of anything to do about that. Two comments. One is that there may be a way to convene some of the right information of science type folks. I think this can be done almost in a domain agnostic way, but some sort of technology information science, computer science kinds of folks to provide input on going forward strategies on that. I do not know if that is within this purview or not.

And then the other thing that I would say is just briefly, and Keith will kill me if I do not do this, call your attention to some integrative work, model integration work that Keith Campbell is doing, integrating SNOMED, LOINC, and RxNorm and something called SOLOR, in a formal way integrating models. There is a SOLAR IO website you can look at. It is an attempt. It is trying to move the ball in a constructive way and just so that you are aware of it, I think, might be helpful.

MS. KLOSS: Thank you. Anyone else at that table?

MR. MOSKOVITCH: This has been really interesting. Thanks very much for inviting us. One area that is getting increased focus is patient matching and the demographic data used for patient matching across different systems. There is increased research and increased attention to whether additional data elements should be used for matching and what standards to be using for those data elements. Having NCVHS take a look at that as part of the gap area and any recommendations to pursue as part of the USCDI would be extremely helpful for the industry moving forward.

MS. KLOSS: We have that down. Kathleen, Dan, Nick?

DR. STEAD: One of the things we put on the governance and coordination slide was to start with the, if you will, lowest hanging fruit, I hate to use that in this term, for whatever is the most important – what are the most important places to start in terms of coordination where we would get the most benefit and therefore we might actually be able to test some processes for helping coordination that is already going on to some degree, but if we could help it go on a little bit more robustly.

What are some of those specific examples? I think I heard a mention of RxNorm and PCS. It would help if we had two or three or four of the key examples if there are

on the tip of people's tongues. I know people have mentioned examples, but I did not get them down.

DR. BROWN: One RxNorm-related thing I mentioned yesterday was CVX. They are CDC’s vaccination codes that are different from RxNorm. It is not clear to me why that would be that way. That is a potential opportunity.

DR. STEAD: I did not get what I was remembering.

PARTICIPANT: I just wanted to say that CVX is integrated in RxNorm now. CVX has RxNorm codes attached to it.

DR. STEAD: If we can find out how that happened then we can note the process. Already done.

Any other example? You said SOLOR was an example of a potential attempt or process.

DR. BROWN: Model integration. S-O-L-O-R for SNOMED, LOINC, and RxNorm.

MS. KLOSS: I think it is in our environmental scan.

DR. STEAD: Anything else? People clearly begin to feel the fruit is not so low hanging.

DR. CHUTE: In the context of terminologies, one often includes identifiers and NCVHS really for the past 20 years has skirted around the issue of national patient identifier. Whether you choose to include that in terminology and vocabulary as an identifier or not, I do

not know. We are all aware of the political exigencies that surround that, but it is a thought.

MS. KLOSS: We have certainly raised in reports to Congress and mentioned year in and year out.

DR. STEAD: And the current effort, I believe, is including the standard matching framework within the trusted exchange framework. I think that is where we are going to prove or disprove that matching is a feasible answer. I think that is probably going to be – is where this stands in the country today. I may be wrong.

MR. MCNEIL: First of all, this has been great for my half day that I was here. I am sorry I missed yesterday. Nice to see psychosocial terminology included in this. I think that is really important.

I think one of the struggles that we have in that space is that we so often couple the instrument to the scale or the metric in which it is expressed. For instance, whether I used mercury or don't mercury, I still express blood pressure and millimeters of mercury. But if I measure depression, every depression scale has its own scale or its own metric in which it is expressed. If we can do anything to begin at least say something about trying to decouple the metric of scale in which something is expressed from the instrument in the psychosocial realm that would be helpful.

DR. STEAD: If I can add to that, from my time with what is now a NAM committee, IOM committee, and the take-homes were, one, certain constructs have a common metric. Exercise common metric being metabolic minutes is an example where you can map from accelerometers or questions to that common concept.

The validated question sets are another standard and if implemented in EHRs or in patient-facing technology would actually capture – standardize the capture process.

The flaw I think from that work and I do not know how we could correctly address it is the inclusion of the – the way those are included in code sets actually do not match either the common metric or the validated questions. What the NAM committee tried to get us to do was actually to get the question standard at the front end and get the common metric standard at the back end and then you would actually take them out of the coding set. You would have the common metric in the coding set probably.

Am I parsing that right?

MR. HAMLIN: I actually have a little addendum to that because the way that they are being defined right now for quality measurement/decision support is we are actually within the logical model building in tool-specific/question-specific terminology so it defines a very specific tool to a specific energy value and the expected

associated attribute of that value. What that value should be should also within the data. We are using very specific terminology. We are getting rid of the vocabularies that say, yes, this was a positive finding for depression screening, for example. Now, we are using PHQ-9 total score equals value X over this amount equals positive finding. It is not in the terminology anymore. It is actually outside in the logical model. It drives that clinical decision support and data capture. We are doing that everywhere we can for the patient assessment level. Anything involves blood pressure, biometrics, patient assessments, everything. They are trying to get rid a lot of that gray area codes.

MR. LANDEN: One of my take-a-ways that is really not surprising, but it is a reaffirmation of no matter what we talk about, it is part of a complex system and something always impacts something else or many other things or is impacted by many other things. One specific example is brought up about the patient's right or ability to direct their medical information anywhere they want to including PHI in the context of thinking that through and some of the rules we talked about of eliminating redundancy.

One of the other initiatives at NCVHS has in process now is kind of an alignment document between us and the HITAC, ONC's federal advisory group. The purpose of

which is again to minimize redundancy and hopefully eliminate any conflict in recommendations that come out of either groups. I think this whole day and a half process helps reinforce the need and gives us more perspective as we proceed as NCVHS proceeds with ONC through that process of developing that guideline as to how the two advisory committees work relative to each other.

MS. KLOSS: Any wrap-up observations from Table 7?

DR. CLARKE: Actually, I am just going to echo Bill's comment that I am really happy to see mental health and psychosocial factors make it to the table. I also pointed out to Vivian that in thinking about the environmental scans and I know function had made it on there and you have examples there, but to realize that even though you are identifying gaps, realize that there are gaps within the examples that you have identified. One of those is actually looking at functioning. And majority of the codes and if you use CMS as an example, they focus on the physical function and impairment and mental health is not included at all. I have to bring that to CMS' attention that mental health imparts a lot of function in impairment. That needs to be there. Identify that within the examples that you are doing when you are doing gap analysis and revisiting it. You need to realize that those have gaps in them as well and acknowledging those.

MS. KLOSS: Table 4? Chief, I think we are a wrap. If there is not anything else, we will go to public comment.

MS. AULD: While we are waiting for public comments, can I make a comment? For the record, I want to thank you, Linda, and you, Bill, for all that you have done to get ready for this meeting and all of your guidance and comments and edits to the paper. They were invaluable.

MS. KLOSS: Our pleasure. We would not be here at this meeting without your work.

I want to let the audience in the room and the remote audience know that this is our moment for public comment. For those remote, you can email us at ncvhsmail@cdc.gov. As of this moment, nothing has come in or you can use the dashboard on the WebEx. Nothing has come in. I see we have someone standing at the mike in the room. Please note your name and where you are and your role.

Agenda Item: Public Comment

MR. RODE: I am Dan Rode. I am a consultant and an educator. A lot of history here in this room and a lot of expertise. I am sure if Linda could keep you here for another year, we would have all this all resolved and we would not have to go any further because it is the right mix of people.

The person that I think are missing and you used the word gap and you used the word community. Part of my role in the last 30 years has been to be an advocate for what you are doing and what you are trying to achieve. But we need to begin and continue to write to your various constituencies to educate people as to what is going on. It is one thing to have these discussions and especially dangerous words like ICD-11. It is another thing to recognize what the purposes are at the grassroots. I include there the providers and the people who begin this process with the data whether it is the patient or it is the provider, the researcher, whoever.

It is helpful if we can begin to tell the story of what has happened and what we are trying to achieve to make things better if we start now and not wait. It is better if we can begin to get people to work with us, not against us. Part of the problem we have had with the transaction standards in the '90s with the ICD standards in the zeroes is the fact that we really did not tell the story to the larger community. I really urge each of you in your role with different communities if we can begin to do that process even though we cannot deliver tomorrow or maybe next week or even 2025 that we get people beginning to think about this because we have had a lot of things and hurdles to overcome.

And one of the biggest hurdles we had to overcome was paper and different data sets depending on what piece of paper we used to use. We need to begin to change that onset. I think between this committee and the HITECH committee we can approach that and go after that goal.

But this conversation has to go further than this room and further than the people that we usually work with to the communities themselves and give them an opportunity to help us because in the end, it is their acceptance or not acceptance creates many of our problems. Thank you.

MS. KLOSS: Thank you. Anyone else in the room? We have no messages on email or the WebEx.

DR. STEAD: With that, this part of the meeting is adjourned.

MS. KLOSS: The subcommittee – all of our meetings are open to the public. The subcommittee has an agenda, as you can see, and the public agenda this afternoon and you are all welcome to be here for that. But obviously, we will be more pulling together and integrating what we heard and getting more clarity on next steps. There is opportunity to weight in. This is the formal.

Thank you for your participation, your willingness to take out two days from your life and we will be in touch by email.

(Whereupon, at 11:57 a.m., the meeting adjourned.)