

National Committee on Vital and Health Statistics  
Subcommittee on Standards

ICD-11 Expert Roundtable Meeting

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P R O C E E D I N G S (9:00 a.m.)

**Agenda Item: Welcome Back and Call to Order**

DR. STEAD: For the formalities, I am Bill Stead, Vanderbilt University, Chair of the Full Committee. No conflicts.

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

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

DR. CORNELIUS Lee Cornelius, member of the Full Committee, Population Health Subcommittee. No conflict.

DR. MAYS: Vickie Mays, University of California Los Angeles, Pop Committee, Privacy, Confidentiality, and Security, Full Committee. No conflicts.

MS. LOVE: Denise Love, National Association of Health Data Organizations, Full Committee, member of Subcommittee of Standards. No conflicts.

MS. HINES: And on the phone? Deb or Frank?

MR. PASQUALE: Frank Pasquale, Member of the Full Committee. Chair of Privacy, Confidentiality, and Security Subcommittee. No conflicts.

MS. HINES: Good morning, Frank. Thanks. I think that is the only member we have on the phone.

Good morning. Rebecca Hines, Executive Secretary

of the National Committee. Glad you could all make it. Do we have any other NCHS staff in the room?

MS. PICKETT: Donna Pickett, National Center for Health Statistics and staff to the Standards Subcommittee.

MS. HINES: Take it away.

**Agenda Item: Recap from Day 1**

MR. LANDEN: Okay, I would just like to briefly run down the agenda expectations for today. We are going to start off with a recap from day one. Our illustrious chairman spent half the night trying to herd all them little cat critters from the stream of consciousness format that we had yesterday into something more comprehensible, digestible, and above all, organized. I think you will be pleased to see the results that we have come up with for there. I am also looking forward to a very fruitful and critical conversation around the synthesis.

After that, we will breakout into our third series of roundtable discussions. This one, this morning, will be to talk about communication topics. That means given all of the research questions, categories, issues we identified yesterday, of those, what is it important to communicate to whom and when? Who are the stakeholders? What kind of messages? What kind of messaging would be appropriate for the topic and the target audience?

Those breakouts will go for about an hour. Then

as we did yesterday, we will do the report outs. After the report outs are completed, we will attempt to do an on the fly synthesis and put it all together to wrap the morning.

After the lunch break, then the subcommittee, the Standards Subcommittee, will convene to review the three syntheses or the synthesis from the three sessions and start drafting the report out, assuming it is going to be a transmittal letter to the Secretary with recommendations on the research topics and the messaging.

After that, the usual public comment and then adjournment is targeted for 3:00 p.m. so that we can all get home safe and sound. Any questions about the progress order for today? All right.

DR. STEAD: Thank you, Rich. So I built this on what we walked through yesterday afternoon. We have incorporated the changes that we said then. We dropped in - into expansion of the structure the new things that seemed to come up during the second round. So, I will walk through this briefly and mainly highlighting the changes. Rebecca has it in a form so that she can edit in your comments and insertions as we go. This will continue to be a living process.

I think I am now to ten categories at this juncture. I have begun to stub in a list of change management strategies. I have begun to stub in a list of

communication topics. Not trying to be holistic on the latter, just drawing down the things that we came out with yesterday that seemed to fit better there than back in the research questions. That is sort of where I am in terms of the current structure of this.

Up to the top, again, please, Rebecca.

Category 1 or the use cases for ICD 11 were mortality and morbidity using the 80-20 rule. I am assuming that that will - that really will be posed as a question. We will probably have some examples, but all of the sort of individual subject area content pieces we will want to frame as use cases, key uses with a purpose and with a relevant set of stakeholders, et cetera. That is what that is asking for. We don't actually have to populate it here.

Then the second category is alternative approaches to supporting comparability studies, both methods and infrastructure. We edited this a bit yesterday. This reflects sort of a little bit of harmonization of those edits, but is otherwise unchanged.

ICD-11 versus ICD-10, post-coordinated extensions, molecules for gaps, sometime needs a new atom. So base concepts, stem codes or extensions may need to be added. Post-coordination can't fix it.

Then computer assignment of ICD codes to generate use cases for promoting interoperable clinical standards.

ICD classifier. This was actually intended to be for the defined ONC promoting interoperability standards. So that was not a general term, if you could capture that, Rebecca.

Ongoing revisions to ICD-11. That is what is the right methods and platforms to support that, both for the evaluation and for the ongoing care, feeding, and maintenance of the system.

Category 3, evaluate the internal consistency and stability of ICD-11. This is new. It reflects an email addition from - a set of additions from Jim last night. I made up the name of the category. I may not have gotten it right if you all want to change it. But the sub-bullets came straight from that.

What will be the impact of semantic drift, NEC - I didn't know what NEC stood for. Not Elsewhere Classified, okay. What will happen when a pre-coordinated term is added to ICD-11 that corresponds to a concept previously represented with a post-coordinated term? How many multiple synonyms post-coordinated expressions - how will multiple synonyms post-coordinated expressions be recognized? How will the completeness of multiple classifications be assured? What will be the cost of missing classification?

That is sort of a category with those as key examples.

Steve.

MR. MCDONALD: I think that is a great addition. One of the questions I would like to know or I think would be worth asking is can the tool called a classifier - it is a piece of software - be used to help ensure the internal consistency of ICD-11 or not. There is this whole category of tools that operate on the structure of the terminology that are used to help maintain the consistency and quality and refine - define redundancy.

So, the question is can we use these tools or not? They are a very important tool set for ensuring quality of large-scale terminologies.

DR. CHUTE: He is referring, of course, to description logic driven consistency. It is true that ICD-11 - the foundation does not have any description logic computable framework. That being said, maybe it could. It does have - well, that was the whole point of the common ontology was to improve that computational capability. We'll talk about that over a beer.

SPEAKER: What ICD-11 does have at present, as a poor man's alternative and I fully acknowledge this is a poor man's alternative, is the Body of sanctioning rules that was mentioned yesterday by Donna. The sanctioning rules are what allow - what capture - for example, if somebody tries to insert a post-coordinated expression when a pre-coordinated expression exists for the same concept

that is exactly what the sanctioning rules are designed to capture and address.

It is not the same as what Steve is describing, but it is an approximation toward that effort.

DR. STEAD: Rebecca is trying to capture the concept. Maybe you all can caucus and try to get a - something that everybody agrees is communicating the right question, not because we - the idea is we don't - it is not that we have to agree on an answer. We need to come up with a question that will yield whatever the answers actually are. Is that fair?

Vivian.

MS. AULD: I just want to caution that we don't put something in there that should be directed at WHO as opposed to HHS. If we are talking about straight 11 that is a WHO issue. We can certainly make a recommendation to WHO, but unless we are coming to them with time, money, resources, we can't make any demands.

DR. STEAD: What we are suggesting - that is a good point. But what we are actually suggesting is the U.S needs to evaluate the answer to these questions. One of the things we could discover is if the resources WHO has are sufficient - the approaches are sufficient or not. And if not, we have got to figure out what we, the U.S., should do with WHO or on our own if we need to.

SPEAKER: I am sort of seconding the idea that independent verification and validation is something that we really should do within the U.S., regarding - instead of relying on WHO for all of these things.

DR. STEAD: I would love to get the top level category right. We are going to do - the richness of the discussion is important. We will make the record easier for people to understand. But getting the right ten or so high level categories is going to make this more easy for us to communicate to the Secretary and sort of keep track of. So we are trying to work at both levels to the degree we can.

DR. BODENREIDER: I think we could put a bullet for independent verification of the maps. As we have seen yesterday, the maps might have different purposes for different countries. If we want to use the 10 to 11, 11 to 10 maps for a specific purpose, we need to verify that they are correct.

DR. STEAD: And we have the question of mapping somewhere else. You can put it here, Rebecca. We will need this as we go down the list to see whether we like it better here or there. This bucket didn't exist back then.

DR. PINCUS: Whether you couldn't actually collaborate with WHO around developing these tools and doing some of these evaluations.

DR. STEAD: We may can, absolutely. The way this

actually - if we can get what needs to be done clear, then what we really need to do is have the department own getting it down collaborating with whoever is appropriate to help get it. That is the intent, not that we would do it in isolation. We do need to end up with clear accountability in the U.S. Does that make sense?

DR. PINCUS: It could be with other countries, as well.

DR. STEAD: Absolutely. This is important. We will see if we pull other pieces up into it. That is a whole new category. Then come on down.

MS. GOSS: Listening to the conversation - if you could scroll back up to F under 3 - I really feel like we have conflated this - a couple things into one. What I heard Keith say about the IV&V role is far greater and global than the mapping issue. I think they are both valid, but I feel like the way this has been morphed, it is now putting the focus on the maps, not on the IV&V more global role that we should be thinking about.

I just - just make an annotation so we don't lose the distinction. There is really - there is at least two things going on in 3F.

SPEAKER: It should be all content, including maps.

(Comment off mic)

DR. STEAD: I don't think so.

SPEAKER: It should just be all content, I believe, including maps, which are a type of content.

SPEAKER: If you take 2 and just say instead of and/or collaborate because that is really - that has nothing to do with independent verification and validation. Just say all content and methodologies including the post-coordination approach.

DR. STEAD: I am actually sort of hearing - we can do this offline. I need to begin to move us. I am actually sort of hearing this almost becomes the top level thing of what we are talking about.

We can fix that later. We have got the concept. We don't have to - this isn't going to turn into legal language. If we can get the concepts down, we can move.

Okay. Compare quality, cost, elapsed time for implementing automated ICD-11 coding of death certificates with NLP based on data from past use cases versus NLP based on the ICD-11 foundation. I tried to reflect the conversation we had with Bob yesterday. He is not here now. I think with other things we have set on downstream; this is probably going to be - this category may get turned into a broader category around NLP around ICD-11, of which this would be one sub - that the mortality piece would be one sub-bullet. I didn't have time to try to morph all of that

last night.

I think this is a generalized principle. This is a specific example of where we need to do that if that makes sense.

Basically, said that - from the point of view of the mortality use case, that would be - to follow the current replacement of the NLP engine and build out some of the specific questions. Does it reduce the decision logic required to assign primary cause of death, therefore reduce the cost and time to convert and maintain? The number of past cases required to train NLP I think was a rich addition. And then what lessons from this are applicable?

We may be able to generalize that category a bit. Otherwise, have we captured the thought?

DR. RILEY: I like this, particularly around the fact that mortality is almost in some ways a pilot or vanguard for the NLP work that we are doing in morbidity. It gets much more complicated there. This is a nice start.

I like Chris' point yesterday that what we don't want to do is find that some flaws in the NLP for ICD-10 and conclude from that that maybe it doesn't work in ICD-11 because ICD-11 has a lot of features to it that might make it such that ICD-10 might not work quite as well for NLP, but ICD-11 would.

So we are not saying this here, but what I don't

want to have happen is us to judge whether we use NLP for ICD-11 coding and not use it because we found some flaws or difficulties in doing it with ICD-10. I don't think we need to say that here. I am just saying it -

DR. STEAD: We will want to capture that in the report somehow. It is an important concept. We have talked about it a fair amount. I did capture somewhere down this thing under communication topics. Actually, maybe that is where this should be. That is where that belongs. We need to drop it back down there.

I have here which ICD-10 transition tactics will be effective for ICD-11? Which no longer apply? Somewhere on - come on down. I thought I had - well, I lost it. I thought somewhere I had the idea - maybe I put it somewhere else - this idea that the - that repetitive map - the constant degradation from repetitive mapping of things that already had been mapped is an important communication topic that I thought I had caught. I don't see it under communication. As we come down, we will have to see if we catch it somewhere else. That is the challenge of working at midnight.

Dr. McDonald, welcome back.

DR. MCDONALD: I don't know why we care how it turns out cost because it is going to happen anyway for mortality. What is the point of doing all of these analyses

when it is a done deal on that one, on the mortality?

DR. STEAD: I don't understand the question, Clem.

DR. MCDONALD: At the beginning, you are going to do all of this analysis about the advantages/disadvantages of ICD-11 in mortality.

DR. STEAD: We do need to know the benefits of ICD-11 for mortality. That would be for different use cases. That would be one of the key drivers for how fast we ought to be doing this. We're not here to decide - this evaluation is not to make an adoption decision, but it will affect the decision about urgency. This evaluation of NLP, of the ability to use the foundation to drive largely an NLP-assisted system, would dramatically affect the conversion timeline. This is all about how we actually execute, not on do we adopt it or not.

Where are we? Okay, Category 5, evaluate the feasibility of using ICD-11 for morbidity without a U.S. clinical classification. If not feasible, how long will it take to develop a U.S. clinical modification? If it is feasible for the U.S. to implement ICD-11 for morbidity before a new CM - is it feasible before a new CM - I didn't include that. You added it back. Can you walk me through that?

MR. LANDEN: Yes. This is midnight editing syndrome where Bill was following his own classification

system and I didn't necessarily march in lockstep. So, it is a different approach to what we have seen for one through four. But this I wanted to capture yesterday - from yesterday's discussion.

One of our key questions for research is about the need for a clinical modification, yes or no. I think several of the groups brought up, well, even if we need it, is it feasible? Don't know the answer, yes/no, to adopt ICD-11 and then at some later time adopt the clinical modification. So I wanted to capture that. If I muffed it, that is what you are here for.

DR. STEAD: Whoever suggested - how about unpacking it? I am having trouble - I get that we are going to adopt ICD-11 for mortality in advance of whatever we do for morbidity. We are going to have ICD-11 in the U.S. before we come at the morbidity. I am just not tracking what it would mean to use it for morbidity while we develop the CM if that is what is being suggested. I am just not tracking.

(Comment off mic)

MR. LANDEN: Or there is a distinct possibility that I just misheard?

DR. STEAD: No, it was said. I couldn't figure - we have now established ownership.

DR. CIMINO: No, I got caught up in the

morbidity/mortality. This is about the clinical modification. Could you implement ICD-11 with the idea that it is - there are going to be incremental changes and then just treat CM as part of that incremental change like it is in ICD-9 and ICD-10? That you could just add those on if you are ready to handle them even if they are not ready yet.

DR. STEAD: I guess what I am not - maybe I am just dense this morning. I would think of that as adopting ICD-11 for morbidity and making it better over time as opposed to adopting it while we develop the CM. I may be missing something. Maybe that is not a -

DR. ROMANO: I think you have it. The point is the CM is - has been an American modification. So there could be other ways of doing an American modification. For example, we could have U.S. extension codes that we would only use in the U.S. It wouldn't be formally an ICD-11 CM. The point is to be - I think we think this needs to be fleshed out a little bit more here about what the criteria are for deciding whether a CM is necessary.

DR. BROWN: That was sort of the point I was trying to make with a gap analysis and then analysis of alternatives to fill the gap yesterday. Like there might be things other than you don't do it and you fully do it.

DR. STEAD: So I think what we ought to say - is

it feasible for the U.S. to implement ICD-11 for mortality, then kill the before a new CM is developed. That is where I got in trouble. Kill the before a new CM is developed and then say and improve its fitness for that purpose by adding U.S. extensions, et cetera. Does that capture the concept, Chris?

DR. ROMANO: Yes, the other thing we talked about, for example - I mean one of the reasons why we have had a clinical modification or why we felt is has been necessary is to support the use cases in the U.S. such as billing, for example. One of the concerns about ICD-11 in the current design is that some of the post-coordinated extension features are optional. If we had rules in the U.S. to make certain post-coordination features mandatory, then that could effectively substitute for having a clinical modification.

DR. STEAD: Got it. Got it. And we have captured - I will come back at the communication topics. I think this will all knit together.

DR. CHUTE: I think this issue has been conflated again. There is a big difference between having proposed or recommended post-coordination expectations within a country - I agree that would be an elegant way to deal with an ersatz CM, if you will. I think we have to be very careful about proposing U.S. extensions because the tragedy of ICD-

10 was the proliferation of national extensions, which are incompatible, inconsistent, the same code, completely different concepts. That is a scenario that I think we should strive to avoid if practical.

It is true that the U.S. may discover that there are gaps that require new extensions and new stem codes. No argument about that. I think a preferred pathway for addressing that is to have them added to ICD, not to make American extensions uniquely.

This gets at the timing issue. Donna, for a long time, has said, well, the international community moves more slowly than we can as a national modification. That is undoubtedly true. But I think the maintenance and update process of ICD-11 is different from that of ICD-10. Hopefully - so framing this into a question, I would want to parse apart adding stem codes and extensions as a U.S. extension from requiring post-coordination as a U.S. modification.

DR. STEAD: Have you captured that, Rebecca? We can come back -

MS. HINES: Be careful about posing U.S. extensions. There may be gaps that require new extensions and stem codes, preferred pathways to add them to ICD-11. Maintenance-update process will be different than it was for 10.

DR. CHUTE: That's true. I just want to emphasize as a new sentence, perhaps, Patrick's point, which I agree with. A U.S. clinical modification - a new line. A U.S. clinical modification may comprise specification of required post-coordinations.

DR. STEAD: So we are getting a number of ways we could use ICD-11 as a basis for a clinical modification.

DR. ROMANO: The concept is not just to evaluate at a high level, not just to evaluate the feasibility of using it without a clinical modification, but to evaluate what form that clinical modification might take.

DR. STEAD: Got it. From just a time check, I don't want to - where - we are capturing key concepts. We are at the end of the time we allotted for the recap. So we are beginning to eat into your round three breakout work. The question is how urgent are the things you are trying to get on the table here at this juncture? Those of you that feel it is still urgent, keep your tents up. Those that don't, please put them down.

Okay, I see Keith's is still up, then Clem, then - okay, we have several. We are clearly going to stay here a while. Is that okay, Rich?

DR. LANDEN: I think we need to get through this and have at least a rough pass of it. We can address it later as part of the overall recap.

DR. STEAD: Okay. I think what we had better say though is we are going to limit this continued conversation of this whole block to 15 minutes. Wherever we are in 15 minutes, we will move into the next round.

DR. CAMPBELL: I'll try to keep it brief. I think that - you know, I just heard an assumption that ICD-11 was for - the U.S. use case was for billing. I think we need to perhaps have an analysis of alternatives as to whether that, in fact, is proper. That really conflates morbidity if you are trying to tie it into billing.

DR. STEAD: Wouldn't that be clarified as we build the use cases under category 1?

DR. CAMPBELL: Perfect.

DR. STEAD: I think that is where that gets resolved. Please put your tent down so we can move around.

DR. MC DONALD: This whole question about assumption that this big extension to CM is good I would like to challenge. I think both Steve and I, as clinicians, found it maddening to have these snowflakes flying at it about different choices when we only knew the general choice. That is one, whether we really need it.

Secondly, there is movement now to change the billing rules, which might have an easing effect on the requirements for billing. So just keep those in mind.

DR. STEAD: That is fine. We will need to unpack

for you a bit some of the stuff that is already out there. We have got some good test cases for some other approaches to handling all of that.

DR. MAYS: Kind of because we are strapped for time, one of the things is that I think the group here represents or kind of the disciplines that sometimes don't fit as well and I am not kind of seeing some of our issues. So I am going to ask rather than just trying to do this one by one, that during a break or at some point if you will look specifically at the things that we suggested and see if they can be woven into what is there.

One of the other issues that the group raised is we are working as if things are this now. Suppose there is things like changes in care like we moved to value-based care or we do different models. We are kind of really hinging on everything is as if nothing is changing in terms of healthcare delivery and healthcare models and stuff. So I think we also need to think about adding in a little more flexibility for change.

DR. STEAD: The thing I would ask you to do, Vicki, is take some time and begin to sort of draft out what you think the key use cases are. That is where we are going to intend to capture that. You can take - so, take each of the use cases that will result from the kind of changes we are talking about, we think are on the horizon

or are actually taking place now. Let's get those identified. We can drop them in as examples under category one. That will - that is where we are going to test what we are suggesting you test fitness for purpose for each of these very different scenarios rather than - that is how we are hoping to capture it if you can help us with that.

DR. BROWN: ICD-11 introduces post-coordination, which is a new work process. I think it would be important to do human factors analysis of the - how that work process unfolds and whether these processes can be done reproducibly and can be done at all. I think it is clear it is hard to do it.

DR. STEAD: That is a different category. Please try to populate it as we get to it.

DR. RILEY: I'll be quick. I think we are all sort of saying there is a reticence to create another CM if we don't need to create another CM. I guess what I am thinking here is that we ought to have some reasonably clear - develop some clear criteria for under what conditions we believe the ICD-11 is not sufficient. And would that then be settle by going into an improvement on ICD-11, some revision of it, and/or something on the post-coordination end? If all else fails, is it necessary to do some sort of CM? There ought to be some criteria by which we make each of those steps and each of them further out is

less of what we would like to have happen.

DR. STEAD: Got it.

MS. PICKETT: I just wanted to mention since I have heard a couple of people mention the reimbursement aspect of - as being one of the use cases that ICD-11, though reimbursement, primary care, case mix, statistics were all part of the thinking in creating ICD-11, it was in and of itself not created as a reimbursement tool. While there are segments of stakeholders within the U.S. who see the ICD, whether it is 9, 10, or 11, as a reimbursement/billing schema, that truly is not the case.

I think under number one where you were listing out use cases, I think if that is going to be - that is going to be important because you will need to list out the individual use cases and look at those separately because, again, I keep hearing the fact that it is a billing code. It was never created as such. WHO has very little - I won't say little concern, but, in and of itself, that was not the primary focus of creating an ICD-11. It was for medical/clinical advances, bringing into a more technological era.

There were a number of things from the slides that you saw yesterday, and that Bob and I have shown you previously. Reimbursement is not at the top of the list. It is not for WHO and other international countries a

showstopper. I think having that in mind as we walk through this exercise would be very helpful, particularly as you frame the questions.

DR. STEAD: Thank you. Linda, do you want to close this round?

MS. KLOSS: Going back to - I want to add another bullet like the one Bill just added. I think we should make explicit that we create some criteria for the use of extensions. I think the impulse here, in this country, will be to add extensions to solve all problems and to create unique extensions. I think getting a handle on that early will be helpful.

DR. STEAD: Okay. Let's see if we can, in the next ten minutes, get through the whole list. Come on let's pop down.

Okay, six, we have now got evaluate quality of WHO mapping for each use case. Can't that go now back up where we have got the - can that go out of this and go back up? We will merge that in up above. You don't have to do it right now. Just put merge by it.

What tools are needed to reduce workflow burden and improve documentation by use case, by stakeholder in each use case? This is where we might capture the post-coordination question. This is intended to get at that bucket as a category.

What are changes up and down to clinical burden  
to -

MS. HINES: I believe this was Jim Simino's  
comment. Is that right?

DR. STEAD: No.

MS. HINES: Yes. It was his comment yesterday  
during the meeting.

DR. STEAD: Somehow, I think that needs to be  
merged into seven. I don't think it is a separate thing.  
There is a - yes, just note that it needs to be merged into  
seven. We will have to figure out how to do it.

DR. ROMANO: Could I just clarify that merger?

DR. STEAD: Yes.

DR. ROMANO: So I think what we are talking about  
is one part of it is to assess the impact, the burden, if  
you will, the changes that would be anticipated in  
workflow. The second part of that is then to develop the  
tools, products, so forth, in order to minimize or mitigate  
those impacts.

DR. STEAD: That is the intent.

DR. ROMANO: So they are related to each other.

DR. STEAD: And we will need to make sure that  
gets clarified. I do think - I agree that if we can come  
out with something like ten big categories, we will be  
better off.

MS. AULD: Going back to the idea of not creating a clinical modification right away, but starting to use ICD-11, we can use SNOMED as an example for how to approach that. Clearly a different world, but it can - the process that we used can be implemented here.

When IGSD was first created within the U.S., we just adopted the international edition of SNOMED. It wasn't until - what was it, two or three years later before we introduced the U.S. extension. That was because we had a definite need to do so. We were filling a specific need. So, we do have criteria for how we approach that that can be shared with the Committee to help inform the question.

DR. STEAD: Please e-mail them to us. Let's capture that if we get our capture system back.

MS. HINES: Jim, I took your concept, which was eight, and made it 7B. Was that what you had meant?

DR. CIMINO: Yes.

MS. HINES: Okay. So that is when we glitched out.

DR. STEAD: Okay, then evaluate alternative approaches to training ongoing support for using ICD-11 costs and benefits by use case. That is where we have the innovative training point - approaches, computer-assisted coding and quality - coding quality assurance, and workforce role changes, coding coaches/quality assurance rather than coders. Got rid of the coders as auditors.

Evaluate alternative approaches to accommodating regional and urgent codes, stem or extension, without compromising consistency. Leveraging related terminologies for domain-specific concepts, such as medication - again, we will have to see how well these merge in.

Then evaluate costs and benefits of alternative timelines for switching from ICD-10 to ICD-11 for mortality. So, again, everything up above this is largely intended to be for everything. These next two bullets are when we try to target for mortality and morbidity.

Clem?

DR. MCDONALD: The point about merging and using other coding systems are valid and right, but the question really is why aren't we using the whole medical record? So emerged the genetic thing that tries to find a phenotype. You look at everything and generate it from some rules. I think in the long run that is what we will be doing.

DR. STEAD: We have got an evaluation topic on that up above.

So evaluate costs and benefits of alternative timelines for switching from ICD-10 to 11 for mortality. What are the costs? Which of those - what are the costs that NCHS has in three different timeframes? It is trying to bracket it so we can get it - what is the difference? How about the states for those same brackets? For the

mortality use cases, the costs related to end user training and databases, et cetera?

Benefits of switching from ICD-10 to 11 for mortality by use case. Compare the cost/benefit ratio of switching in three years, six years, or nine years. Identify the key barriers to achieving the earlier target dates. Those are just a way we could approach that.

Then evaluate fitness of ICD-11 to support convergence of clinical and administrative standards for morbidity. Can we use interoperable representation of research and clinical term classification nosologies to simplify distribution and deployment? Can a post-coordination model support complete and safe retrieval of encoded data with respect to recognizing concept equivalence and coverage? How does the post-coordination affect electronic transactions? How might EHRs and related software support post-coordination?

Those are adds from yesterday afternoon. Can ICD coding be implemented for the use cases as a computable service on top of standardized clinical statements captured by the EHR using the promoting interoperability standards to record clinical care? It sort of matches with the classification engine we had up above.

What are the costs of supporting A through C through use cases? What are the benefits by use cases?

Finally, I hope, evaluate feasibility of different time frames for transitioning to ICD-11 for morbidity.

Evaluate alternative guardrails, carrots and sticks to hold stakeholders to an implementation timeline to avoid costly delays.

Evaluate alternative approaches to scaling, lessons learned, and pilots for broad deployment across the health system.

Evaluate the feasibility of repurposing and reusing for ICD-11 the same testbeds, tools, databases, techniques as were used for the conversion to ICD-10.

Evaluate the impact of ICD-11 on different models of care, especially value-based care and impact windows of opportunities. My own opinion is that needs to be a use case, but be that as it may.

How will ICD-11 interrelate/impact other standards, content standards - okay, I actually had that - appropriate both places. I had that as a communication topic, I believe. Be that as it may.

Then what are the implications of technical changes such as technical structures and code links to HIPAA? This is all standard pieces, which I have in a different place. So, we will see them again in a minute. Just so people are seeing them.

I am going to stop reading because we are out of time. Come on down.

So then a change management bucket. For each use case, map barriers to change, resources available to support change, implementation tactics. Tactics to address participants and transactions that are not HIPAA covered entities, i.e. ways to successfully encourage entities like Worker's Comp, et cetera, to use ICD-11 despite lack of mandate. Engage stakeholders from the sum of use cases at every step. So when people said clinicians, we have got to get everybody. Design end-to-end testing into the implementation and refinement cycle. Not think of it as a one-time thing.

Then communication topics. What is the urgency of the path forward? You are going to, in these breakouts, now going to be focused on what these topics need to be. This is just a starter set that dropped out of yesterday, things that were said that belong, I think, better as communication topics.

Urgency of the paths forward and timeline for key decisions. Is U.S. going to support post-coordination for mortality? Which extensions would the U.S. adopt for mortality? Does the U.S. require a clinical modification? Is the U.S. going to proceed with a regulatory path forward for morbidity? Will it be the path recommended by NCVHS?

Will it be the same NPRM Final Rule path as was used for ICD? What will the timing be for morbidity? I think mortality is not a part of that. Be that as it may. I don't know how that got - come on down.

Which ICD-10 transition tactics will be effective for ICD-11? Which no longer apply? Implications of ICD-11 for standard - for related standards and services - this is where I tried to sort of build out all of that, which is now dual under evaluation. Obviously would have to be evaluated to be communicated. So those are outlined there and trying to get the key things that relate to the existing HIPAA world, the implications for FHIR, terminology service vendors, EHRs, billing/practice management software developers, clearinghouse and information exchanges. That is a good add.

ICD-11 is intended to be the last decadal update of the classification from WHO. We have a plan for the continuous updates. The U.S. has to. Quality and safety costs of mapping - repetitive mapping, in particular - that is where that communication piece came in. We will have to build it out.

So that is sort of where we are. I think we best move into the breakout, Rich. We will continue to iterate this, update it. It will re-appear at the end of the - early this afternoon.

MR. LANDEN: Thanks, Bill. I think that was a tremendous piece of organization from all of the material that flowed yesterday. So, now, into the breakout sessions. We will still target an hour for these. The format and process is the same as yesterday, but focusing on communications topics, as I said earlier, identifying the stakeholders.

(Breakouts: Roundtable Session 3)

**Agenda Item: Report Outs to Full Group**

MR. LANDEN: Who wants to go first? Alix, technical issues and opportunities. We will do the same format. Rebecca will capture as much as she can as we go. Please be cognizant of her scribing efforts. Make every effort to assist her. Thank you.

MS. GOSS: The Technical Issues and Opportunities group had some really robust discussions. So much so that we had more than the allotted numbers on the page.

I think that the first one I want to bring up is a great phrase. ICD-11 is not your father's ICD. This really - we should all thank Chris for that sense of humor. Unfortunately, he is not here to get that accolade.

This is really about how is it better, how ICD has evolved, what it is, and why do I care type of aspects related to the architecture of 11, the positive value perspectives. Those are all part of the ICD-11 is not your

father's ICD.

The second key communication message that we identified was how 11 will improve the data capture and research value in the sense of secondary uses.

DR. CAMPBELL: As I hear that, I want to -

MS. GOSS: It was yours. Please morph it. No, it was more like if I got it wrong, please -

DR. CAMPBELL: It is how it promises to improve. Just a little bit of a hedge there. We haven't proven yet that it is going to do all of those things.

MS. GOSS: The what you need to do to get ready sort of timeline messages, the activities and timelines.

CM is not needed with 11.

DR. BODENREIDER: I think the idea was if CM ends up not being needed, we should advertise this. People are going to count on it coming. If it is not needed, we better advertise early.

MS. GOSS: The next one was mapping related implication and considerations, the related messaging. I know there was a request for specifying the stakeholder. We focused more on kind of the bigger opportunities. All of this input for - the key communication messaging really should also focus around a framework of first covering the basics. This is not a subpoint. This is more of a wrapper for all of this, Rebecca.

We really want to focus on covering the basics then doing a deeper dive into the content before getting into segment-specific audiences. I'm sorry Rebecca. I really wanted you to stay at the top of first covering the basics, then the deeper dive. It is kind of a sequence of methodology. We need to start building out our specific stakeholder messaging to cover the basics then the deeper dive and then into the segment or an audience-specific education.

Am I to proceed to communication channels? So we feel that there needs to be both passive and proactive outreach, which is an overarching theme. Passive in the sense of the website kind of information you can find on your own versus getting out into specific environments to create activity.

So, our first one is around creating a proactive level of outreach. Our first idea - so whereas you've got this as sort of a round bullet, I would make it a number one. The first point was more of a philosophical approach like we did above.

Number one was to incentivize competitive technology demonstrations. We were talking around the algorithmic activities that might be able to be generated to make ICD-11 deliver on its promise. Competitive technology demonstrations.

DR. CAMPBELL: A catch phrase would be the XPRIZE for deriving administrative data from clinical data.

MS. GOSS: So your first point, creating proactive bullets is really a part of the overarching statement. Thank you.

Giving an example, now that we have given one from a proactive approach, wanted to highlight Wikipedia as a we need to have a very solid Wikipedia page.

DR. CAMPBELL: That is under the passive.

MS. GOSS: That is a passive example. Yes. I don't have these broken out by proactive and passive. What I was trying to say was that we thought - generally, as an introduction, we thought there needed to be proactive and passive - both approaches. So I don't have these segmented as you were trying to make them.

Number three, content and documentation freely available via the web. This is another bold statement that gets into both the algorithmic and value-added sort of features.

DR. CHUTE: The back story on that is what we want to avoid is competing proprietary algorithm development that creates slightly different inferred codes from the same data because of the proprietary nature of those algorithms. The algorithms and the approaches have to be public and open so that we can have consistency. Otherwise,

we get variation that is arbitrarily created.

MS. GOSS: The next one was education packets and recorded webinars.

The next one is federal vehicles should be leveraged. Lot of people pay attention to what comes out of the federal government, such as CMS, AHRQ, VA.

The recommended - I am going to move on to recommended - recommendations regarding timing for communications. We felt that the timelines will differ per activity that we elect to pursue. We thought the key point at this juncture was to develop a strategic plan for communications and have it be done by professional communications people.

There are some things we can do now like the 101 education and the competitive technology demonstrations or even tout some of the mortality plans. There will be other things that will need to be pursued once we have a little bit more - you know, the research facts, et cetera.

DR. CAMPBELL: For your previous slide, I think we were thinking that the - having it professionally done was a strategic communication plan as opposed to we figure out the plan and then hire pros to do our poorly done plan.

MS. GOSS: Team, anything else we want to offer?  
We are good.

MR. LANDEN: Next? This will be the -

MS. SKURKA: Ours is group four. The first section, the key communication messages - the first one we had for clinicians. Really the message is - because it says specify the stakeholder. But some of the messages would be good for several audiences.

The new system represents best medical knowledge in 2019, advances in medical practice based on research. So a strong message to the clinicians about how good this system is kind of a with a caveat. Yes, there are a lot more codes, but it is better.

The second question we had was a message - why now when we just moved to I-10? We would anticipate hearing that from the country. Our message is, well, you can't jump from 9 to 11. There is a process here. We did go to 10. There was a pathway. It will be easier this time because of that work.

Our third one was the I-11 was built to live in an electronic world. Tools have been built accordingly to facilitate this process and reduce burden.

Our fourth one was based on past experience, cost-benefit decisions will be made along the way and research will inform this.

Number five, we targeted one specifically for coders who could be threatened by this and the electronic nature and can it be all auto-coded, et cetera. So, that

message was keep advancing your skillset and using technology to embrace the changes you will see in I-11.

And kind of an overall comment we had was transparency in this process and we are going to avoid any fake news.

So our communication channels - certainly medical specialties. We have got to get all physicians onboard. Then professional organizations. We need the buy-in of AHIMA. We have someone at the table, here, of the AHA. We have somebody at the table of the other professional organizations, the AMA. We have somebody at this table AHIMA. We have the sitting president at this table.

And communication across all healthcare settings. And then kind of tied to what group one said, we think that communications should be linked to the I-11 website so a positive message comes out and they can link to the website and see what is current there, as well. And at the World Health Organization site, yes.

Finally, recommendations for timing regarding communications. We think that the NCVHS should reinforce their recommendation regarding using a sub-regulatory process. There is a need for HHS to make decisions regarding this recommendation.

We think that we should share a research plan and findings going forward.

Finally, to start now because I-11 is approved and the regulatory process is underway - regulatory process should be underway.

MR. LANDEN: Who would like to go next?

DR. CORNELIUS: Why not? As I chat, my team members will be more than happy to complement the words that I share.

We ended up boiling it down to four types of stakeholders and a message for each type. We suggested, in essence, four communication channels, but we kind of put a dot, dot, dot about the timing.

So, first, one of the messages was to the payers. We were stating that this will increase the complexity for the payers from about 10,000 concepts to infinity. In parentheses, once they figure out how to capture the coded data, then all things will flow.

MS. HINES: Once they figure out how to do what?

DR. CORNELIUS: Once they figure out how to capture the coding data - you only have to do it one time. So even though the complexity is increased, you don't have to keep repeating it.

So then for the professional associations, the message is conversion is coming. They need to develop their own engagement strategy using the opportunity to improve documentation, identifying the stem codes and extensions

that are most relevant for that particular association.

Three, for the quality performance measurement entities, get ready to update, redesign processes, and branches across - and also to branch out across HHS to be involved like AHRQ, NLM, CMS, FDA.

Then for the providers/clinicians, if the premise was that you have to code, then the better you document then the less you will have to code. So the premise is that physicians will not have to code and, therefore, they would have to do a better documentation so that they don't have to code.

DR. ROMANO: And then we have to demonstrate that we have - that the tools are available to support automated or machine-assisted coding so that they no longer have to code.

DR. CORNELIUS: Then, in terms of the communication channels, one of the ways to think about the channels is related to training. So we talked about CME, CNE, med school, nursing training. Then we talked about web-based content needs to be created along with a formal marketing process. We talked about the role of advocacy organizations in marketing and promotion, to tap into that.

Finally, we kind of paired off this issue of the regulatory versus sub-regulatory tradeoffs. If we go down the sub-regulatory process, we have to figure out the

alternative marketing strategies under this approach.

DR. PINCUS: I think just also to point out that we - these are kind of market segments or audiences that are sort of selective. There are many other segments that would also need to be addressed across a broad range of groups. I think these were the ones that we identified as being sort of particularly important to focus on first.

Number two is that it is also important to combine sort of the communication out efforts with the engagement and needs assessment in efforts early on.

DR. TCHENG: Just one other comment. One of the themes that permeated our discussion was that the marketing messages need to be reality-based as opposed to promissory of - that was associated with the ICD-10 rollout. I would not promise that we are going to save lives and reduce costs and et cetera. Get away from that type of a message. Instead, what does it actually mean in terms of operations, in terms of better quality coding, et cetera?

MS. HUE: So, our group worked a little backwards. We first specified the stakeholder and then we created our message. So this mainly applies to clinicians, but also applies to several other stakeholders.

Our initial message was to state that this would reduce burden and cost. It would be well worth it. ICD-11 would be well worth it. With ICD-11 also comes ease of use.

This is still part of the message. It is more efficient. The hope is it results in less denials and returns. Keeping hope alive. Less requests for additional documentation. Simplified billing. Improved quality of data.

And the message also of - similar to what another group mentioned, we are aware of what worked and what didn't with ICD-10 so we would use lessons learned to make improvement.

I will just quickly run over the stakeholders that we had listed for that was clinicians, vendors, software engineers, publishers, payers, standard setting organizations, clearinghouses, and clinical content developers.

Our next group that we looked at were the coders. The message was that the actual process of coding is not changing. One of the concerns that we assumed that they will be interested in is credentials, but I said that was really more for the training and implementation team. That question comes up if they have to get recertified.

Our next group was the educators/academic institutions. The message was that we would make toolkits available and work collaboratively.

The next section was our communication channels. We basically listed various channels. First being the internet, such as YouTube, other websites, blogs. Then we

had webinars, seminars, podcasts, social media. Next we had newspaper, the old-fashioned way, mail professional journals. We had TV and radio, electronic billboards, and just to be funny, Broadway musicals.

Our recommendation for the timing is just as soon as possible.

MR. LANDEN: One more?

DR. RILEY: Okay, mortality. So we have less stakeholders to deal with, which is helpful and nice. There are three key ones.

With the states, one of the things we talked about a fair amount was timeline and the rollout in that timeline, making sure that that is realistic, we sort of minimize delays in it. The bind I think that we are going to find is that we want states to have sufficient sort of advanced notice to be able to reach out to state legislators, get resources in place, do those sorts of things. Yet, not be sitting there waiting for us, particularly waiting at the national level for us to roll things out and be ready to go. Timing issues are going to be important there. Timelines are going to need to be realistic and pretty clear moving forward.

Related to that is the role of NCHS to the states and reaching out to the states and making sure they understand what NCHS will do in terms of tools and

resources and that sort of thing versus what the states are going to be responsible for, which I think is fairly minimal from what I understand from Bob yesterday, but still some things they are going to need to do like changing some of their data fields to make sure they are adequate for ICD-11. So some system changes and structural things that the states are going to be able to do. We are going to need to make sure that is communicated well.

For the researchers, a similar sort of prep and timeline rollout as for the states. That is pretty similar.

There is going to need to be, in some form, outreach, publication, et cetera, on mapping and bridge finding, how that work is done. Maybe even putting those resources out on GitHub and websites and that sort of thing so that is easier for researchers to be able to do that trend and bridge analysis from 10 to 11. So that is one of the critical things that we think needs to happen there.

Then policymakers is our third group. We are going to need to manage expectations for them. On one hand, we want to communicate that ICD-11 is going to provide more specificity, potentially provide better data on causes, manner of death. On the other hand, to use Olivier's example from yesterday, if a staffer goes to Bob and asks alligators versus crocodiles, how many were injured or killed from that, we are probably not going to be able to

answer those kinds of things. So we just have to be thoughtful about not promising the moon to policymakers, but making it clear that there will be more specificity and potentially some improvements in cause and manner of death as a result of that.

In terms of communication tools, the wealth of WHO tools as well as the NCHS tools and resources that are available, making sure those are on the website. NCHS obviously has a pretty clear and well-developed network of state vital statistic programs, coroners, et cetera, that they have at their - to be able to sort of do outreach in terms of communication directly with them, whether that is through meetings, webinars, direct contact, all of those sorts of things that I think is there.

The other part of that, though, is making sure since this happened from 9 to 10 and we believe some of the state vital statistics folks are still around from that 9 to 10 transition, bringing them in and getting input from them about how we might improve that transition from 10 to 11 based on experiences from 9 to 10, what they needed, what worked, what didn't, that sort of thing as part of that effort.

Outreach through journals, publications, various funding agencies, NIH, AHRQ, SAMHSA, and others, as well as professional research organizations around the timeline and

the resources available.

Actually, I think in terms of timing of communications, we already talked about that. That seemed to be a critical issue for us right at the top. That was a key issue there.

MR. LANDEN: Thank you. There was a lot of good thinking and a lot of work to be done. It is always good to have a plan.

MS. HINES: It looks like there are a lot of commonalities between the tables. It is just a question of figuring out a logical structure for the recommendations.

**Agenda Item: Synthesis: Refined Research**

**Questions and Key Communication Topics for NCVHS**

**Consideration**

DR. STEAD: I think the best use of our time - first, whether people want to make comments about each other's tables in any way. Otherwise, what I would suggest we do is I have spent the last hour and a half resynthesizing, post-our recap this morning, what we had then. We can start back at the top and walk through it. It is now back down to 11 categories. We will see whether it is getting clearer and has a little bit more richness or not and what other pieces you may want to try to build out.

Maybe we can get that done before lunch and then after lunch, we could get - that will give us that time to

begin to synthesize this next block, if that is good for people. I am seeing shakes so we will go ahead.

Started by just beginning to stub in, again, at high level, example of the perspectives we mean by different use cases. So we put one bucket for population health and public health perspectives, things like health equity, et cetera, what all will fit into that line. It could become quite long. Another bucket for healthcare delivery perspectives. Another bucket for coverage and payment perspectives.

We can decide whether there are others. It might be good to have a bucket at that level for research perspectives. I am still trying to keep it up. Would that be a good add? Let's add a research perspective.

(Comment off mic)

DR. STEAD: I think quality - I mean what we have traditionally thought of as healthcare quality would clearly be in here. What we are thinking about of things such as community health and wellbeing would be in here. Okay?

DR. ROMANO: Supporting the addition of research perspectives. Perhaps fit policy somewhere in there? It might be under population health. It might be -

DR. STEAD: Policy - we would have policy up - the idea of it up a level. Yes, policy perspectives probably

would be a good add.

The question is what are the axes we want to be able to populate out? One of the things, you will come at everything below it differently based on sort of what this anchor is. I think policy fits in there.

DR. ROMANO: My other question is I keep seeing reference to the 80-20 Rule. I might be a little confused about what the applicability of the 80-20 Rule is.

DR. STEAD: What I am basically saying is let's identify the use cases that cover 80 percent of the need in that space so we keep the most important ones, not the much longer tail that will make up the other 20 percent. It's the Pareto principle. Is that fair?

MS. GOSS: I would like to clarify when you say 80 percent of the need, it is within a given space because not all spaces are equal.

DR. STEAD: Absolutely.

MS. GOSS: I think that is something I just want to make sure that Rebecca captures because it is not 80 percent of the global need. It is 80 percent of the need in a given segment.

DR. STEAD: Absolutely.

DR. ROMANO: Right, and the danger is that if you ignore the 20 percent, then that is an important 20 percent. Those voices will drown out the others and cause a

lot of trouble.

DR. STEAD: There is some truth to that. There is also truth to the idea - we can elect a - if we don't - we will get more traction if we figure out - if we use - what we are suggesting here, and this is a big shift, is a pretty rich framework for looking at different perspectives. If we pay attention to the top 80 percent in each of those perspectives, you can actually get fairly far down, but you are always still trying to avoid solving the last problem that will never get solved. But that is the reason it is important.

This rule would apply all the way through the cascade. That is an important concept. We wouldn't apply it at this level. I think that was Alix's point. There will be some text required in the report to unpack all of this.

DR. MAYS: For this issue about research, I think it would be good if we said research and evaluation perspectives. Everything is not going to be -

DR. STEAD: Good add.

DR. MAYS: Yes, it needs to be there. The question is do we want to link policy to that? If what we are looking at is this being kind of the axis that things are subjected to, it is after you do research and evaluation, is there a policy or is there a procedure or an approach that you want to suggest.

DR. STEAD: I think the challenge then is you really could be arguing we should take policy off of this level and do it in all of them. In essence, policy - okay, then can we - would you agree to take it back off? Policy is history. Evaluation has added.

DR. MAYS: I think it is going to be text in the report so that it is clear that it is throughout.

DR. STEAD: Okay, evaluate alternative approaches, methods, and infrastructure. We worked a lot on wording to try to get this a little bit clearer. Develop alternative approaches, by which we mean methods and infrastructure, to support comparability studies such as. These bullets are examples of things you would like to be able to compare.

DR. MC DONALD: You could use the medical record to - for some use cases without having to smush them all into -

DR. STEAD: Let me ask you to hold that thought. Test it as I go down the list. This is your first time really seeing the list top to bottom.

DR. MCDONALD: I read pretty fast. I can see all of the bullets.

DR. STEAD: You can't see what we haven't projected.

DR. MCDONALD: The other problem is I have to leave. You can do what you want.

DR. STEAD: I think you will - we will send it to you and let you comment by email. This is trying to get at the level of platforms that will support comparability studies, both during the evaluation phase and on an ongoing basis.

These are a number of the kind of things we want to be able to compare: 11 versus 10, mechanisms of covering content gaps such as mandated post-coordinated extensions, addition to basic content, alternative approaches to accommodating regional urgent codes, stem extensions, without compromising consistency brought up from below, leveraging related terminologies for domain-specific concepts such as medicines, toxins, and devices, computer-assignment of ICD codes from EHR data versus manual entry of ICD codes, concept that ICD is a classifier, the assumption that EHRs are capturing data using the Promoting Interoperability Clinical Standards.

I am not sure that doesn't get at what you are saying. You can edit it.

DR. MCDONALD: What happens is everybody wants to get their stuff - it is like getting that camel through the eye of a needle if you're sort of putting it in one field. There are lots of other places and we are now capturing things like that in Meaningful Use. There are like 32 fields describing various attributes of behavioral health

and things like that.

DR. STEAD: I think that is our intent. I think that is our intent here. Our intent is we would actually be computing ICD out of much richer source data.

DR. MCDONALD: The question is whether it is still - whether you could say some stuff like the hemoglobin A1C level without making an ICD code out of it. You want to have the numeric value in there for some outcome study or for some outcome -

DR. STEAD: Let's note the thing and keep moving. I think we have heard.

DR. MAYS: I have one here, too, and that is whether or not this is the place where we can talk about kind of the fit for all disciplines, who should be using ICD. So, for example, is dentistry going to fit - we want to evaluate their fit.

DR. STEAD: Not there, please. I want that to be - go back up to one. Go back up. One of the things that - one thing I stubbed in and eventually took out was you could have had a bucket here for disciplinary perspectives. I want to figure out and I need your help to figure this out, how we get the high level structure here that makes sure that everything below is being tested. This actually becomes the -

DR. MAYS: The test for everything.

DR. STEAD: The framework for testing everything below from the right perspectives. So if you can help us get that in there -

MS. HINES: So, bill, would A and B really where you get in the full range of clinicians and providers?

DR. STEAD: At one point, I had a long list. Let's people think that. We will have two more passes at this before we are done today. Think over lunch about how that could be reflected.

DR. ROMANO: I am just a little concerned there is a little bit - seems to be some conflation of concepts or a little bit of a mish mash in here. I wonder if some of these things are about - a couple of these items seem to be about evaluating content gaps, which seems to fit more in number three. Some of this seems to be about developing or testing implementation tools, which I think falls into a later category.

The header, here, you have is about comparability studies, which implies that you are comparing ICD-10 and ICD-11.

DR. STEAD: What we are trying to do - maybe this is a bridge to far - is framing here the comparative platform. So leveraging - comparing - so we may need to get a versus in each one. If so, please help us do it. Computer assignment of ICD codes from EHR data versus manual entry

of ICD codes. Whatever the techniques we've got below, we have to have a way to compare the results. The thought - this is intended to get the platform - methods and infrastructure platform that will let us do comparisons. These are the kind of things we want to be able to compare. They result from the things that are below.

We can maybe capture - one of the things that we have been evolving through this set of iterations is, in essence, a framework for structuring research questions for a very complex and dynamic space. We have got to have some way of harnessing it. Explaining that will probably actually be a useful part of the report.

DR. ROMANO: I guess I am arguing if it is too broad a category to be useful because almost everything in research involves comparing things. It seems like there is a set of activities around comparing ICD-10 with ICD-11 and using those comparisons to identify what is missing in ICD-11 or what needs to be improved or what needs to be - what tools need to be created.

There is another set of questions that is around once we have all accepted that ICD-11 is fit for use in the U.S. then how do we develop the computer tools to support the implementation of that? How do we compare those computerized tools with other methods? That seems like a fundamentally different comparison.

DR. STEAD: I think that we are going to need to do - I think we are going to need to let people sort of try to draft some alternatives for us.

DR. PINCUS: I think what Patrick is getting at is that eventually this list may evolve more into a matrix than a list.

DR. STEAD: That is a good point.

DR. BROWN: I have a quick potential friendly amendment that might fix what Clem wanted. On 2e, if you said EHR data and content that would open it up to the sort of parallel structure of NLP perhaps for - like with mortality. That might also then make Clem happy because that would include whatever you want in there.

DR. STEAD: That occurs later. Go on and put it in here. We can figure out what it looks like as we come along.

Have we done enough on 2? Come down to three.

Evaluate consistency, stability - content, consistency, stability of ICD-11. Pull this up as sort of bucket one. Put the specific questions under representative questions. Added in the ones Jim emailed us after the first break, whenever it was.

Let's come on down. Four, compare quality, cost, elapsed time for implementing automated ICD coding for death certificates in NLP based on data from use cases

versus NLP-based on ICD-11 foundation. I elected in the end to leave that mortality only. I think it is a bridge too far to do more than say let's try to reuse it, which we saw it several times coming downstream. It really is - it will get too complicated. I left it that way. Is that okay?

Evaluate costs and benefits of alternative timelines for switching from ICD-10 to 11 for mortality. We didn't change that, but I got them up where they are together - next to each other.

Then come down to six. Evaluate the feasibility of using ICD-11 for morbidity without a U.S. clinical modification. This was a lot of new, so let's look at it pretty hard.

A, develop clear criteria for ascertaining whether ICD-11 is or isn't sufficient.

B, is it feasible for the U.S. to implement ICD-11 for morbidity and improving fitness for purpose with U.S. post-coordination requirements and extensions over time. Note, be careful about posing U.S. extensions. There may be gaps that require new extensions/stem codes. Preferred pathway is to work through WHO's process to add them to ICD-11. Develop explicit criteria for use of extensions and post-coordination that fits together.

Then if not feasible, how long will it take to develop a U.S. CM? How much will it cost to develop? How

much will it cost to maintain?

Presumably, up here would tell us what the benefit would be. Does that compute for people?

Seven, evaluate the fitness of ICD-11 to support convergence of clinical and admin standards for morbidity. Can we use the interoperable representation of research/clinical classification nosologies to simplify physician(?) employment. None of those bullets changed. I think they are as they were this morning.

I would think this, again, would get at some of Clem's piece, but I am not sure.

Then evaluate impact of ICD-11 on workflow documentation quality by use case - on workflow and documentation quality by use case and stakeholder. Then I split out what are the changes up and down from what are the tools. I added what is the time horizon for transitioning to voice and NLP data capture and coding with clinician - NLP data capture and coding with clinician review, which I think is an endgame. We all agree it is the target. The question is what is the realistic timeframe?

Does that now work?

DR. MAYS: We were just trying to consult where we think this issue about SIREN as a model for embedding SES and social determinants data into the U.S. modification. I didn't want you to get too far into eight - sorry, seven

seems to be all about clinical issues. So is there somewhere where this one can fit?

We were trying to get this social risk factors into some place. It appears that maybe it is seven, but seven seems to be - to just say clinical and administrative standards for morbidity. Denise, did you have another term?

MS. LOVE: Yes, either reword that so that it is broader than clinical and administrative standards or have a separate - the fitness for the socioeconomic population health aspects.

DR. CAMPBELL: Just add the word social - clinical, social.

DR. MAYS: That will work. We didn't want it to be just clinical and administrative.

MS. LOVE: Yes, I think making that broader is helpful.

DR. MAYS: That would be perfect.

DR. STEAD: That good? Okay.

DR. CAMPBELL: I would make that same change for morbidity, in addition to mortality. I think you had it in eight - well, there was a - in other places in this document.

DR. STEAD: We will make a note to check.

DR. ROMANO: Under number eight, I think maybe a little bit of tweaking on the heading there because I don't

think it is that it is that ICD-11 is directly affecting documentation quality. It is the documentation quality will affect our ability to implement and take advantage of the opportunities in ICD-11. It is sort of the other way around. It is evaluating the impact of ICD-11 on burden, efficiency, workflow, and the implications related to documentation quality or the needs for documentation quality that follow. That causal arrow is more going the other direction.

DR. STEAD: Evaluate impact of ICD-11 burden, efficiency, workflow, and documentation quality? What are you saying, Patrick?

DR. ROMANO: I am just saying that - well, it may need to be in a separate sentence, but and consider implications related to documentation quality, I suppose. Consider implications related to documentation.

MS. HINES: After this? And consider implications. There we go.

DR. STEAD: Is that beginning to feel good? Okay.

DR. BROWN: You call out tools and things like NLPs. Is this the place where human factors valuations would fit in?

DR. STEAD: Yes. How do you want to work that in?

DR. BROWN: Maybe just add tools, methods, or analyses.

DR. ROMANO: Evaluating impact on workflow is classic human factors.

DR. BROWN: Great. I think it will fit okay there. It is really important.

DR. STEAD: I just was wondering whether it needed to be its own sub-bullet.

DR. BROWN: I just don't want to lose the thought because it matters so much.

MS. HINES: Human factors.

DR. STEAD: What tools and methods for analysis are needed to reduce workflow - that is good. Okay, I think that captures it. People good? Okay.

Evaluate alternative approaches to training/ongoing support for ICD-11, costs and benefits by use case, innovative training approaches, computer-assisted coding and coding quality assurance, workforce role changes, coding coaches/quality assurance rather than coders. Anything else that the trainers want to make sure we got in there or we got it?

Evaluate the interrelationships between ICD-11 and HIPAA and other HIPAA and promoting interoperability standards. What are implications of technical changes such as technical structure code links to HIPAA-specified transactions and operating rules for X12, NCPDP, CAQH CORE, and NACHA? What will the role of SNOMED be? Can entities

code in SNOMED and translate to ICD or is SNOMED obsolete?  
Is that the way we want to work that?

DR. CAMPBELL: I would work on rewording that last sentence. It has the potential to be -

DR. STEAD: What would you suggest?

DR. CAMPBELL: It pulls into the question are the Meaningful Use standards - what is the role of the Meaningful Use standards with regards to ICD-11? It doesn't single out just one thing there.

DR. STEAD: Okay. So what you would do is come up here and say what is the role of promoting interoperability standards. What is the role of the Promoting Interoperability Standards, instead of SNOMED, relative to ICD-11.

MS. HINES: I see. That is the sentence I already typed.

DR. STEAD: And then the rest of that goes away. Can entities code in one of those standards - that is a good way to do it. Now you can kill the middle sentence because you have replaced it. That seems a little better.

MS. GOSS: This may be a little too narrow, but when we say promoting interoperability, do we really mean U.S. CDI or something else?

DR. STEAD: I thought the current name for what I think of as the U.S. CDI and - I think that they are the

Promoting Interoperability Standards.

MS. GOSS: Oh, I think of it as Promoting Interoperability Program with multiple aspects related to standards and the data classification standards. I am splitting hairs. Thank you.

DR. STEAD: Throughout the environmental scan and the TNV letters, we have basically - I mean NCVHS has said there are HIPAA-related standards and there are Promoting Interoperability Standards. We usually say formerly Meaningful Use. If we need to fix it, we can fix it.

MS. GOSS: My problem was the word standards.

DR. STEAD: Okay. Got it. Is the rest of that - I didn't know - how does ICD-11 coordinate with detailed clinical documentation? This was probably Jimmy's point. Is that worded appropriately?

DR. TCHENG: Yes. So the issue is if you look at capture of information for registries - and other details for clinical documentation to assess quality and performance, ICD-11 is actually not granular enough. The example - by the way, it is about 2,000 concepts in the ECHO, not 20,000. I looked it up. It is 2,000.

DR. STEAD: Okay. So what we ought to have is -

DR. TCHENG: But it is still - you get the point.

DR. STEAD: We might have with detailed documentation, such as registries.

DR. BROWN: There was another place where other terminologies were called out like medications and toxins, someplace up above.

DR. STEAD: Yes. That is about how we - it is a slightly different way of calling it out. We can look - yes. We will see where -

DR. CAMPBELL: I think what this speaks to - I am not sure it is really captured. Maybe it is not important for us to speak to it that way - is that the 2,000 terms for the echocardiography dictionary are kind of saying what is the level of detail that we need for clinical care and clinical decision-making. I think this is pointing out that ICD-11, although it is much improved, we still doubt that it is fit for purpose for primary clinical documentation.

I think that - you had a different bullet item that was higher up, which was is ICD-11 fit for x. I think this is one of - you know, a detailed example of one of those x from up above.

DR. STEAD: I think you are right, Keith. Does that mean we should kill it from here and leave it just above or move it up?

DR. CAMPBELL: I would move it up because I like to preserve thought.

DR. STEAD: Make a note that we want to move it up.

DR. CAMPBELL: If you go back to one, what are the use cases for ICD-11. I think there was a very specific - documentation of clinical care is one of the questions that people are going to ask. We had to fight within the VA - the inevitable question is going to come up within the VA of why can't we replace our problem list with ICD.

DR. STEAD: So do you want to make a sub-bullet under healthcare and drop that use case in?

DR. CAMPBELL: Yes. Does that work for you?

DR. TCHENG: You have captured the concept. Under healthcare delivery perspectives, I think we need to think about the things that - where ICD-11 should work reasonably well, which we have already articulated, for example, performance assessment, quality measurement, community health and wellbeing. The concept of actual clinical documentation is another level deeper than that. I would separate those two concepts out from under the bullet of healthcare delivery.

DR. STEAD: So what you are really saying is under use cases we may want to have which uses in this perspective are appropriate for ICD-11, which uses are not - are inappropriate. Let's just stub this one in. It would have the example - okay. And that is - then under which are not, you would have documentation for clinical care.

DR. CAMPBELL: We expect that you will probably

come to that conclusion. I am not sure we are concluding that yet. The battle I am trying to prepare for is, you know, again, we had people say ICD-10 is coming so let's use it for clinical documentation for proc lists.

DR. STEAD: Right.

DR. CAMPBELL: Having someone who has actually studied - and we were having to do our own research. We were able to find things like, well, ICD-10 won't do outcomes because it doesn't cover whether breast tumors are estrogen sensitive or not.

DR. STEAD: Okay. We will still have work to do on this. We will have work to do on harmonizing that. I guess that is what lunch is for.

So we have killed it from there. Bottom of ten, it can go away there. You have got it up above.

Okay, evaluate feasibility and - this one will need a little more work. I am getting tired. It would sort of be the parallel to the mortality timeline comparison of cost/benefit of transitions of ICD-11 for morbidity in 2025, 2030, 2035. It seems like a good range.

Evaluate alternative guardrails. Evaluate alternative approaches. Does that work?

MS. KLOSS: If you put 2025, 2030, 2035, it is going to settle on '30.

DR. STEAD: Excuse me?

MS. KLOSS: Could you put '25, '27, '30? Little sense of urgency. Our first recommendation is getting the financial support to do the research. I am just thinking that we need to convey some urgency to get going.

DR. STEAD: Good point. Everybody good with that?

MS. PICKETT: Linda, I have a question. I think the 2025 came from your table. It was based on the fact that we implemented 10-CM in 2015. Is the logical starting point actually when WHO approved ICD-11? The starting - you can't start to evaluate something until you know something is stable and approved. I am just questioning whether 2025 is the correct number.

DR. STEAD: They have approved it. Haven't they?

MS. PICKETT: In 2019, not 2015. We did 10-CM implementation in 2015.

DR. STEAD: I understand.

MS. PICKETT I am just trying to figure out the starting point.

DR. STEAD: I think our bias, right or wrong, at least from the point of view of opposing questions is that ICD-10 is actually much older than ICD-9 was when we started the last journey. There is an urgency - if you look at the number of things people are having to do to work around, there is an urgency to moving if it is feasible. We wouldn't say do it, but to have that as one bookend I think

was a good idea.

MS. KLOSS: My guess is it is not going to happen in 2025 or even 2027, but I think if we start out by saying, oh, it could be 2035, then it is highly likely somebody will say well then we will worry about it in fiscal 2034.

DR. STEAD: If that. People good with '25, '27, '30 as an initial - okay. Evaluate alternative guardrail, blah, blah, blah. Evaluate alternative approaches. Scaling. Evaluate feasibility of repurposing/reusing some of the infrastructure.

MS. PRELLWITZ: One last thing before we finish. If we could just - my apologies. Could we go back to bullet point ten, please? There was one area we might want to clarify. It is 10c when we are talking about overlaps with other code sets. If we are going to try to go for funding, we want to make sure we are clear what types of uses for 11 we are speaking of, just from a coding perspective.

While we may not all like the term right now, people think ICD-11 as both diagnostic morbidity/mortality coding and procedural coding. Obviously, within this room, we realize that is beyond - half of that is beyond the scope of this discussion. So when we are talking about other code sets, we just want to make sure that we understand what the comparison is so people don't get

misconceptions of what this change is going to mean.

DR. STEAD: Why don't we simply say ICD-10 PCS is out of scope.

MS. PRELLWITZ: Just like the discussion that someone identified that ICD-11 wasn't necessarily appropriate for clinical documentation - deep clinical documentation, so we wouldn't want to include that in a comparison study.

DR. STEAD: I would put up parens - space paren ICD-10 PCS is out of scope just to remind people.

MS. PRELLWITZ: Do we want to say as procedural coding? From a coding perspective, people will understand what that means. So it is not just PCS. It is just that we are only focusing on diagnostic morbidity/mortality. We are not focusing on procedural coding for this discussion just because we haven't had those talks yet.

DR. STEAD: Okay. Good catch.

MS. HUE: I think it was up at number 6, the very last one, where it talked about the - yes, cost to develop and maintain. Do we want to insert implementation in there, as well, how much will it cost to develop, implement, and maintain?

DR. STEAD: Good catch.

DR. RILEY: Can I go back up to timing real quick? Just the inconsistency - I understand why it is later for

morbidity versus mortality, but we said 3, 6, 9 years, in terms of comparing cost/benefits for that timeline, which would be '22, '25 and '28. Then down in morbidity, we have a different sort of timeline. I just want to make sure we are explicitly being inconsistent here or are we trying to time these up.

DR. STEAD: No. We are trying to say morbidity can and should go first - excuse me, mortality can and should go first. I think that time window - the 3, 6, 9 is probably the realistic range with the current world aiming for the middle of that in some way. But we know that wouldn't work for morbidity.

I think we think if we do mortality right, we can learn a lot that will help with morbidity. That is the sense I have gotten. Does that compute?

DR. RILEY: Yes, but if you are saying that and you are thinking six years is probably the likely that they will select based on Linda's point that they will always grab the middle one here that puts us at '25, which means probably '27 is the likely - that middle that you've got for the -

DR. STEAD: I am actually hoping the data will suggest we can and should get mortality done in three years.

DR. RILEY: That would be great.

DR. STEAD: I mean I hope - I understand all of the reasons that might not be able to happen. The purpose of posing the questions is if they come out with certain answers then it could become compelling to do that.

Come on down. We didn't affect these. I think there are still some pretty good principles. My communication stuff I am assuming will merge into what you all last did. They were things I was just carrying along. I think we may have - we've got some places we want to tease a little bit, but we may be to a reasonable version one for the research question categories. Is that where people's heads are?

Do you want to - Rich, I am assuming that we ought to go on and go to lunch. Would you - unless you are at a point you would like to share anything based on this morning. We have two minutes. Everybody can pause, jump up and down.

MS. GOSS: Actually, I am curious who is staying - who is returning after lunch that is not a subcommittee member? Okay, one table. Great.

MS. HINES: And I would just like to let you all know, since I don't think we were explicit, that once the draft meeting summary is done, we will circulate it and do our best to do so so that you have two weeks to review it, let us know if we missed something. This isn't your last

crack at this.

DR. STEAD: Since we are going to lose a number of people -

MS. HINES: Yes, I want to collect all of your stuff.

DR. STEAD: Just some things that will help me. One, the scoping document, which we emailed you as one of the prereads, includes what the NLM is going to do in the rest of the analysis where Olivier presented the preliminary results. They are going to do a substantive amount of additional work that will flow into a peer review publication. That will provide a good basis for how we do a lot of this. That is in process.

We will produce a meeting summary, which will be able to - we will grab all of your pieces of paper. Rebecca will get them typed up so that we will capture some of the detail that hasn't shown up on this list. That will be in the narrative report. Our goal of the narrative report is to bring people along that were not in this room without it getting to nauseating detail. We will be able to attach or to link into that report all of the prework. So that will be a useful body by itself.

We are then assuming that we are going to have two relatively short attachments. If you look back at the guidelines for adoption and the criteria - no, the Criteria

for Adoption of Vocabularies and the Guidelines for Curation and Maintenance that we developed after last July that were attached to the letter to the Secretary, we are assuming that what you have just seen will turn in to one such attachment, a couple of pages, that will in essence be the high-level approach for the research evaluation.

There will be another similar length list of the key communication messages and stakeholders. We will attach them to a relatively terse letter to the Secretary saying this is - it is now and this is what needs to be done and here are these pieces. Then the report will provide the additional detail.

So, that is the work we are going to do. We will - as part of the process that we have had certainly in Linda's and my tenure on NCVHS, the report of this will come to all of you in a form where you will have time to read it and email it back to us before it becomes final.

Linda?

MS. KLOSS: That second letter can reinforce the point that our table made that early action on the regulatory decision will be important to overall communication with stakeholders.

DR. STEAD: Correct. So that is how this will all play out. What we are going to do this afternoon is try to actually take a cut at the letter and the rest of this

thing. We are hoping to walk out of here with something we are editing on our way to the fall meeting, no doing de novo. All of us have day jobs, too.

MR. LANDEN: With the usual apologies due to lack of time - I didn't have a whole overnight to work on this like Bill did last night. It is not intellectually well organized, but at least it takes the disparate groups we have heard, consolidates the overlaps, and categorized them.

It will need further work. There is a lot more detail in here than will be in the - what will be attached to the letter, but all of the detail will be incorporated into the report. So we are still making that differentiation between the higher level stuff that is going to be transmitted in the recommendation letter versus more of the detail that will be available in a separate document.

All right. So what I heard from across the groups is, number one, seemed to be a strong consensus to start immediately. Don't wait for anything. Start getting the word out. The messaging, of course, will vary depending on where we are in the stages, but start now.

Utilize a professionally developed marketing and communication strategy, including passive communications or pull mechanisms like websites, Wikipedia-like information

sources that stakeholders can locate. Also use active communications or push methodologies where information will be sent to the stakeholders.

Leverage personnel and lessons learned from the recent ICD-9 to ICD-10 conversions. Make no promises that are not demonstrated or proven or validated. That was the no fake news bullet.

Target audiences. I think we have a good list. Providers, clinicians, caregivers, including their trade associations, for example, ADA, AHA, AMA. Payers and their trade associations. Professional associations subdivided into physician professional associations and specialty societies who, sub-bullet under that, focus on aspects of interest and utility specifically to their membership scope. Other professional associations, nursing, coding, AHIMA.

DR. SIMINO: How come nobody is - we want to empower patients, but we don't burden them with this. They could at least have the grace to die from official ICD-11 -

(Laughter)

DR. SIMINO: But seriously, is there a role for patients and the public?

MR. LANDEN: I think that is a great question. Most of the documents that we draft from NCVHS we do include reference to what does this mean to patients. It is

kind of interesting that patients did surface from any of the tables. I am very glad you raised that. I will add it to the list.

DR. ROMANO: It was in our table discussion. We talked about the role of patient advocacy organizations, in particular, as prominent participants in this discussion. Certainly, Donna is familiar with the role the patient advocacy organizations have often played in the ICD-10 CM process.

MR. LANDEN: Good. I will add that in then.

DR. PINCUS: You might also want to link with PCORI, which has developed strong relationships with different patient groups.

MR. LANDEN: Okay. Where was I? Okay, states we got on the mortality side, the NCHS context. On the morbidity side, it is the state Medicaid. They all flow up into state government and legislative hierarchies.

MS. LOVE: And state data collectors, state data agencies that collect the all-payer data.

MS. HINES: Is that on your sheet, Denise?

MR. LANDEN: I have got that. SO under states, I've got mortality, morbidity, and data agencies.

Vendors, developers, and intermediaries. Those would include EHRs, billing, practice management, coding systems, clearinghouses, clinical content developers,

clinical decision support developers.

Other affected associations and organizations such as the SDO, the DSMOs, WEDI, HFMA, HATA, EHRA, HIMS.

DR. STEAD: Linda has her -

MS. KLOSS: Rich, did you mention the health plan IT systems because that was such a pain point in the -

MR. LANDEN: I mentioned payers and trade associations.

MS. KLOSS: With regard to technology?

MR. LANDEN: Not specifically.

MS. KLOSS: Payer technology systems. Health plan systems.

MR. LANDEN: I have edited it as a sub-bullet under payers, IT systems. For other affected organizations, HFMA, HATA, EHRA, HIMSS, coders, coding professionals, quality performance metrics developers.

The next concept is the channels available to use for the outreach marketing - medical/nursing schools, professional training and accreditation programs, advocacy organizations, professional and trade journals, blogs, et cetera.

Outreach initiatives should be accompanied by feedback channels to learn from and improve adoption path or outreach efforts.

Messaging topics should include the - should

focus on the key messaging topics, enhanced computability capability of ICD-11 and the opportunities that that enables and should tradeoff investment in computing technology in exchange for eliminating coding by providers or staff.

Finally, leverage WHO and NCHS tools and information available on their website.

Now, those were the things I heard in common. There were some individual suggestions that I put into the bucket called possible messaging bites. Not your father's ICD. Begin to get ready now. Plan your transition. Leverage your ICD-10 conversation experience and personnel. ICD-11's promise to improve. And the point we talked about if a clinical modification is determined not to be needed, it is important to explain to industry all about that, including essentially that it is still - it is nonetheless a mandate, same as it had been - would have been through an NPRM final rule process.

Mapping/implementation considerations. New ICD-11 represents the best up-to-date 2019, although we may want to tweak that date because of when it was put together, not when it was approved. Clinical knowledge and research as opposed to ICD-10's base, which was back in - I have to check the timeline - the 1980s or even '70s.

Question, why change so soon after the ICD-10

implementation? In part, the answer was ICD-10 was transitional.

Coders should view the transition as advancing their skillset and embracing change. ICD-11 is coming and all stakeholders need to plan for how they or their membership will achieve implementation.

So those were the messaging bites. Other ideas that surfaced among the individual tables - competitive competitions to demonstrate new capabilities of ICD-11 with publicity and prizes. Make content and documentation freely available on the web so as to ensure all coding algorithms achieve exact same results. All impacted federal agencies should be leveraged to help with the outreach. NCVHS should reiterate its recommendation to HHS for sub-regulatory adoption.

There is to be a mechanism for ICD-11 - to share ICD-11 research findings and other information useful to stakeholders and implementers. Reduce burden. Positive return on investment and efficiency. Simplification. Billing enhancements. Improved quality of data. Painful lessons learned from ICD-10, do not repeat. Make toolkits available.

The communication channels identified include internet, YouTube, blogs, webinars, podcasts, webcasts, social media, seminars, meetings, and conferences, TV,

radio, newspaper, mail, journals, billboards and musicals. While the last one is a little bit facetious, there have been some interesting things that did exactly happen with some of the aspects in the past that involved plays and musicals and balls, so not out of the question.

Feedback?

DR. CAMPBELL: The XPRIZE got morphed a little bit. So it wasn't about trying to convince people of the value of ICD-11. It was how can we make the transition to ICD-11 work better. One of the things to think about is how much money was spent on the ICD-10 and having some sort of XPRIZE type competition that looks at how can we make the transition less expensive, how can we make it more beneficial to the clinicians and maybe see if it provides some benefit to the patients.

The specific idea we articulated was how can an XPRIZE - or how can we extract the administrative codes from the clinically collected data that is already in the health record. Hopefully, with that reorientation, it makes sense.

DR. STEAD: Other comments or have we earned lunch?

DR. ROMANO: Just quick, I think in terms of the lessons learned from ICD-10, just to flesh that out a little more. Aside from the regulatory process that was

drawn on forever, I think a couple of things came out of our discussion. One is that probably the benefits were oversold, and the burdens were undersold or minimized. It is important to really have an evidence base.

When we collectively go out to the field, we need to engage stakeholders in a process of testing, really, instead of sort of coming up with some fake numbers and trying to pitch them as if they are the truth. It is better to sort of engage a broad set of stakeholders in helping to generate those numbers, helping to see the benefits and the burdens, and really having more of an engagement process so that we don't need the regulatory process because everybody will be onboard.

Part of that also is being upfront about acknowledging - in the previous case, it was that there was this proliferation of codes, 100,000 codes, for all of these crazy pre-coordinated concepts. Now, it is the other direction. Everybody is going to be complaining about these codes that go on forever because they are post-coordinated with ten extensions. How do we communicate that clearly and make it manageable?

DR. STEAD: Got it. Okay, I think it has come time to say, for those of you who are going to leave, we really are grateful for your effort. We have - there is no question we had the right people in the room. I have never

seen a group that engaged and worked so consistently throughout this whole process.

Thank you. We will thank staff and others when we close down the subcommittee. Before we lose those of you who are leaving, I just wanted you to know how grateful we are. Your expertise and engagement were simply awesome.

(Recess for lunch)

**AFTERNOON SESSION****Agenda Item: NCVHS Standards Subcommittee Working Session**

DR. STEAD: Colleagues, we are convening a subcommittee working session for the Standards Subcommittee and our experts that have been so kind to stay from the roundtable.

Before we get into the activity this afternoon, I would like to take this opportunity to acknowledge a very important member of the NCVHS team, who is retiring at the end of this month. Hiding.

(Applause)

Debbie Jackson, a senior program analyst, has been with NCVHS for almost two decades. She has played a significant role in supporting the committee's success through these years during the tenures of Marjorie Goldberg, the previous Executive Secretary, and Jim Scanlon, the Deputy Assistance Secretary for Planning and Evaluation for Data Science and Data Policy. The success of both the Committee's 50<sup>th</sup> and 60<sup>th</sup> Anniversary Symposium was in large measure a result of Debbie's expertise and dedication to her work. We will miss her at the 75<sup>th</sup>.

Let's acknowledge Debbie Jackson for her decades of service and dedication, both to HHS and, in particular, NCVHS and each of us. Thank you, Debbie.

(Applause)

Now, I will turn it back over to Rich and to Alix to lead the subcommittee session.

MS. GOSS: I do think that we have a general game plan that Rich and others have sort of been vetting over the last day and a half or so as to how we might proceed. I think it might be helpful if we talked about it from a capstone kind of global perspective, understanding - to make sure everyone understands what the process is going to be and enabling us to focus in more on what is the priority activity of today or the next amount of time around what is the content of the letter that we want to send along with the great attachments that we have been vetting.

So I think if we could start there, Rich, that might be helpful.

MR. LANDEN: I think that is a good approach. We appreciate the efforts. They exceeded my expectations from the expert panelists - the expert participants today and yesterday. I think a lot of the heavy lifting is done.

The syntheses that we have been doing as we have gone along have brought us fairly closely. I believe we are of a consensus that we will model our letter to the Secretary on Dr. John Lumpkin's letter to the Secretary from 2003, which is up on the screen now, in which that NCVHS recommended adoption of ICD-10 to the Secretary.

Content obviously will change, but essentially, it is going to be a short transmittal letter with just some very key ideas from our topics and issues, discussion yesterday, along with some summary of the messaging topics and path from today.

The bulk of the information will be in attachments A and B, again, same - the synthesis from the breakout sessions. Supplemented by the meeting report, which will be a separate document available on the website and will not go along with the letter.

DR. STEAD: It will be attached.

MR. LANDEN: It will be attached to the letter for reference. Bottom line is the meeting report will be available for reference, whatever mechanics we use to do that.

MS. HINES: The research outline will be attachment one. The meeting report will be the other attachment.

MR. LANDEN: Okay. Thank you for the clarity.

So today we will see what progress we can make on agreeing to what the content of the letter is and just kind of honing the two attachment documents. The summary of that will go into the body of the letter. I do envision if future work or validation is needed, we will use the ICD Working Group for that.

MS. HINES: Yes, we will definitely keep that going.

MR. LANDEN: And then we will bring back a final draft for review and approval of the Standards Subcommittee, which will then be forwarded back, I presume looked at by the Executive Committee, and then put on the agenda for approval at the October full NCVHS meeting. We are consistent. All heads are nodding.

Anything to add, anybody, or questions?

MS. GOSS: I have two things to add. The first one is a tremendous acknowledgement of the working group that has enabled this event to come together and with participants that were so impressive, knowledgeable, and really thoughtful about their input over the last day and a half. I really want to applaud you.

From a personal perspective, it has been a huge burden off of my shoulders as I have been focused very much on the Predictability Roadmap.

That leads to my second point, which is that this timetable of walking out of here with the agreement on the concepts of the letter, building up the ancillary attachments, and getting that approved at the fall NCVHS meeting is great because it is also going to allow us to do the parallel work that we need to for the July visioning workshop as the subcommittee is balancing a lot of really

critical issues right now. So I really appreciate the team effort.

DR. STEAD: When I read this as I was getting ready for the last two days, it seemed to me it was a model in simplicity and clarity. We ought to really think about the degree to which we could use this framework and, in essence, make - we don't need to do wordsmithing. Get down to the key themes that we want to drop into it.

One paragraph tied into the role of NCVHS in supporting the HIPAA standards. The work that the subcommittee had done on the feasibility and desirability of replacing the current diagnostic and inpatient procedure coding system - because a lot of the work was there. We will want to change that in this. And the expanded versions of both the clinical manifestation for ICD-10 and PCS.

So that sort of introductory piece and then, in essence, the reason it is important, the age of ICD-9 and the fact that the update process no longer really accommodated the changes that need to be made and the fact that the committee had had hearings and so forth - come on down, Rebecca.

Concerns that had been raised by the community, determine the cost and potential benefits and implementation issues of the migration to CM and PCS. Since they - they included the RAND study, which had been done as

part of that evaluation.

Come on down. Basically, made the basic statement that we had received a lot of input. That we felt that a successful transition was possible. The industry needed a minimum of two years. And that such timing should be further clarified and refined through the regulatory process.

So it built that in and then, basically, simply said we think that we should proceed with this, but that we should use the rulemaking process to identify what could be done to minimize cost, what could be done to maximize benefit, what are the potential unintended consequences, what is the timeline, what are the additional steps.

The only reason I pull us back to this level is it is really up a level. If you look at all of the work that we have done and all that we have learned, what we know are the key - we know this is urgent. It is here. We need to figure it out.

We have also heard the complexity of the questions that need to be dealt with to figure out how to do this well and, ultimately, to figure out what the best timeline should be. Our job isn't to communicate the answers, which some of our letters are much more detailed because we are actually saying this is, in fact, the policy approach and it is down another level. This is up a level.

In essence, what I would suggest we do is target this kind of a two-page letter. It seemed to me - I will just put as a starting point the things that we might consider including. One would be the urgency. That needs to be two or three sentences, not a page. Second is because the World Health Assembly has acted, this is now coming. It is going to be part of our life in mortality. We have to figure out the next - the path forward with morbidity.

The second is that -

MS. GOSS: Rebecca, I think you need to modify the first sentence - the this is happening de facto for mortality. I didn't want to lose that. I think there is an important distinction in the letter that we need to make between the two paths here, even though they will all converge.

DR. STEAD: Good point. It seems then we need to link back to the criteria for adoption and for - I guess, actually, we want to first link back to our proposal - our recommendation for using a sub-regulatory process. I don't want to - I will come back to what I think is a sidebar we might want to discuss about that. So that would be the first thing that we do.

The second thing we would do was reference the criteria for adoption and guidelines for curation and - dissemination and curation that we have already submitted.

And then point to the extensive work we have done to inform recommendations about the research questions and communication topics. A very high-level statement about the - about why the research needs to be done and why it needs to be done now. And a very high-level statement of the strategic communication process and the fact that key stakeholders need to be engaged now if they are going to be able to move it forward. And then include the attachments.

I think that is, in essence, what I would put as a straw person for the key points that we want to get into the letter. With that, I will open it up.

MS. GOSS: In regards to the framing of this, it resonates for me. I wonder if there is a closing ask. At some point, I think this is all about we need you to pursue the necessary research or assessment or something. We are asking them to take a specific action not only on the research, but also on the communications. I think while they are off getting the analysis completed, we need to be having that professional communications and outreach program development to be undertaken.

So I feel like there are two parts to this, above and beyond the ask of please look at all of this great - you know, these attachments.

DR. STEAD: Okay. Yes. I think our asks are to conduct or contract for the research evaluation. That is

one ask. We need an equally precise communication ask. I think this is the right level for us to be trying to get agreement.

MS. LOVE: Minor point, the sub-regulatory process, do we want that so high up? Is that significant or is that more down in the hows? The urgency and what is happening with ICD-11 - it just seems to me -

MS. GOSS: I think it is part of the closing request.

MS. LOVE: Yes. I think that would go lower to me. And then do we mention mortality or are we just doing morbidity?

MS. GOSS: Yes. We do in the beginning. Adopted ICD-11 - de facto mortality. Need to figure out paths forward for morbidity.

DR. STEAD: We need the research evaluation for mortality to be able to determine the benefit and cost of different implementation timeframes - different implementation approaches and timeframes.

DR. CORNELIUS: What you just said was kind of what I am hoping that when we get to the research and evaluation that we tweak a little. We read that - we have the other letter. All of a sudden, we are doing a money ask. It is sort of like, well, so, help us help the Secretary understand exactly what you said. We need the

research and evaluation to be done for this, that, and the other.

MS. HINES: What I heard - where you going was do you want to try to wordsmith the actual final closing request and get consensus on that?

DR. STEAD: I think getting consensus on - we are together. We are talking about one to two pages max. Getting consensus on the key statements would be extraordinarily helpful. We can add packaging language around it.

DR. CORNELIUS: I am not worried about the 2003 letter as I am about us putting our energy on what is in front here and then trust to the bodies - integrate those two parts.

MS. HINES: The three elements of the closing request I heard were the recommendation to go with the sub-regulatory process, to recommend that HHS conduct or contract for the conduct of the research and evaluation outlined in attachment one, and provide leadership on outreach and communications about the upcoming transition.

MS. GOSS: I think we would want to start with you need to quickly get the research and evaluation done. Meanwhile, you need to get the communications planning done. Then when you are ready to pull the trigger on all of this coming to fruition, please recall our recommendation

to do the sub-regulatory process to advance this.

MS. LOVE: That is almost not like an ask. That is just an explanation. The two asks that Alix just said with the sub-reg as an explanation. When we are ready we have laid out a sub-regulatory process.

I wanted to say one other thing when you are ready. On the cost, as I looked at that - up higher - the costs of potential different implementation approaches and timeframes, but also the costs of not timely implementation. Is that implying -

DR. STEAD: Yes.

DR. CORNELIUS: Opportunity costs.

MS. LOVE: Yes. There are huge costs for not moving ahead, as well.

MS. GOSS: I think it is cost and implications. If we don't move forward, we would be violating a legal agreement that the United States - to adopt ICD-11.

DR. STEAD: I think the main thing we want to emphasize is the opportunity cost of - I think we have a chance to avoid opportunity costs. We have a chance to reduce the burden and cost of implementation. Those are - there are real opportunities in those areas if there is some way to communicate that around morbidity and mortality. Maybe we, therefore, need to split it. How do we do that without getting it too complicated?

MS. LOVE: I am assuming some things are going to be in that. One of them is that ICD-10 is - life cycle is over or whatever term we want to use that no longer meets the health care delivery - reflects the health care delivery system. I am trying to think of the word - archaic.

MS. GOSS: The ICD-10 framework - the international community has moved on to ICD-11 from ICD-10. It reflects a tremendous amount of enhancements and kind of taking it to the next generation and provides a more stable environment for us to work in in the future because it will be iterative updates as opposed to full-fledged pivots. I mean there might be a nice way to -

MS. LOVE: Yes. I think we need to be succinct.

MR. LANDEN: One of the key points, I think, was the ICD-10, even though it is only four years old for us, is based on science, technology, medicine, research back in the 1980s. It is already obsolescent.

MS. LOVE: That's the word I was looking for. My brain is stuck.

DR. CORNELIUS: I keep hopping on that economic where are the opportunity costs. Not just the time, but the cost, the forgone cost of not doing this. We are talking about things that are obsolete. We are talking about the time is now. All of this is tied to resource management.

DR. STEAD: We will get further if this is short and has extraordinarily explicit asks and then extraordinarily explicit reason that he should care.

DR. CORNELIUS: What would that reason be that he should care?

MS. KLOSS: We are having some anxiety over here about using words like obsolete. This is too fresh and too painful. I think that we should be cognizant that the agencies will take offense at having gone through so much painful work fairly recently.

MS. GOSS: Is it in the context of ICD-10 as a body of work is obsolete, even though we are using it - the world has moved on and we need to start planning for us. I think we should recognize the pain that has still only been four or five years in our world. We are really talking about a lot of years out from just this starting point.

MS. KLOSS: I think we can lay out the dates. I think we can do that by talking about - briefly describing the benefits of 11 without dissing 10. I just don't think that serves our purpose.

MS. GOSS: I want to be mindful of time. I think we take it - if anyone has a heartburn about it, speak up. Otherwise, let's take it as a point and be sensitive to not do that.

DR. CORNELIUS: I think we could still hold on to

the concept of opportunity costs without talking about obsolete. On the other side, talking about things like natural language, innovation, whatever, pulls together the community. Use that to say that is why we need to do this. We need to do this because this is an opening bridge to things that could happen without ruffling people's feathers.

DR. ROMANO: I just wanted to suggest an alternative framing maybe. You could say that it will be obsolete. It is not that it is obsolete now. It is that as we look towards the future and as all the countries around the world adopt ICD-11, WHO will no longer be supporting ICD-10, which is the base code set. Then we will be in a situation where it will become obsolete. Donna and her team and whoever follows her will be left trying to prop up a code set that is not supported by the international community.

MS. PICKETT: Just to follow-up with Patrick's statement, WHO is no longer updating ICD-10. 10, for the most part, is dead. I mean it will continue to be used until countries are able to transition to using ICD-11. But in terms of an active updating process for 10, WHO has ceased that and now it is focusing their work on 11 and its updating features.

From a morbidity perspective, also to follow on

with what Patrick is saying, in the letter back in 2003 to the Secretary, 9-CM, again, had been in place for more than 25 or 30 years. The ability to update 9-CM - first of all, WHO did not have an updating process for 9. So, for 9-CM, we did have an updating process, but even then we were still having issues trying to incorporate newer knowledge into something that had been created many, many years ago. We didn't have room in many institutes to add a lot of new things. We were still adding, but that was getting to be a very huge challenge.

The issue we have here, fast-forward, is that while WHO, again, is not updating ICD-10, we still do have an active updating process for ICD-10 CM. Again, how you explain - Linda, I think your approach might be a good one in that instead of kind of dissing 10 CM, if you are going to promote something, you promote what the benefits are of 11. Somebody will point out to you that we do have a vigorous and active updating process for 10 CM, which was just implemented three years ago.

MS. HINES: That is great. So what are the top five features to put in a letter of ICD-11? If you had five words. That is what we need.

MS. GOSS: We have a very short amount of time to get this consensus. This is your opportunity.

MS. HINES: What are the five qualities or

features?

MS. AULD: You might want to emphasize the fact that ICD-11 was specifically created for electronic health records now. It wasn't created years ago with the intent that it could be used in computers. It was designed for computers as they exist now. This is a huge opportunity that HHS should take advantage of to look at how we can exploit that and possibly consolidate rather than having a new clinical modification. Whether we can exploit ICD-11 as it is created and in the long run end up saving money. There is a better way to say that. Why should we create our own clinical modification if we can work with WHO to exploit ICD-11 to meet our needs and possibly meet them even better than what we have now is doing?

MS. KLOSS: Another advantage would be comprehensive and its better ability to support initiatives such as interoperability, population health improvement, the things that are on the Secretary's priority list.

MS. HINES: Anything else?

MS. KLOSS: One more thing. We think that it would be useful in the letter to say that the approach we are recommending is the result of an assessment of how we can improve upon what happened with ICD-10. The timing of the research is a key element of changing the process. I think that is really an important driver.

MS. GOSS: I think it builds on what Vivian said. It sets the context for how we do the value proposition of why this is - sorry we tweaked everybody's nerves with obsolete, but I think the point was 10 is old. We are ready to go to 11. We learned from everything up to this point. Now, let's embrace that and take it to the next level. I think that is kind of how to put the positive spin on it.

MS. HINES: Linda, you said the key element of the research is -

MS. KLOSS: Beginning with a robust research plan around mortality and morbidity is something that wasn't done in the past. This is a key insight that we have had on evaluation of past transitions.

MS. PRELLWITZ: I have one more question, just reading this letter. This may be something the Committee has already assumed. If I were to read this letter and I maybe hadn't remembered what the charge of this committee was, it would make me think that I-10 is old. We are going forward. 10 is being removed off the map. So, my question would be do we need to add anything that supports the fact that we are looking - the question is will they get confused if they still see ICD-10 PCS in use?

MS. HINES: Should we have two sentences about PCS out of scope?

MS. PRELLWITZ: Or just understanding what the

scope is. From an optics perspective, it would make me think that, oh, it is all going away. Great. Wait a minute, this is still here.

DR. STEAD: We can say we made the recommendation to clarify that - as we recommend it, clarify that ICD-10 PCS does not need to be included in this. At the same time, we do the link to the criteria.

MS. PRELLWITZ: Yes. Just because if they are looking at the transition from 9 to 10, we transitioned both sides at the same time. We are making a conscious decision to make a split. Just making sure people remember that.

DR. CORNELIUS: I am starting to feel a little funny about what is happening.

MR. LANDEN: Yes, that is where I was going to head. That is a valid point. I think we address that in a reference to our recommendations from last year. Exactly what you said is a very clear point in that. The sub-regulatory adoption and the exclusion of PCS from consideration I think is borne out well in the attachments. I am starting to get the sense that our one-and-a-half-page letter is now approaching six pages.

MS. HINES: I don't know. I just want to push back a little bit and say the reader may not be reading the previous letter. I think having a sentence with a footnote

is not going to add a whole lot of extra here. It is probably worth defining the scope up front. That is just my perspective.

DR. CORNELIUS: I am going to be honest. Part of what I am hearing though - I am hearing - one of the advantages I have of being sort of an outsider to some of this is as I am listening to this conversation, I am hearing things happening right now that does not reflect the last two days. For example, what I am hearing is a conversation about what is happening with - what is already sitting out there in this world about ICD-10 and how we are relating it to this letter. Are we sunseting something? Is it alive or dead? I am like, wait a minute, that sounds to me like political.

I think we have a very straightforward committee task. Our committee task is how do we move forward to a letter. That is what I thought we were working on. The letter deals with what you put up before - can I finish? You can say what you want after I finish - and how to be cogent, but it sounds like we are doing a lot of group processing.

MS. HINES: So sorry. I apologize for interrupting. I am just like champing at the bit to say what we did over the last day and a half was develop the attachment, the first attachment to the letter. All of the

work that has gone on over the last year is the letter.

The attachment with the research plan and the communication plan, all of that work, that is the attachment. That is a whole other task that we are going to - developmental work we are going to have to do. The last year is what this letter has to reflect. That attachment that we spent - all of the plans for the research questions that we think HHS needs to conduct and the leadership they need to provide on communication, that is what we spent the last day and a half doing.

MR. LANDEN: If I could chime in, I hear what you are saying. I am in not total agreement. I think the purpose of the letter is to convey the payload. The payload is what has come out of the last day and a half. The vehicle for conveying that needs to ensure that the recipient will have all of the context that they need to understand why the payload is being delivered.

I don't necessarily agree that the letter cannot address contextual or ecosystem issues that were not part of the scope of the last day and a half. Which is not to say that we are changing anything about the last day and a half. Just saying that is the payload. The delivery system is a different issue.

MS. PICKETT: Just by way of history, one of the reasons that the 2003 letter could be as concise as it was

was because of the attachments that went with the letter. So the intent of the letter, for those of you who sat around while it was being drafted, again, was to make sure what was coming across was your bottom line.

What is it that you want the Secretary to do? If you want it to include background information, those were the attachments. There were three attachments that went along with this letter, one of which detailed the history of all of the testimonies over the course of the five, six, seven years of active work of the committee. I see this as being somewhat similar.

The fact that in the draft points that we have on the screen now are referring back to the letter to the Secretary about a sub-regulatory process, if that is something important and we don't want that to get lost that, too, could become a new attachment, even though you have already forwarded it to Secretary. If you don't want somebody to have to funnel back through pages and pages of letters of recommendation, you attach it to this. If they want to read it, they have got it, but they don't have to go back into their correspondence file by five months and try to pull up that letter or search a website.

That might accomplish I think what I am hearing from everybody is you don't want to lose the important work that has been done, but you do want to call it out. You may

want to call it out as an attachment and not expand this letter, as Bill was indicating, to something that will become five or six pages, which back in 2003 we all knew would never get read. If that is the case, keep it short. Keep it simple. Include as attachments those things that you think make your point. You can raise it as a sentence in the body of the work of the two-page letter.

MS. GOSS: I think there was a subtext to some of Lee's commentary, which resonates very closely to my observation. We have pivoted to a subcommittee's discussion around a letter that this is our work product. I think we were trying to make sure - at least I am trying to make sure that we are, as a subcommittee, very much in line with this. I think it is very important to hear from the audience and their commentary to help us think through this, but the sense that we started to make it the kitchen sink because of a broader conversation I think was sort of my concern.

I think Donna gave us an excellent solution about linking back to the letter. I think that also covers the very valid point about what is out of scope. I think we are going to have a very interesting balancing act for how to keep this letter at the right level to reflect what the subcommittee and, ultimately, then the full committee thinks is the critical stuff.

The bandwidth of the reader, the recipient, is limited. We have got to hit that - we spend a tremendous amount of time, as Linda knows, trying to really find the sweet spot. I think from some of our prior efforts, especially related to the Predictability Roadmap, having a right, positive kind of tone in this is also very critical. My preference is to keep this at a very high level, shorter, sweeter, at this point with the kind of multitude of attachments so the reader can go where they want to.

MR. LANDEN: Let me propose this. I have one eye on the clock. It is already almost two o'clock. My sense is we have got total consensus based on Dr. Lumpkin's format from 2003. Keep it to two pages. Hit the highlights. We have a lengthy list of ideas to include in those two pages. My sense now is that it is probably time to let one or two people - I am thinking Rebecca and myself - draft kind of the wrapper of the letter.

The pieces that I think are still missing is what is it from yesterday's two breakouts and this morning's breakouts that actually rises to the level of putting in the letter, itself. That will be the hook that will lead the reader into the attachments with more detail.

Rebecca's point was maybe including the language. I am thinking since our process is we still have at least another iteration with the ICD workgroup and another

iteration with the Standards Subcommittee, my sense is I have enough to craft some language as a point of departure. If people agree with it in those two groups that will surface.

MS. GOSS: I am not hearing any high-level recommendations that have been coming out of it. I do think we are putting a lot of substantive weight into what those attachments end up producing.

MR. LANDEN: Right. If that is all right with the subcommittee.

MS. GOSS: Rich, is the lead-in the criteria on adoption that says that cost/benefit should be determined before going forward? Isn't that what we quote to lead in to what the attachments are?

MR. LANDEN: I don't know. My thought is what are the - the question in my mind is what are the key one, two, three, four, five recommendations coming out of yesterday and the key communication items coming out of today at very, very high level which address that. What is it we need to look into for - we are asking for a study. We are asking for a communication strategy. What goes in the body of the letter to clarify or support those asks?

MS. KLOSS: Unless you break out research for mortality, research for morbidity, and then integrated communication strategy.

(Comment of mic)

MR. LANDEN: Let me react to that. I am thinking we need to have if not high-level categories, then some for instances of what is in the attachment.

MS. GOSS: We usually provide some narrative context. We can link it then - have a recommendation and then we can say to this point kind of the kernel and then there is - and see this for more detail than you need.

MR. LANDEN: Bill, do you have thoughts?

DR. STEAD: I am not sure. How is that for unusual?

I thought the very simple bullets at the end of John's letter of the kind of things that needed to be considered were useful. They were at a very high level.

I am almost - I really think we almost want to keep it at something like at this level. The attachments are what you would do to answer these questions.

MR. LANDEN: I am thinking the same thing. My question is what are these five bullets coming out of yesterday's discussion?

MS. LOVE: I almost feel like those questions are politically fraught, the first two or three.

DR. STEAD: To Rich's point, if we could identify those five questions for this letter -

MS. LOVE: If you could frame them based on what

we found over the last couple days, I think that is an excellent idea.

DR. STEAD: Alix is shaking her head.

MS. GOSS: No, I am shaking my head because he said she lost connectivity. I am like no, she didn't. She is switching screens. Sorry.

MS. LOVE: So at least I think the timeframe one is fine. They would have to be adapted to reflect our conversation.

MS. GOSS: I am going a totally different direction, which is I thought the bullets at the end were going to be these are our recommendations. If you don't want to put specifics for each one of those, then you could make a jump - a closing paragraph that says for further background context see blah, blah, blah.

Bill, you are really thinking that we are going to try to ask very specific kind of thought-provoking questions as our closeout?

DR. STEAD: I think the idea that Linda said that there are max three recommendations - fund or conduct the research to evaluate mortality, same for morbidity. Launch a strategic communication - the recommendations would be at that level.

MS. LOVE: I think you can get them both in. You are saying a high-level statement about why the research

needs to be done in the near-term. That is where you could ask those relevant questions from our discussion, the last couple days, bullet those. Then have recommendations pulled out at the very end.

MS. HINES: Denise, I put, for example, see meeting highlights. I was on the same page with you.

MS. LOVE: Because that is where those questions could be embedded, not at the end. If you want recommendations, then we say therefore we recommend one, two, three.

MS. GOSS: That's fine. I think that there is an ongoing historical conversation around don't bury your recommendations because you are not going to get the reader past page one. I am starting to have that thought.

MR. LANDEN: We have a couple more passes. I am less than clear on what bullets we are proposing to incorporate. Rebecca, are you clear?

MS. HINES: I am.

MR. LANDEN: Okay.

MS. HINES: I think I am hearing - the great thing is there is email so we can all continue to communicate. It is not like we have a drop dead when we all leave here that is it.

DR. STEAD: Do you think you are hearing well enough that you could actually stub something? Is that what

you are suggesting? That would be awesome.

MS. HINES: I think your document from this morning, Bill, if we can agree on three boiled essences that is the equivalent of what was in the '03 letter. We can find the equivalent of these from the boiled up product you developed. I think that is what Denise is saying.

MS. GOSS: That is really resonating for me.

MR. LANDEN: Yes. We will look for our three or so shiniest nuggets from yesterday.

MS. HINES: That are high level enough, but specific enough that convey the depth of what is at stake.

MR. LANDEN: We have consensus. Next question is how do we do that? Is that something we want to do here?

MS. LOVE: Can I ask a dumb question? On the recommendation of leadership in outreach and communications, that is making the assumption that the Secretary is going to move forward.

MS. HINES: To ICD-11?

MS. LOVE: Yes.

MS. HINES: Well, they are because mortality is a de facto, which we said in the beginning. Right now, we have recommendation that HHS conduct or fund the research to evaluate the path forward to ICD-11 as described above and in the attachment. Two, the committee recommends HHS provide leadership on strategic outreach and communications

about the upcoming transition to ICD-11. Three, I have no idea how to word that.

DR. STEAD: That plays into the wording Linda had about the key lesson from ICD-10 was to do the research to inform how to optimize benefit and minimize cost and engage the stakeholders from the beginning.

MS. GOSS: I am struggling with that because we were trying to make this a recommendation. I think that is what she wanted. I think it is NCVHS recommends as HHS advances the U.S.'s full adoption for mortality and morbidity, they apply the opportunity to use sub-regulatory processes.

MS. HINES: That HHS use sub-regulatory processes.

MR. LANDEN: Specifically, the ones we have recommended.

MS. HINES: My only question is if we don't talk about that earlier in the letter, is that going to come across like where did that come from? If we just throw that in at the end -

MS. GOSS: Please see our attachment of our prior letter submitted in February.

MS. PICKETT: Rebecca, scroll - no, number three. You have now modified it. Is that still under the recommendation section?

MS. GOSS: It is and it should say - NCVHS

recommends is how it should start.

MS. PICKETT: I am wondering if rather than just saying link back to the NCVHS sub-regulatory process letter, do we want to be explicit and indicate that the reason we want them to look at it, link back to it, recall it, is that it relates to a facilitated, expedited implementation? Just to say link back to doesn't tell me what the Secretary should be considering. Why do we want the Secretary to link back? What does that have to do with this?

MS. KLOSS: The way our table framed that in our recommendations was that that would help inform timetable. So we kind of want that consideration of the process for adoption to be paralleling the research to inform adoption so that those come together rather than be one after the other and just extend this timetable. I think that is how we thought - we thought an early consideration of that would inform the timetable.

MS. PICKETT: I think being explicit about that would be helpful so that the Secretary understands what the recommendation is that is being made to them other than Secretary we are recommending you go back and read the letter.

MS. HINES: For the transition from 9 to 10, it was a regulatory process. Is the reader going to know that?

MS. GOSS: Maybe not, but at some point we can't write a book. There are going to have to be some assumptions about that. I suspect this will then go down to the Division of National Standards and they will be fully aware.

MS. HINES: So Donna, the recommendation is that as the country advances full adoption of 11 for mortality and morbidity that HHS make an early decision on going the route of a sub-regulatory process. This would facilitate a more timely, less complex transition and implementation. Is that close, not quite, good enough?

MS. GOSS: It is about timing. It is not less complex transition or implementation. This is just about speed to market.

MS. HINES: Which would reduce the cost to the healthcare system.

MS. GOSS: Timely transition to receive the full benefits of ICD-11 or something like that. We are wordsmithing at this point

MS. HINES: The main thing is to capture the essence of what you all agree on. Rich can fix it.

MS. AULD: At the top, you might want to start off by saying - where you are commenting that ICD-11 is coming, you might want to make that a little bit more explicit and say that NCVHS is recommending that HHS take a

proactive approach to addressing this rather than reactive. There is a better way to phrase that. It is essentially the whole reason why NCVHS has been proactive. You want to encourage the Secretary to do the same.

MS. HINES: Proactive approach to the transition to ICD-11?

MS. GOSS: I think it is to fulfill our obligations related to ICD-11 to garner the benefits to enable the healthcare system to garner the benefits.

MS. AULD: The whole evaluation and decision-making needs to be proactive rather than - it is there. You are going to have to do something. Don't wait to see what the rest of the world does. Frankly, the rest of the world is waiting to see what we are doing.

MS. HINES: Something like that.

MS. GOSS: No pressure there, Vivian.

DR. LANDEN: I am seeing heads nodding.

MS. HINES: Before we leave here, do these three articulations have the essence, the right meaning? Is there any meaning not here that should be here? In other words, is recommendation one - that is the right - that is what you want to say.

MS. GOSS: Considering the last couple of days and the sidebar conversations, I think it is spot on. Somebody would have to have some great epiphany or that we are all

really braindead and we've forgotten a critical component, which could seriously happen. I think Linda might have found it.

MS. KLOSS: The only thing for consideration is whether you have a recommendation for research on mortality and a recommendation for research on morbidity.

MS. GOSS: That's a really interesting point. We said as described above and in the attachment. I thought we might have some aspect related to mortality even though it is a slam dunk that we have to do it. I think there is an opportunity for NLP to be sort of further advanced. I see head nodding.

Would we want to then make that very crystal clear in our recommendations by not having number one just be one bucket, but to make it two parts? They are very different paths. There is a lot of aspects to that consideration.

MS. KLOSS: I think the subcommittee could give consideration as to whether a single document - whether there is a mortality research set of question and morbidity.

MS. LOVE: The recommendation could be bundled for both.

MS. GOSS: I thought that was what we were doing was kind sort of describing the separate paths above, but

we didn't get into this opportunities for further enhancements to the mortality auto-processing leveraging NLP.

DR. STEAD: We could, in fact, and it might make it simpler, divide what I did into two pieces and simply repeat the parts that are applicable to both in each one. That can be done. We can think about it.

MS. KLOSS: My only reason for thinking about that is it may come through a different funding stream.

MS. GOSS: That is a very good point. We are writing just to the Secretary of HHS.

DR. STEAD: We can noodle that.

MS. GOSS: My point being I am not sure, Linda, what - from HHS's perch, how they - what would land better? I am struggling with that. If anybody has any suggestions about whether it is - it is such a divergent set of path and funding streams. It could be a no-brainer that that is the right thing to do. I just don't know.

DR. STEAD: We could also make - in many ways, we can put the attachment here. We could cut it into a block that is specific to mortality, a block that is specific to morbidity, a block that enables both. The different funding streams could go after whatever they want. That might be -

DR. ROMANO: I was just going to keep in mind that, of course, there are multiple agencies that might

have a stake in this, that might have an interest. I don't know to what extent - obviously, it is up to the Secretary to kind of divvy things up.

It might be interesting as you develop the appendices to think about - obviously, the mortality domain is traditionally CDC's.

In terms of morbidity, obviously, CMS has interest with respect to all of the payment and quality measurement applications. AHRQ has interest with respect to quality and safety applications as well as burden. The director of AHRQ has taken a specific interest in efforts to reduce provider burden and improve the way the healthcare system operates from the provider perspective. And then, of course, NLM has interest with respect to all of the integration of the different code sets.

So it might be helpful to kind of think about even how there would be some parsing out of the research topics.

DR. STEAD: As I listen to that, I think it is a very good point. As I listen to it, I wonder if that is another piece of the communication strategy.

MS. LOVE: I kind of hinted at lunch at getting some of the federal agencies like AHRQ embedded.

DR. STEAD: That is a good - did you get that note, Rebecca. It would be different from the letter, but

it would be part of the communication strategy.

MR. LANDEN: I think have a good handle - not perfect, but good, on the letter. Are we ready to move to talk about the attachments?

DR. STEAD: I, at least, don't have the stomach to talk about mine anymore. I can think about how to do this to it.

MR. LANDEN: I am more interested in ensuring that we have a process rather than actually doing anything with the attachment. If I am interpreting you correctly, are you volunteering to take another tweak with yours as I will with mine today and then bring them back?

DR. STEAD: I will volunteer to do that this week.

MR. LANDEN: The product then would be suitable for use as an attachment to the letter.

DR. STEAD: We were huddling at lunch. I don't know what feasibilities are. We actually have several of them here. If it turned out to be feasible, I think it would be wonderful if we could maybe have a workgroup call like Thursday - a week from tomorrow, which happens to be the last day before I turn into a pumpkin for two weeks.

If we could do that by then we might have a first draft of the letter and a first draft of the research and communication attachments. The workgroup, we could then sort of - try to get them out in advance of that call. Have

that call. That might get them in a form we could share them with the subcommittee.

MS. HINES: What would you get out to the subcommittee, the research outline?

DR. STEAD: What we would basically do is I would deal with my research piece. Rich would deal with the communication piece. You and Rich it sounds like would deal with the first cut of the letter. We would get them out to the workgroup before next Thursday's call. We would have a call. Following that call, we could make whatever edits we all thought we should make. Then we could flip it to the subcommittee.

MR. LANDEN: That would take us to two more weeks, three weeks until it got back to the subcommittee?

DR. STEAD: Then we would have the drafts of - the roundtable report I think would be coming in from the contractor in roughly three weeks.

MS. HINES: Optimistically, the 28<sup>th</sup>. If not, right after Labor Day.

DR. STEAD: Let's say right after Labor Day. Let's say - we might set a workgroup call for the week after Labor Day if that worked with people's schedule.

MS. GOSS: That actually works out pretty well with the schedule that we have for the month of August and knowing that we wanted, from the Subcommittee's

perspective, to pivot in early September to be focused on getting this body of work advanced in time for the fall meeting. It makes sense to me. We have the rest of August scheduled around Predictability Roadmap.

The timing works. That also gives folks time to prepare the report and for the Subcommittee to receive a complete-ish package.

MR. LANDEN: The timing feels good to me. I need to ask does that give us sufficient time for the executive committee review and getting things into the e-agenda book in time for the October -

MS. HINES: It does, Rich. We can talk offline.

MR. LANDEN: Sounds like a plan.

MS. AULD: I am speaking on behalf of Donna, too. There are two points that we need to consider in the attachment. I don't want to wordsmith. One thing is that we need to be very clear about what we are asking people to compare. When ICD-10 came out, the way it was presented, it was literally called ICD-10 whether they were talking about 10 PCS or 10 CM or whatever. I think we need to be very clear what we want compared to help them make sure they are being within scope and what is being compared is clear. Does that make sense?

DR. STEAD: Let's pause on that. What we have drafted is to basically say the first thing we have got to

have are - is an evaluation of the alternative approaches to comparing A to B, whatever A is and whatever B is, given the complexity of ICD-11. We have also then said the U.S. should validate, in essence, the content.

Our categories and even the questions are one level above - in most cases, compare A to B. We have a list of As and Bs. I am not sure - it is very different than when we had two tabular lists and we could compare them. We are not - we are in a very different space.

Bear in mind all of the work that Keith and the group at the NLM - not Keith - that Olivier and the team at the NLM are doing, that work is underway. It will be done. It will be available shortly after this letter goes out.

MS. AULD: One of the reasons I raise it is because this morning there were several comments being made where it felt like people were creeping away from the intended scope of ICD-11 and trying to make it fit into other areas as well. It is - this is food for thought. Yes, current versus visionary. This is food for thought as you are going through and revising and tweaking your document.

DR. STEAD: Keep your eyes open and your participation on the workgroup calls to help us. I am not sure I am processing right now, but my brain is a little tired.

MR. LANDEN: Vivian, your clarification, your

reference, was it more about the computability opportunities or more about the use for billing and administrative purposes or both?

MS. PICKETT: I think as Vivian and I have been talking, when you redo the longer document that we were reviewing this morning, I mean there were a couple of things like the clinical documentation decision - there were a number of things that were brought into the conversation that we know is a goal. It is a vision. But how much can you measure something against something that is still visionary? You want to keep it in mind because that is where you want to move, but we also have the here and now. I think it was all kind of being morphed into one big thing, as if some things were actually currently in place when, in fact, some of the things were not.

Again, laudable, visionary, but - can we keep the train moving, but if it doesn't do what the visionary component is, does that stop the show? I am not sure how that all works out. I leave it to the visionaries to continue that conversation. Again, some of the ideas were being crunched into one. I think it was clear that some of those things were not in one place now.

MR. LANDEN: I do recall that conversation surfacing a couple time the last day and a half. We will try to keep that in mind as we draft. Certainly, as Bill

said, we will trust that you will look over our shoulders and pat us on the head with two by four if we don't get it right.

MS. AULD: There is a second point we wanted to make, which is just to be aware - I don't think you need to change anything in everything we have been working on so far, but when we were going to ICD-10, when all of those negotiations were happening, the copyright decisions and licensing, et cetera, had been settled between NCHS and WHO. It has not been settled for ICD-11. There is still a lot of outstanding issues. That may factor into where this all ends up eventually and what are the options as we go forward. So just to be aware of that.

MR. LANDEN: Thank you for that. Is there anything else? We have the process for the letter. We have the process for the attachments. We have a meeting of the ICD working group to be scheduled hopefully next Thursday. Follow up after that. Subcommittee, full subcommittee, beginning of September some time. Executive committee, Full Committee, that is the October meeting.

Are we missing anything? Let's declare victory and go celebrate.

DR. STEAD: I think we have public comment.

**Agenda Item: Public Comment**

MS. HINES: We do have public comment. Let's begin

with the room. Also, I need to stop sharing my screen and we can put the public comment slide up.

We are now into public comment. I know there is one in the room. I have received one electronically. If anyone in the room would like to give public comment, we need to take the mic back to the stand.

AMY BLUM: I know everybody is tired so this will be fast.

MS. HINES: Please state your name and organization affiliation.

DR. BLUM: Amy Blum, National Center for Health Statistics. I am speaking as a classification person with the Division of Healthcare Statistics, but also as an HIM professional and a member of AHIMA.

I have been a classification specialist at NCHS since 1991. I was a project officer for the development of 10 CM, which began in 1994. I was involved in the entire 22 year implementation process. I am currently on the Technical Services Branch of the Division of Healthcare Statistics. We run ambulatory and inpatient healthcare surveys.

To respond to some comments made by committee members, the first group I met with at the start of the 10 CM implementation development was with the Worker's Compensation community. The first request was for

laterality. Their second request was to expand the external cost codes for injuries related to animals and machinery, where their large worker compensation claims occur. So, yes, we did separate crocodile and alligator for a reason. It might have gone too far, but it was asked for.

The injury community requested that concepts of initial encounter, subsequence encounter, and sequela so as not to lost information on the original injury even when a patient is seen at a later date for an old injury related visit.

The American College of ACOG request the fetal numbering codes.

Every code in the ICD is there because a constituent asked for it. Any codes currently in 10 CM missing from 11 will need to be added. Though a clinical modification has been created for ICDs in the past, it really shouldn't be needed for 11. However, the annual updates and the coordination and maintenance process does need to continue. A classification is dynamic and must be updated. The United States will always have to be independent of WHO when maintaining the ICD-11 for morbidity.

Just like with 9, 10, and 11, things do get old and out of date. I suspect someday we will be here talking about 12. A much more efficient and effective

implementation process is essential for 11. However, as a federal standard, some rulemaking must occur. A proposed rule, a public comment period, and a final rule must be published to prevent litigation that can delay further implementation. Once an implementation date is set, however, it should be adhered to.

Multiple administrations and many classes of NCVHS committee members will pass before 11 is implemented so a long-range plan is essential.

Nothing in 11 in the United States should be optional. What is optional will not be captured. Much of the original objection to 10 CM was the cost of converting legacy systems. The conversion to 11 will be more challenging and expensive. Therefore, it must be required that all extensions are required to ensure that they are programmed into all systems.

There is the issue of principle diagnosis, the official coding guidelines, the UB, the 1500s, survey tools, and all of those things that need to be decided when we are talking about a code that does not have a fixed length. Those are very important considerations.

A cost-benefit analysis is really somewhat questionable. What are we going to measure? How can it be quantified?

The committee needs to design and test an inhouse

project that somehow is designed to support implementation. I don't know what that will be, but that is something the private sector does need to consider. We really don't have any way of measuring 11 or its validity just yet.

It must always be remembered that, first and foremost, the ICD is a statistical classification with the function of providing useable, reliable data on healthcare for all users. ICD-11 is a technically sophisticated product, but unless it can fulfill this purpose there cannot be a case for its implementation. Right now, we really don't know what that is. Although, I do think it is a very fascinating classification. I hope that someday it does get implemented. Thank you.

MS. HINES: Thank you very much. Anyone else in the audience or the room today with public comment?

Moving to online, I have received one thus far. This is from Suzy Roy with SNOMED International. She is the customer relations lead for the Americas and collaboration specialist.

On behalf of SNOMED International, I would like to thank the NCVHS for allowing us to listen in to this ICD-11 expert meeting.

Most here know that SNOMED International is a member-based not-for-profit standards organization that owns and maintains SNOMED CT, a clinical terminology

focused on providing the encoding needs of all healthcare professionals for capturing, sharing, and analysis. We currently have 39 member countries, including the U.S., which whom we work with and support.

Based on the past two days, we would like to remind that SNOMED is currently implemented in the U.S. in the electronic health record and beyond, FDA devices and biologic clinical application forms, for example. SNOMED CT is used in over 80 countries. SNOMED is designed as an ontology with the concept model based on description logic. The terminology has grammar and machine-based rules. Post-coordination is a key component of the design. We work with other standards to ensure data can be shared and reused in a safe way and meaning is not changed.

We have tried and tested processes and tools from the ability to receive requests for change to editorial, technical, and education training advisory groups supporting a community of users. We have an established and stable update and release delivery.

Finally, we are here because we are committed to supporting our members, the United States included. Of course, we will continue our collaborative efforts with other standards develop organizations such as WHO to ensure our standards work together according to their different purposes and scope, as well as with clinical groups to

ensure that SNOMED remains clinically up to date and relevant.

On the broadcast, there are no comments. I will check one more time to see if there are any last submissions. I believe those are the only two public comments we have received. I will turn it back over to Bill Stead and Rich Landen.

MR. LANDEN: Thank you, Rebecca. Unless there is anything further from the Subcommittee members, we stand adjourned. Thank you all very much.

(Whereupon, at 2:30 p.m., the meeting was adjourned.)