



HIT Standards Committee Semantics Standards Workgroup Final Transcript May 4, 2015

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Semantics Standards Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also as a reminder, if you are participating via the webinar feature, if you are using the public comments, we may share those public comments during the public comment period at the end of today's call. And with that, I'll now take roll. Jamie Ferguson?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jamie. Becky Kush? Andy Wiesenthal? Asif Syed?

Asif A. Syed, MD, MPH – Director, Medical Informatics & Healthcare Strategy – American Medical Association

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. Betsy Humphreys?

Betsy Humphreys – Deputy Director – National Library of Medicine

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Betsy. Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Eric's here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Eric. Harry Rhodes? John Carter?

John Carter, MBA – Vice President – Apelon, Inc.

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. John Speakman? Margaret Haber? Is Larry Wright in for Margaret Haber?

Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute

Yes, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Larry.

Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Mitra Rocca? Rosemary Kennedy? Stan Huff? Steve Brown?

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

Yup.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I'm sorry, was Steve here?

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

Yes, Steve is here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Steve. Thank you. Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Todd. From ONC do we have Tricia Greim?

Patricia Greim, MS, RN-BC - Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology

Tricia is here, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Tricia. And Mazen Yacoub?

Mazen Yacoub, MBA – Healthcare Management Consultant

Hi, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mazen. Anyone else from ONC on the line? Okay, with that I'll turn it to you, Jamie.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Great. Thanks everybody for joining today. Our primary agenda topic today will be the review of the Group 2 comments that have been drafted thus far. I will also give a very brief overview of the presentation of our recommendations on the interoperability roadmap to the Standards Committee. And then we also want to review the work plan and see if we can use our time today to schedule some calls for the Group 1 assignment for those aspects of our comments. Is that agenda acceptable to everybody or is there anything else that we need to add or some things to subtract?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Sounds good.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay. Thank you. So I'll start off just on the review at the Standards Committee a couple of weeks ago. I presented our recommendations; I really focused on those things that had changed because, if you recall, we had gone over the recommendations, the draft recommendations the previous month with the Standards Committee that we got a little bit of discussion and there were very few changes from one month to the next. So I just focused on the changes.

The primary changes, there were just a few sort of copy/editing things, but the primary changes were three; one was the addition of our comments on the UDI. The second was the addition of comments on the need for device interoperability to be mentioned more in the roadmap. And the third was a clarification around the multiple methods of interoperability that needed to be enabled, including data aggregation via multiple models.

And so on the UDI, I think that some of our...so in the first place, thank you for those who drafted both the UDI and the device comments, and Todd, I know you're on the call so thank you for that.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Albeit tardy, thank you for your patience.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

No, well, it was in time so that was just fine; and thank you. One of the items that we had discussed previously was not in our recommendation. But one of the things that we discussed previously was a preference for potentially restricting the use of the UDI in certification to the GS1 standard and I think that's not going to be possible for the implanted devices, so I'm glad it was not in our recommendation because the implanted devices include things like heart valve tissue that have to be identified with the blood banking standard.

So I think that from an operational perspective the proposal still or I guess the proposal in the NPRM, switching gears to the NPRM still leaves us with the operational issues of the multiple barcoding standards. But that...we weren't at that level of detail in our recommendations; we just said that it needed to be included. So...and really, in terms of the Standards Committee there was no discussion. I mean they had seen our recommendations the month before and there was really almost nothing said about it. So; any questions about that? Okay.

So then, I think Eric, I want to first of all thank you and recognize your leadership in leading the calls for the certification comments that we're going to review today. And if we can switch to those slides, I'll hand it to you to take it away.

Eric Rose, MD, FFAFP – Director of Clinical Terminology – Intelligent Medical Objects

You bet. It...my pleasure and thanks to the ONC staff who made this really, really easy. The format that they provided in terms of these word document templates, I think would be a great thing to continue using, especially the fact that they hyperlink out to the web-based version of the NPRM, showing the exact text; it was really...it made it phenomenally easy to just focus on the topics at hand. And I want to thank Betsy Humphreys, who provided some feedback in writing and Steve Brown and Asif, oh darn, I'm forgetting Asif's last name, who participated on the live calls, from the AMA.

So the...we had 11 items to go through, and I have not seen these slides, which were put together by our colleagues at ONC as a précis of the Word document. So, a couple of things; first of all, if you want to see the kind of the raw, the actual proposals for the text of public comments that our little workgroup thought should be submitted on behalf of the...of the Semantics Standards Workgroup, the Word document that was attached to the email that went out this morning would be the straight dope. But the...what's showing now is kind of the extract of it. So if we can go to the first slide, I'm not sure how this was...okay, so I think we probably have one slide per...for each one of the 11 bits of the NPRM that we were assigned.

So the first one is family health history and the requirement is to continue to be able to use SNOMED CT. There is a second requirement, which as I understand it is an optional bit...an optional capability that would lie outside of the, I believe what's being called the core EHR certification, but would use the HL7 Pedigree which adds lots of additional kind of metadata around family history including the...a relationship...a coded expression of the relationship of the family member to the patient and codes for age of onset, I believe and so forth. Or at least structured data around onset.

So, we had two bits of feedback; one, actually Betsy, you might be able to answer...just answer this right off, you know, right off the top of your head, but there's reference made to SNOMED CT US Edition and it was not clear to myself or the other folks whether that means the union of SNOMED CT International plus SNOMED CT US Extension, but it's being referred to as the standard identified in §170.207 (a)(4).

Betsy Humphreys – Deputy Director – National Library of Medicine

Yes, the US edition of SNOMED CT is the integrated distribution of the SNOMED core and the US extension.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Okay.

Betsy Humphreys – Deputy Director – National Library of Medicine

And in fact, we no longer produce the de...we no longer directly disseminate the extension as a separate, although people who want it can extract it from the other. And the reason why we now have the US edition which integrates them is because we were getting all kinds of requests for it, people saying why were there two things that they had to concatenate, why didn't we produce it that way.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah.

Betsy Humphreys – Deputy Director – National Library of Medicine

So since that is the way we're producing it, and it is in response to very considerable input from everybody, and of course we announced it in advance and told people we were going to do it and got no pushback, in terms of the change. We were just telling ONC that they should refer to it correctly in the new rule, do you see what I mean? Because that is what is being disseminated now.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Makes total sense. I would suggest that we still include that in our public comment, just to encourage them to perhaps include some explanatory information in the final rule for those who may not be familiar with that repackaging, but it makes sense.

Betsy Humphreys – Deputy Director – National Library of Medicine

Okay.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

And so our...it also, we thought that the...as far as inclusion of the Pedigree, that ought to be questioned; it's unclear whether it has...meets any urgent, real world needs and it seemed to us that the fact that it's not an absolute requirement is, umm, doesn't really mitigate the fact that including it is going to potentially divert vendor's EHR development resources away from other things. Because the reality of the market is, if anything's in there, the expectation of customers is that it's going to be built. So I don't know if you want to move on to the next slide or how you want to structure this, Jamie, but I'm happy to keep going and be interrupted if folks have...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, no, I think that's right, we should just keep going through it. Thank you.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

And so if someone can advance the slides that would be lovely...oh, they...okay, the slide has been advanced. Okay, so the next slide was about the minimum standard code sets. And, the...our...actually, I guess we did not have any...I'm looking at my notes and I'm...let me just get undiscombobulated here. We did have comments about the object identifiers...I think that's part of this section.

So there were a...the substance of our feedback on this one had to do with the recommendation to use NDC codes for...to represent vaccines in the use case of recording administration of a vaccine. And there was a fairly carefully laid out rationale for that in the NPRM preamble, but we felt it needed to be questioned. So the advantages of adding NDC codes to CVX codes as the standard for recording immunization administration were around two use cases; one is pharmacy employee management and the other was barcode scanning for medication administration.

And we felt that those were not without value, but also depended on a lot of other integration between pharmacy systems and EHR systems that may not be widely available. So if that's really the use cases that need to be supported, there are a lot of other certification requirements that might be necessary. And the other point we made is that if you have a CVX code and an MVX code and a lot number, you can...that's really the information that would be necessary to support investigations about vaccine adverse events. The other...we had are the ones that I think most of us are probably familiar with about NDC which are itemized there in a little bulleted list, so I won't repeat those. But, NDC codes are pretty notorious for being problematic for the reasons that are laid out there.

So, that was our...those were our thoughts on this slide. And again, maybe we can advance or if folks have other thoughts or objections or additions, I'm happy to be interrupted. But, uh...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Keep going.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...okay, we're going to keep going, once more into the breach. So, okay, so on to demographics. The main area in the demographic section we thought worthy of comment was regarding the use of the CDC race list which I encourage everyone to look at. Its 900 codes long and I think it...it is intended to be as inclusive as possible a list of terms that individuals might use to describe their own race if they were queried. But it's...it really seems like it would be unwieldy to manage and it's really unclear how using this list as opposed to the OMB list, which is what is required in the current...the rule that's currently in effect, what additional advantages that would provide in terms of the...what we presumed to be the ultimate goal of recording this data, which is to identify disparities in healthcare and health outcomes.

So the other thing that was noteworthy was that the CDC race list is actually structured in a way that it can be...that the race codes can be collapsed into the higher level, more coarsely granular OMB list and the NPRM proposes to require that that collapsing be capable...be a capability of EHRs, that they be able to capture the CDC codes and then output the OMB codes. And it was our feeling that that really is a capability that ought to reside in analytical systems, not necessarily the EHRs themselves.

Go on to the next slide, I think we'll get into some more clinically oriented stuff. So there are a lot of new requirements, new proposed requirements for vital signs and most of which seemed to make a lot of sense in terms of both requiring the capture and the standards that are required, except for a few. So

there was a little bit of murkiness around calculated values, like BMI and the proposed rule seemed to imply that direct user entry of those values might be required.

And our proposal was that if a system...if an EHR system does what an EHR system really should do, which is calculate those values based on the other values that have been entered, that it's really superfluous to require a functionality for direct entry of things like BMI or mean arterial pressure and so forth.

The...another area of concern that we had was the identification of specific LOINC codes for recording vital signs and there were a couple of problems, in our view with this. First of all, the...it's a dicey thing to specify any particular code from any coding system in a regulation because the coding systems can change at any time and it's a little hard to change regulation quickly. So that's one issue.

Another issue is that the NPRM proposes to require certain coarsely granular LOINCs for certain vital signs, and there are cases where LOINC has both coarsely granular and more specific codes for the same sort of thing like body temperature. They have a LOINC code for just plain old body temperature and they have LOINC codes for body temperature measured orally, measured tympanically and so forth.

So the...and the proposal is to require use of the LOINC codes that don't have specificity regardless of the specificity that might be known or captured at the point of care. And we felt that that was ill-advised, that trying to normalize onto these coarsely granular LOINCs would be sort of a willful discarding of clinically significant data and that these measurements aren't semantically identical and basically the requirement ought to be capture...a system must be able to capture, for instance, body temperature and must use a LOINC that's appropriate to the piece of, you know, the data that was captured.

So there were...the last sort of third of this slide is on a very, kin...a bit of minutia, but it seemed worth calling out which is that the NPRM proposes to require capturing date of birth and sex along with certain other calculated vital signs, which actually seemed questionable to us for the reasons that are stated there. And it's a minor point, but we felt that calling out...worth calling out; so I won't go into the details, but you can read either the slide after the meeting or our...or the comments in the Word document.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

So, can I ask a question real quick here? This is Todd.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Was there consideration in this about vital sign parameters that were device acquired and you may or may not be using, and typically aren't LOINC codes or SNOMED codes coming out of that. Was there any consideration around that and how to handle that?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So, yes. So the NPRM actually, and we didn't comment on this because we felt it was actually a good idea and appropriate, but the NPRM does require the...that certain metadata be captured along with a vital signs measurement including the...what they describe as the measuring or authoring type source.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Right. Right.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So that...and, you still have to associate it with a LOINC code. So if you are importing heart rate or blood pressure or O2 sat from an external device and the external device doesn't, you know, somehow that data needs to end up in the EHR. Under what the NPRM is proposing to require, have to end up associated with an appropriate LOINC code; now that could either be because the device sends the EHR a LOINC code or because the EHR knows that that particular piece of data should be associated with a LOINC code. The NPRM doesn't get into that level of sort of micro-specifying...

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Right.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...how things work and appropriately so. But it doesn't...but you still have to...the EHR still has to associate the data with a LOINC, which is, I think, appropriate.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Well, yeah, and I'm fine with that. The problem is that, and I think this is something that Betsy could also speak to, is depending on the method of which this is acquired in given parameter, I always recommend to maintain both the MAT, normative MAT version, as well as whatever the source set. So you always can go back and know exactly how that was reported out, primarily because it's not necessarily a 1:1 mapping and a lot of times, especially when you get multiple sources for something, it's very useful to know that.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

So Todd, this is Jamie. I guess my comment on that would be that now we're kind of moving the...with that recommendation, we would be in effect recommending that the EHR would incorporate what the FDA would call a software device that's not an MDDS because it would be performing a transformation rather than just conveying the data. And so to me I would recommend against including that as an EHR functionality.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

I don't see that Jamie because I'm saying to include whatever it was that was originally reported, which would imply no transformation, it would report...literally just be whatever it was, you'd be storing whatever it was that was reported, unless I'm missing something.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Well no, because then...the transformation from what was originally captured by the device and originally sent out of the device into the LOINC code, that transformation is a software device, right?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

So you're saying that transformation would have to happen somewhere else.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah. And so therefore...

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

It has to...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

...yeah. So what is the thing that, you know, what was the original measure? So if you're...basically if the EHR is taking in one thing and then also recording a LOINC calculated from that, then that makes the EHR into the software device.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So these questions, now I think it's a very relevant discussion and they...these questions may not apply to this particular proposed requirement because the requirement really is...the exact verbiage is, enable a user to record change in access...blah, blah, blah, blah, blah.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah. Okay.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So the...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

But really doesn't consider the devices at all.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...that's what I...premise that there's any electronic transmission of the vital signs data into the EHR. It's predicated on the premise of the user hand entering vital signs data. So, so I think that they relate to potential future certification requirements that ingest, electronically ingest vital signs data from devices; but I don't think it would apply here.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay. Umm, so Eric, I was going to make actually a couple of different comments on the stipulation of specific LOINCs. You said a couple of things that I think were not captured in the written notes, but perhaps should be. That the...essentially restricting the specific LOINCs to the more granular level could potentially discard important relevant clinical information.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

And so, I think that was the way you said it and I agree with that, I just wanted sort of the notes to reflect that. And then I guess the other things that you didn't say but that I'll say is, I would say we should include a recommendation more generally against requiring specific codes at a lowest common denominator level.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yes, yeah, I like that. I think it's reflected in the proposed comments that we submitted in the Word document, Jamie, but I appreciate you calling that out and I think that that general principle of don't require systems to dumb down codes...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...if they're capable of capturing codes at a high degree of specificity.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Exactly. And I like the way you said, essentially require LOINC, or just the use of an appropriate LOINC code.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah. Because, you know, next month there might be a way to capture temperature by tricorder and a LOINC code for that, you know?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, let's hope.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Thank you.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Okay. So are we ready to move on to the next item?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

I think so.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Which I think are, ah, smoking status. So the current CEHRT rule requires capture of 8 specific SNOMED codes and the NPRM proposes to lift that restriction and allow use of any SNOMED US edition code to represent smoking status, which we think is a great idea. And we had two other comments here. One is that the 8 specific SNOMED codes are still required as part of the common clinical data set for electronic transmission in a summary care record. And we propose that that restriction be lifted as well. And we

give in the indented bullet there, one example of a perfectly legitimate SNOMED code that would be...could be clinically useful and is not, not only isn't one of the 8 SNOMEDs that are in that set, but is not in...is not a descendent of any of them, it's in a different branch of the SNOMED hierarchy.

So our proposal is just let people use any SNOMED that reflects smoking status. And the other suggestion was we should clarify here that we're talking about smoking tobacco, because there, as we all know, are lots of other things that can be smoked. And it...presumably the intent here is because of the immense public health importance of tobacco smoking. So...and Betsy had also provided a comment here about an IOM committee that had proposed two data elements for recording tobacco use and exposure and that that be considered.

Betsy Humphreys – Deputy Director – National Library of Medicine

This...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So, if we're ready we can move on to the next one, which is probably...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Was there a comment? Sorry.

Betsy Humphreys – Deputy Director – National Library of Medicine

I was just going to say that...this is Betsy; that the IOM committee that was looking at the social and behavioral data elements that were suitable for inclusion in EHRs we thought did a pretty careful analysis and recommended this two question smoking thing. And although in general I'm not in favor of changing the rules, I just...since they had done this study and it appeared to be a good one and it was shorter than the one that was recommended, thinking of burden and all those other things, NLM was wondering whether going with the two question one was not a good idea.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Okay. So I think we can probably move on to the next section which is on social, psychological and behavioral data. So as with vital signs, the NPRM proposes to add a number of additional structured data elements to be captured and encoded and we didn't...we agreed that most of these seem to be of value and most of the proposals regarding how they be coded makes sense with a couple of exceptions.

The...one has to do with the use of LOINC answer codes. So most of us I think are familiar with the fact that for the most part LOINC codes represent observables, things that you can associate a result with; in other words, questions like hair color or first date of last menstrual period or pain level on 0-10 scale. Things that are represent the question of a question/answer pair. And there actually are some LOINC codes that represent answers like 3 on a 3-5, you know, on a 0-5 scale, things like that, or blue. And traditionally in a lot of HL7 standards and in other use cases, traditionally it's been SNOMED codes, particularly SNOMED codes from the qualifier hierarchy of SNOMED that have been used for that purpose. And so some of the proposed requirements for social history requi...would require the use of LOINC answer codes to record the values, like stress level on a 0-5 scale, I think it was.

So we thought that that needed another look and it needs some careful analysis. It would certainly be disruptive to have to, for EHR systems and for EPs and EHs to have to manage another terminology that is LOINC answer codes in addition to managing SNOMED as a terminology for recording answers or

result values. That doesn't necessarily mean it's the wrong thing, but it would be a pretty disruptive step and shouldn't be taken lightly.

Betsy Humphreys – Deputy Director – National Library of Medicine

This is...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So the...we had a couple of other concepts, excuse me, a couple of other comments, one of which is the second or the third high level bullet there. We saw in the NPRM a number of cases where they said, such and such code pending. And we really don't think that there should be a regulation that hundreds of thousands of providers are going to need to adhere to that is contingent on a code that doesn't exist yet. And if ONC knows something that...if ONC has some kind of assurance from the SDOs in question that those codes are going to be released that's good and that should be made public and transparent. And otherwise our recommendation is not to create a requirement that...to use a code that doesn't exist yet.

We did think that it was actually a really good thing to separately record gender identity from biological sex because that's important and relevant information in a health history. It was really striking that for sexual orientation, again the NPRM stipulated specific codes and limited them to 3; I think they're heterosexual, homosexual and bisexual and of course there are a lot of other ways that people identify their sexual orientation beyond those 3 and it didn't seem logical to have a requirement other than just use SNOMED to represent sexual orientation.

So the only other...there were two other high level comments we had. It was...and they're related; one is that striking in its omission here was the, unless we missed it, was the ability to record substance use other than alcohol and tobacco. And that's kind of a big, big thing in social history in medical care and the flip side of that coin is that there really are an awful lot of specific data elements that the NPRM proposes to capture, including things like how often do you go to church? How often do you talk on the telephone with your family and friends? Things that are not irrelevant, but if you look at the big picture, it's just an awful lot of specific clinical data to capture and especially given the absence of anything about psychoactive substances; and dietary habits was another one. It just seemed like it had gone overboard a bit.

So, there...I think we can go to the next slide, unless there are comments on this one.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

And the last one...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

...sorry, this is Jamie. So I do have a couple of comments on this. So first of all, I agree with everything that you've talked about and thank you. Thank you very much; this is really good work. I guess my first comment is that on the second bullet, in terms of the comment on getting answers in LOINC. It seems to me we might want to strengthen that and say that there should be a general rule to use LOINC for the

questions and SNOMED for the answers, except where there's a good reason not to. And in this particular area, I mean I'm not looking at the word document, I am just looking at the PowerPoint, but it seems to me we should have a workgroup recommendation, use SNOMED for this, period.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Umm, that seems fair as long as we do have that stipulation that if there is a good reason, and there may be in some cases where...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, so absolutely but it has to...that should be essentially justified and the general rule should be the other way around...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yup.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

...is what I'm suggesting.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yup.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

And then similarly on the third bullet, it seems to me that that could rise to the level of again a principle that we would recommend, you know, not to include anything that's pending period.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

You get no argument from me on that.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay, so I guess what I'm suggesting is we should perhaps strengthen both of those.

Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology

Did we also hear...Jamie, this is Tricia; did we also hear a common theme coming through about, and perhaps you said this and I missed it because I was writing notes, the...a general comment not...to avoid identifying specific codes?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yes.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

That was the previ...that was one of the previous slides, yeah.

Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology

Yup, thanks.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

I mean, I think just as a comment on that, so I agree that should be a recommendation. There are multiple ways in which value sets can be updated outside of being named in a regulation and Betsy probably has more to say about this, but that could be essentially done in sub-regulatory guidance.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

This is Steve, just quickly regarding the question/answer thing. As long as it's clear how questions are to be roughly formulated so it doesn't get over-generalized; I mean, you could say for example, is there a third heart sound and rales present as a question as opposed to what was on physical exam. And so clearly you'd do those differently depending upon how you word the questions and answer pairs and I...as long as we can make clear the intent so that it can be operationalized, then that's okay.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah. Yeah.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So the last four sections I think will go pretty quick, I think we're on the home stretch here. None of them are quite as complex as what we've dealt with so far. If we can move to the next slide, it deals with how to represent what somebody does for a living. And the...this is one where there were a few areas where the...where ONC has rather than proposed a specific requirement is asking more an open-ended question about what would be the right approach for capturing this or that bit of data.

So there are occupation codes that are managed I believe by the CDC, that are used by lots of government agencies like NIOSH for very important work in terms of tracking statistics on occupational health. And that was mentioned in the NPRM and the...our recommendation actually is to use SNOMED if at all possible for a couple of reasons...well, for the reasons that are laid out there. It's pretty rich in terms of its coverage of occupation. It's...the burden on implementers is going to be less than managing yet another separate terminology.

And it ought not to diminish the importance of being able to provide data captured in clinical settings to government agencies that are trying to help improve occupational health. But it ought to be possible to manage the...to somehow harmonize data captured in SNOMED on what somebody does for a living with the terminologies that are used in, you know, by different federal agencies for occupational health. So our suggestion was a bias for using SNOMED here.

W

Here, here.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

...for me.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So, if we go to the next slide it's kind of a related issue which is around capturing data around uniformed military service. And there were two reasons cited for capturing this data; one is that certain types of service are associated with particular health risks and that that's...that may be important in clinical decision support, in reporting and population management and so forth. And the other was that certain types of service are associated with particular benefits and that managing those benefits effectively is important for the health of those populations.

So our feeling, however, was...we had a couple of perspectives on this. For the first point, it's certainly not the exclusive...the health risks associated with say combat service are not exclusive to those experiences; they may exist in other occupations as well such as law enforcement, non-uniformed that is and also some of the types of uniformed service that were mentioned don't necessarily carry those same risks like the US Public Health Service or the National Oceanographic and Atmospheric Administration.

So, as to the issue of benefits management, if that's going to be a goal of capturing occupational data, there are a whole host of other requirements that are going to have to be put into place in order to ensure that benefits can be managed effectively for members of a certain population. So basically we didn't think that those arguments held too much water and we felt that this really was likely to be covered adequately with information about occupational history; not that uniformed service is just any old occupation, but the fact is that as is pointed out here, there are different types of military occupations that are reflected in the occupation hierarchy in SNOMED and also there are codes that are not even part of the occupation hierarchy that can be captured in SNOMED like exposure to combat, which may be relevant to future health risks.

So we felt that those...as far as being able to capture the data that'll be necessary to provide appropriate care for the particular health risks of these individuals that capturing occupational history and capturing just general diagnostic history, including health risks, would be adequate.

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

(Indiscernible)

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So, also on this slide we have the last two...

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

Hang on one second...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...a rare event, for the..

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

If I may, I think there may well need to be some enhancements to SNOMED and I think we need to get Nancy's, probably someone like Nancy Orvis or someone and get their input on the kinds of things that they're also looking at. Last...I fiddled...we fiddled with this, or I did anyway, there were some sort of coarsely grained overlap that was okay, but some of the finer grained things that may not be there; so I think the friendly amendment is that we may need to expand it a little bit and we probably, I've got to...the wording, but, you know, need to make sure that we're not creating more of a problem than we are solving.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm. So that's Steve, right?

Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration

Yeah.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah, thank you Steve and I'm...I should have mentioned that, because that did come up in our discussions. One of the things Steve pointed out is that there is a very richly populated terminology for MOS codes, Military Operational Specialty so...which may be appropriate for care of active duty military personnel and perhaps even the veterans about, what did somebody do in the military; was it fixing helicopters or was it, you know, community outreach.

Okay, so for encounter diagnoses the proposed change was simply to allow SNOMED CT in addition to ICD-10 CM. And there was no...we didn't have any objection to that. And the last one was on medication dosing where the proposed requirement, if we understood it correctly and we think we do, makes perfect sense and needs to be rephrased a bit in order to really reflect its intent. Basically the proposed requirement was that systems be capable of preventing a user from using non-metric units for dosing oral liquid medications. So, you can't say take 1/2 a teaspoon every 4 hours, but you can say take 2.5 ml every 4 hours. And there was some data cited there that indicates that that reduces the risk of medication administration errors.

So it seemed like a great idea and the way it was phrased though seemed to preclude appropriate dosing in certain cases where non...where the medication was something other than oral liquid, like an inhaler or a topical medication. So we just proposed some rephrasing there to make it mean what they want it to mean. And that's it.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Great.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

This is Mitra Rocca from FDA, I have two questions; sorry, I was muted before; I couldn't ask when you were on that slide on NDC versus CVX.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah, what was your question?

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

So we, for this, we actually reviewed this NPRM, FDA, members from different centers twice and we provided 28 pages of comment to ONC. So FDA prefers to use NDC codes for vaccines. The Center for Biologics actually uses NDC and we spoke to CDC and they also would like to move to NDC codes.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Umm...

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

But for historical vaccines, they are going to continue using CVX.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Umm, so, that...I wonder if you can comment perhaps on the reasons why you consider NDC preferable for recording vaccine administration.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Yes, that's right and the manufacturer also use NDC codes.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

This is assigned to our group 1, which is led by John Carter, so we haven't met yet; we can...I noticed...I commented on that, but I will...I actually just emailed the Center for Biologics to get extra reasoning from them.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

I see. Well the thing about...I can at least comment from my perspective. The thing about having a different requirement for administration versus historical is that as soon as you record that a vaccine has been administered, by definition that is now historical data. So I think that the dichotomy be...positing a dichotomy between the two is...there's...it's a false dichotomy and, excuse me, the perfusion and pace of change of NDC codes compared with CVX codes is such that it would really create some problems, I think, for implementers in terms of managing the master lists for one thing, but also all of the configuration of clinical decision support and reporting and so forth around determining whether a patient is up-to-date on their immunizations.

Imagine if instead of managing, you know, maybe the whatever they are, maybe between 50 and 100 CVX codes, you had to manage between 500 and 1000 NDC codes; it's...plus there are well known data quality issues with NDC codes. It's not centrally managed and I believe that the manufacturers do the best they can and yet because it's so decentralized it's just...it's a bit of a Tower of Babel. So we had a pretty strong consensus that using NDC codes was...requiring use of NDC codes would be a mistake.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Oh, okay.

Betsy Humphreys – Deputy Director – National Library of Medicine

So Mitra, in...this is Betsy. In terms of a lot of the requirements within, you know, for drugs...

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Yes.

Betsy Humphreys – Deputy Director – National Library of Medicine

...the standard...the requirements are to use RxNorm, and of course if people have NDCs and are using NDCs in other ways then it's very easy to map from the NDC code to the RxNorm code...

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Right...

Betsy Humphreys – Deputy Director – National Library of Medicine

...and then the standard for the EHRs is the RxNorm distribution. So why is that model not suitable for vaccines?

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

For vaccin...oh, that is actually excellent question. We only like work closely with CDC when they ask us, they would like to move to NDC was actually their...it came from CDC and we have jointly...the Center for Biologic has jointly this reporting on vaccine adverse event reporting that is jointly between CDC and the Center for Biologic and the Center for Biologic uses NDC and CDC was using CVX; so that was like a disconnect between the two. But the model we have for drugs at the Center I am, using RxNorm would work for them, too...I can get more detail for you and Eric on...

Betsy Humphreys – Deputy Director – National Library of Medicine

Maybe we need to think about it because...

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Yes, yes, I agree.

Betsy Humphreys – Deputy Director – National Library of Medicine

...that's what we...what we have done in terms of the use of RxNorm is we have, in some ways...the EHR developers from having locally to keep track of all the NDC...

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-
Food & Drug Administration**

Oh, I see, you are right. Yes, I agree. And we are actually developing a central database with collaboration with NIH on NDC because Eric is right, it is...when NDC codes expire, retire and then a new manufacturer picks up the same NDC code for a new medical product. So they are reused, so that makes it more complex.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Folks, I'm going to have to drop off and then rejoin because I have to switch from a landline to a cell, but I'll rejoin shortly.

W

Are we scheduled for 60 minutes?

**Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute
for Health Policy – Kaiser Permanente, Institute for Health Policy**

Yeah, it was just...it was only scheduled for one hour.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology –
Office of the National Coordinator for Health Information Technology**

Yes.

W

Oh, one hour, okay.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology –
Office of the National Coordinator for Health Information Technology**

Shall we transition...

**Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute
for Health Policy – Kaiser Permanente, Institute for Health Policy**

But I think we've, you know, yeah, I think we've completed the primary agenda item of reviewing those comments and so if we can hang on for just a few more minutes, then we can try to schedule the Group 1 and then take public comments. Is that okay?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology –
Office of the National Coordinator for Health Information Technology**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National
Coordinator for Health Information Technology**

We only have 1 or 2 more minutes because there is another call following this one.

**Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute
for Health Policy – Kaiser Permanente, Institute for Health Policy**

Ah, okay, all right.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So we have to move fairly quickly. Sorry.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

All right. So what I'm going to say is, let's perhaps use a Doodle Poll or some other mechanism to get Group 1 scheduled, is that okay John, with you?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

This is Michelle, so a Doodle Poll has been sent and I believe a Group 1 meeting has already been set up.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Mazen, I saw it come through, if you want to speak up and let us know what the date is.

Mazen Yacoub, MBA – Healthcare Management Consultant

Thursday at 11.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay. All right, great. Then I think we're ready for public comments.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay. Operator, can you please open the lines?

Public Comment

Caitlin Chastain – Junior Project Manager – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment, please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And while we wait for public comment, just a reminder, a template was sent out for Group 1 so if you haven't submitted comments to John Carter, if you could please do so and the rest of the te...the ONC

team, that would be very helpful in preparation for the meeting on Thursday. And it looks like we have no public comment.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay. All right, well thank you everybody and Eric, a special thanks to you for your extra work on this. I appreciate it.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you everyone and thank you Eric.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

We're adjourned, thank you.