



**HIT Standards Committee
Semantics Standards Workgroup
Final Transcript
May 15, 2015**

Presentation

Operator

All lines bridged with the public.

Michelle Consolazio, MPA – 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 Semantic 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, and I'll take roll. Becky Kush? I know Becky's on. Jamie Ferguson? Andy Wiesenthal? Asif Syed? Betsey Humphreys? Eric Rose?

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

Eric's here.

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

Hi, Eric. Harry Rhodes? John Carter?

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

Good morning.

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

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

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

Here.

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

Hi, Larry. Mitra Rocca?

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

Here.

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

Rosemary Kennedy? Stan Huff? Steve Brown? Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Good morning, from Southern California, where it's actually raining.

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

[Laughter] Yea!

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Yea! Yeah, it sure is awesome.

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

[Laughter] Thank you, Todd. And Patricia Greim from ONC?

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

Present.

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

Hi, Patricia, and Mazen Yacoub?

Mazen Yacoub, MBA – Healthcare Management Consultant

Here.

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

Hi, Mazen.

Mazen Yacoub, MBA – Healthcare Management Consultant

Hi.

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

Anyone else from ONC on the line? Anyone join after we went through? Okay. With that, I'm gonna turn it over to Becky, but before we do, we may not take the full time today, so hopefully all of you on the West Coast can be ready for your normal day to start after, [Laughter] but with that, I'll turn it to you, Becky.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well, I'll just say that I really appreciate everyone doing so much work while I was gone in Europe all month, and I think the best thing we're gonna do today is to go through a summary of that; is that correct?

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

Yeah, we're gonna go through the finalized slides for the presentation next week at the Standards Committee meeting. Go ahead, [Cross talk]

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Okay, and do we have, also, a meeting on Monday? Mitra was asking if there was [Cross talk] and Monday to go through this so there are opportunities for people to comment.

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

Yeah, so we are gonna see how today's went, to see if there was still a need for Monday's meeting. If we are able to get through everything today and have a good feeling for how, the place that we're at by the end of the meeting, then we'll cancel Monday's meeting; and if not, we'll quickly follow up and quickly touch base. I don't think we'll take this whole time up for sure, but—so we'll check in at the end of today's meeting.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Okay, and I think that there also was a comment to say that there are some who feel that some of this work is very much geared towards the health care needs and that research is still something that we should not take off the plate. I know I've heard from a couple of people about that concern, not just myself. So I don't know if there's room for adding a general comment like that.

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

So the proposal that you have is to include a comment?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yes, and then we can go through the comments to see where there's good, and I'd encourage Larry and some others to speak up as far as _____, especially if I lose this call, because I am traveling.

But in general, we're trying to create a learning how system is in _____, we need to be aware of where we don't want _____ that opportunity.

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

Great, yeah.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I don't want to hold anything up, I just wanted to state that I have heard from some committee members about that, and some of them aren't on the call today, so I'll say that on their behalf.

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

Thanks, Becky. And you know, that's certainly the wider scope of reusable data, the idea of portable data for multiple uses can't be emphasized enough, I think, so let's find ways to fulfill that request.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

That's a good way to put it. Thank you, Trish.

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 address the—

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So, do you all want to go ahead through these slides because—

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

Sure.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

- you're familiar with them and did such a nice job putting them together?

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

Sure. Could we advance to the—yeah, thank you—the, the due out today that I have is, like, two, two issues. One is the opportunity for group one to report to the full Semantic Standards workgroup, the subgroup one, and also the opportunity to resolve, perhaps, the, there's a—so, just to summarize, at the end of the last Semantic Standards workgroup, we were discussing, we were discussing immunization codes, and we, we, we came to time before we really resolved that issue, and I say that because both sub-workgroups addressed vaccine codes—one, in terms of orderables and prescribables as pharmacy domain, and one as vaccines, so we do have that to cover.

What's showing on the screen right now is the work plan, and just what we've already said, that we're meeting today for group one to report out to the full workgroup, and then we still have a Monday meeting scheduled in order to finalize comments, which we will use if we need it, and we can always adjust. Next slide.

One request that Jamie had was to catalogue some of the general themes. This might be a place to put in the comment about the research, just—for those of you who don't have the visuals today, I'll just

read the general themes—specify code systems and avoid identifying or specifying specific codes in regulation, because coding systems evolve. So, if the NPRM would identify a particular code and the code systems evolves to more specific codes, it would penalize systems that were using a more specific code or a more detailed level, and that was one of the justifications for the general theme.

If NPRM identifies required—yeah, general coding regulations, okay. So, in general, use LOINC for questions and SNOMED for answers, unless there's a good reason not to following the assessment scale guidelines that have been issued by Tramento, and then regulations should not be based on any premise of action by entities outside the regulator's control, and that was specifically in response to the NPM reference to a pending code. The general theme recommendation was that we should have publicly available assurances from standards development organizations that the code will be released and available, but then again, that kind of is taken care of if we don't identify specific codes in the first place. So—but that might have been referring to a pending code system, so we may need to check on that reference.

So those were the general themes so far that have emerged.

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

So this is Larry Wright from NCI.

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

Yeah. Thanks, Larry—yeah?

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

Two comments—first, on the second point in the general themes on the use of LOINC and SNOMED, that sounds like a, sounds like a very broad assertion that LOINC should be used for all questions and SNOMED for answers, and I think the point came up in the more specific context of where LOINC and SNOMED are used for a given purpose, a good way of defining their roles in combination was that LOINC was generally used for questions and SNOMED for answers, but it was only within that circumstance and not as a sort of broad prescription across the whole content.

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

Okay, so this would be an opportunity to—for the workgroup to say, “Hmm, this might not fit along a general theme.” Is that your suggestion? You'd like to remove it, or you'd like to adjust the wording?

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

I wasn't under the impression that it was intended to be that general, that it was more for that specific purpose, that those who were closer to the discussion should chime in on how they viewed that.

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

Yeah, this is Eric. I might be able to offer some perspective here. So, the context in which this came up was the proposal to use LOINC answer codes for some, for some data elements, I believe it was around social history, where LOINC did provide answer codes for, that sort of went along with LOINC observable

codes for, for things like, “What’s your stress level?” where the LOINC answer codes would be, you know, on a 0 to 5 scale, where the LOINC answer codes would be, represent the values of 0, 1, 2, 3, 4, or 5.

And the point that we had made was just, as a matter of practical usage, for implementers, for EPs and EHs, it’s gonna, that would complicate—that would likely complicate things substantially, that the SNOMED qualifier value hierarchy in general is intended to serve that purpose, and so we were proposing a—the real, the real gist of the, the specific recommendation from which I think this was extrapolated was that, if there’s, unless there’s a really good reason to represent the answer part of a question and answer pair, that SNOMED is likely to be a better choice than LOINC.

No, if it’s clear that SNOMED simply doesn’t have the semantic coverage in a particular area, then LOINC might have to be used, but, but—but, to do so is just gonna create an extra terminology maintenance burden for implementers, and complicate things, somewhat. So there may be—there may be a way to extrapolate that as a general theme without, you know, without necessarily making it overly, overly blanket, [Laughter] so to speak.

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

Okay, well—

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Which—this is Todd, this is Todd. Yeah, I would agree to that. We could choose the wording to make it clear, because this is—as it’s stated, it’s extremely general. [Laughter]

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

Great, okay. Who would like to take on crafting a better statement?

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

Patricia, why don’t you put together a proposal, and we can share it with the group?

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

Perfect. Thank you. That’s great. Next slide.

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

Okay, and then my second point on general themes is related to the comments Becky made earlier, which is that we’ve tried to register the various NCI representatives who’ve been on the Content Standards committee, the issues that we’ve seen in the, the lack of alignment with research standards, but also with lightly used clinical standards, and we’ve gone out to our various clinical and research partners, you know, sort of trying to discuss these proposals with them and get feedback and, in general, find that very few people are using or familiar with the proposed standards. And it’s made us nervous that there may be need for a broader evaluation of the impact of these proposals on working systems, on the standards that people are currently using, and the ways that we can make a smooth transition in trying to improve and harmonize coding without totally disrupting and leaving gaps of coverage and so on in the things that are emerging.

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

So, um—so in the general themes, Larry, you'd like to include that caution that—especially research that has not been impacted by meaningful use directly and may be out of sync with some of the movement in the clinical world and that that is going to have a potential adverse impact?

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

So, that's particularly striking in the research domain, but we've also found it in looking at clinical data. I mean, we do a lot of processing on statewide EHR data for various purposes such as cancer registries, and find very little—

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

Ah, right, right.

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

- very little clinical data that's coded in SNOMED, LOINC, or RxNorm. [Laughter] And so—

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

Okay, yeah.

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

- the standards of specifying those things as the standards represents a huge sort of break and transition, and, in the participation that we've had, we haven't seen that really addressed and a plan put together that reflected the, the current community practice and the issues that would arise in that transition, so it's just a concern we have about how we can promote standards use in a way that will really be responsive and implementable in the community. But clearly we have a [Cross talk] that from the cancer perspective and I'm very interested in learning from other people's experience and seeing whether there are others that we should have brought into this process to try and get a, a broader set of inputs.

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

Okay, thank you. Thank you, Larry. I will take—I will take up Michelle's recommendation that I draft a statement that will, that you can review to see if it really reflects the concern accurately and completely, so I will do that.

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

Thank you.

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

Thank you. I'm now looking at the time and getting nervous. John Carter is due to report out on group one, and John, you have a hard stop, you must leave us early, correct?

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

Thank you, yes. I'll be needing to sign off just about a quarter 'til.

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

Okay. Perhaps you'd like to, we can come, circle back to the CVX/NDC discussion.

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

Yeah. I think that the rest of our comments are in line with what we've already talked about and with the comments that were generated by the other subgroup, so let me just run through these really quickly in case there's any, any concerns.

The pharmacogenomics data we were concerned about was potentially a little bit ambitious, as written in the, in the document. Again, we've already talked about specific versions—specific codes or specific versions being named. We'd rather see something like a minimum version specified—a floor rather than a ceiling, so that if people are updating to the latest, that there's no ambiguity, that that's a good thing.

Barring any questions or comments, I think there is nothing else on this slide to talk about.

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

Thanks, John. Any questions? Let's advance.

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

Then really, the substantive notes here are about NDC. Our group included representation from the FDA, and who are, I think, at the agency level, advocating fairly strongly for the use of NDCs in this vaccine context, and—and I didn't know if that was in line as, as you said at the beginning, Tricia, the, the discussion was still ongoing at the end of one of the prior subgroup calls. So I didn't know if, if what we're saying is in line with what the rest of the group has, has come to or not, as a consensus, but—but our subgroup found that NDCs, although they have certainly suffered from some terminological problems in the past, we tend to agree with the justification that was presented in the notice that those situations are better than they used to be, that this is not, not a badly—not as badly managed as it, as it may have been in years past, and that the extra detail found in NDCs is a good thing, although there are valid points about other kinds of details, such as lot numbers, which are not included in NDCs. Nonetheless, NDCs are used in a variety of settings and so on and so on.

So, we were generally in favor of the use of NDCs for vaccine codes, where they're, where they're available, not something that anybody in the group felt they needed to lay down on the railroad tracks and get upset about, but we were, we were generally well disposed toward the use of NDCs in this context.

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

So this is Eric, and my group came to rather a different conclusion, and I don't know if this is the right point in the meeting to, to sort of lay out our reasoning, if that—if so, I'd be happy to do so.

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

Eric, I had hoped to address that before we got to this point, but there is still the open reconciliation for those two points of view, and—yeah, go ahead.

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

Anyway, this is Mitra Rocca from FDA. I actually reached out this week to CDC, and they have commented on the NPRM as well, and the idea of using NDC actually came from CDC and they contacted our Center for Biologics, and they asked us if we can develop NDC-like codes with 10 digits for that. I didn't know the whole historic information from the connotation of CDC and FDA _____ where I am _____.

So, and then, the person from CDC said they would like to use NDC codes for administrative, administered vaccine, and a CVX code for the historical or forecast references.

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

We do have—I think we may have a slide, but—[Cross talk]. Okay, okay, yeah. I'm sorry, Mitra. We may have a slide that, that is intended to capture some of the different points of view on that. Would it work to hold that discussion until we get through the less controversial parts of this?

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

Sorry.

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

No, no, please don't apologize. [Laughter] Okay, we're going to just parking lot this planned discussion, targeted discussion, and continue with the report of other items—thanks. Next slide.

Was that it? That—

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

We somehow, our group—and I'm grateful for this—ended up with a smaller number of sections to review, and so we, we really only came down to, to just a couple of issues there, so I think that may be it for us.

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

Oh, great. Okay. I thought I might have included the comment that we made at the end of the last meeting in a slide that came before the report out, if we could back up and look, see if there's a—oh, yes. Thank you. It's slide four on this deck.

Okay, slide four on this deck just summarized what I documented, this is all—the slings and arrows can come up to me, so if I missed something or if there are additional points to be made, this is now the time. Well, I'm probably rushing this—are there any comments about group one's report out, before we go to the burning discussion about CVX and NDC?

Okay. The floor is open, and I'm inviting—I will happily read these for the folks who don't have the visual, and I'm inviting corrections, additions, or deletions.

The National Drug Codes are not currently centrally maintained, and problems with data quality at the NDC codes, problems are well documented. That was one point I heard. The other point I heard was, the profusion and pace of change of NDC codes, such as those NDC codes that get retired, pose problems for implementers just by sheer volume, I think, might have been a better way to represent that. The Center for Biologics use—the Center for Biologics, the Center for Biologics [Laughter] use NDC, and CDC wishes to use NDC instead of CVX, and the National Institute of Health is creating a central database to support this effort. Did I get that correct?

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

Okay, so the—actually, the correct name is Center for Biologic Evaluation and Research, CEBR.

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

I will correct that—thank you.

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

Okay. [Laughter] And yeah, that is correct, I [Cross talk]—

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

Thank you very much.

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

You're welcome. The CDC reached out [Cross talk]—

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

And that's how we'll emphasize—yeah, yeah. Thank you.

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

You have it captured correctly, and then the last meeting, sorry, that is, Betty asked me if RxNorm captures—if you can use leverage, RxNorm could capture in the future NDC code for vaccine, and I don't know the answer. I was actually going to reach out to John Kilbourne, who is the RxNorm expert at NLM to find out your—and you have it captured, here.

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

Sure. I—I did capture the proposal, yeah, I captured the assertion that RxNorm actually addresses this theory well for prescribables, and I just lost my, um—I think I, I think I maybe unplugged and didn't know it, and I just lost my power.

Yeah, it can—RxNorm captures this for prescribables, and that was one comment. I'm retrieving my screen, here. Yeah, and—because it insulates implementers from having to manage large volumes of NDC codes and it manages the cross reference to the community agreed upon NDC code within RxNorm. So, that's when, I recall, Betsy Humphreys asked the question, "Could we use RxNorm for vaccines to similarly solve this concern?" I do recall a comment that using NDC for vaccines administered and CVX for historical vaccines was problematic because, as soon as the vaccines are administered, they become part of the historical record. That didn't seem like a clean break in the conversation.

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

I know this came from Eric, this comment, and so CDC wants to use CVX codes for historical vaccines, like these are like the older vaccines that already have CVX but they don't want to go and map those to NDC. That is what they meant by historical, so they already have CVX, but for the new vaccines, they propose to use NDC. Like, everything that the manufacturer—

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

Oh, okay. They weren't—oh, okay. That's very clear now, Mitra.

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

I'm sorry, this is Eric—

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

It was a graceful migration strategy.

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

I'm sorry, Eric—go ahead.

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

No, I'm sorry, but I don't think that's correct. I think that that comment—you're talking about the second to last bullet that's currently being displayed, right?

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

Yes.

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

Yeah, so I—so I think that it was derived from a comment that came from my workgroup, and I don't think it's being correctly interpreted. The point is that in any, at any care practice site for an EP or an EH, there is a record of, in the EHR, of the vaccines the patient has received in the past. And some of those

may be vaccines that were administered outside of that care setting and recorded as historical vaccines. The patient says, “Yes, I had a flu shot last winter no this date from the pharmacy,” and the provider enters it so that the historical record of vaccines received is complete. And some of them may be vaccines that were administered at that care setting so that it would be—so, the use of CVX to record vaccines administered allows a process where, by recording the administration of the vaccine at a care encounter, that, that documentation action populates the list of vaccines that the patient has received.

And if, if—if there’s a requirement to use NDC codes, then either the implementer has to do two documentation actions when they administer a vaccine to a patient, which would be a terrible disservice to, to the end users and to these organizations to require that, or they have to somehow have a way of, of, in their system have a library of vaccines with both NDC codes and the CVX codes somehow cross mapped to a single data object so that when they document the administration of a vaccine, the record of what vaccines the patient has received is up to date. And that record has to be a single—you know, you have to have a single, homogeneous set of codes of all the vaccines the patient has administered to do things like clinical decision support or, or reporting.

So that’s the point that that was making, that this, this idea that, that it’s somehow okay to require two different coding systems because they're, they're for two different types of data is, is based on the false premise that those two different types of data are separable. Does—does that make it clearer?

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

I know that—no, Eric, I know from, like, the _____ Public Health Emergency Response co-lead is actually from CDC, and he keeps making the CVX code through NDC, and I think maybe the CDC is tired of this cross mapping and they just want one coding system, and they reached out to FDIC _____ to see if they can leverage NDC.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

So, so it—well, but that’s not what the NPRM is calling for. The NPRM is saying, use CVX for historical vaccines and use NDC for vaccines administered, and my point, the point that my workgroup came up with—

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

See, and that comes from—

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

- is, is that that, is that that proposal is, is a very bad idea, for the reasons that I, that I just outlined. And I just wanted to understand from the group if the explanation I gave was clear or not, because I don't think it's, I'm not sure—I'm hearing silence, which suggests to me that it isn't clear. So, for Rebecca and Larry and Todd and the other folks on the call, are you guys tracking what I'm saying? When the patient goes to the, to, to the doctor, and the doctor has a list of what vaccines they've received in their lifetime—hopefully—and the patient gets a flu shot at that visit, that flu shot needs to populate, needs to be added to the list of the vaccines they've had in their lifetime. Because that list of vaccines they've had in their life time might, for instance, be used to generate an automated reminder to the patient that you need XYZ vaccine.

So you can't have a different—if you have a different coding system for recording the administration of the vaccine and for recording the fact that the patient has received that vaccine, then you either have to do duplicate data entry, or you have to have some way of cross mapping these new coding systems. Either way, it creates problematic complexity.

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

Hey, Todd—John Carter, here. I noticed in the notice that it actually, specifically references an available map from CVX to NDC or the other way. Have you looked at that, and are you persuaded that that is valuable, or that the presence of such a mapping is too complex?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

I—I haven't, and—

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

Because it looks [Cross talk].

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

- I haven't, and I don't buy it. It, it doesn't make sense, because, because NDC codes can be created by manufacturers any day of the week. That's the, that's the point about NDC codes not being centrally managed. The manufacturers get a stem unless, if somebody—if I'm not correct, please, somebody correct me, but—my understanding is that the manufacturers get a stem, a certain number of digits, and they're told, "This is your NDC code stem. Whenever you make a new packaging of a drug, you know, make sure that you add a unique, you know, you create a unique code that starts with these numbers, and let us know what it is and what it means."

And so, so I don't see how it'll be feasible to, to manage an up to date cross mapping, and I think that until there is proof of feasibility, I think it is—I think it's just asking for chaos to require these to be recorded. And you know, the other point that my workgroup made is that the putative advantages to doing this are, are highly questionable, which doesn't seem to have made it onto this slide, but—but the NPRM cites two putative advantages. One is that it will facilitate pharmacy inventory management and bar code scanning, and the second is that, is that it will facilitate—the phrase was, "Can improve patient safety with better specificity of vaccine formulation," but for that, our point was that, if you have a CVX code, which is currently required, an MVX code, which I believe is currently required, and a lot number that, that should provide the same information if there's an adverse event for, for adverse event reporting.

So, it seems to me that the advantages, the stated advantages are, are—you know, questionable at best, and the, the disadvantages are, are, are enormous.

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

So, your point is, the focus on CVX as opposed to NDC.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Yeah, there are 100, about 180 CVX codes today.

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

Gotcha, yeah.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

And, you know, Lord knows how many NDC codes for vaccines, but probably between 20 and 200 times that number. There's actually 168 CVX codes today.

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

And the other, the other thing that, that didn't make it on here is that organizations have already made significant investments in building, building reporting and decision support and other logic around CVX codes to represent vaccination data, and they'd have to rebuild all of that if NDC codes are gonna be used. And imagine—imagine the challenges in maintaining, you know, a decision support rule when suddenly you have to have, if you want to know if somebody's had a flu shot, instead of 4 or 5 CVX codes, you check 400 or 500 NDC codes you have to check for. This, this would be enormously disruptive. Unless—unless there's something I'm missing, but this was the consensus of our workgroup.

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

Right.

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

This is [Cross talk] this is from [Cross talk] reading. They would like to replace a code structure like a three digit CVX code pair with something completely new, like a 10 digit NDC code. Isn't CDC the one who are filing CVX codes?

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

No, CVX codes have, unless I'm mistaken, are—I think it's an HL7—no, I'm sorry, it is NCIRD, the National Center for Immunization and Respiratory Diseases maintains CVX. That's part of the CDC.

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

Part of the CDC. Yeah.

Betsy Humphreys – Deputy Director – National Library of Medicine

One of the—this is Betsy Humphreys. Sorry I'm late into the call, but I've been listening to this for a while. One of the concerns that NLM expressed when we were reviewing drafts prior to publication of the NPRM is the issue of—you know, interpretation of what it means, and I think it relates to the previous comments that have been made. That is, that if we're incorporating these codes into people's electronic health records and transmitting them from one spot to another, our recommendation was that, if you had to go in this direction, you should also send the CVX code, because people would actually know what type of vaccination or immunization the person has gotten, [Laughter] as opposed to just having a 10 digit code and there being sort of no face way of figuring out what it was. It relates to this other issue of, do we believe that there is a good place to look these up that's readily available to everyone, or not.

Male

And then the other premise here is that the CVX plus the manufacturer is an equivalent to the NDC from an information standpoint, we get the same set of data.

Male

CVX plus MVX plus lot number, yeah.

Male

Good, okay.

Betsy Humphreys – Deputy Director – National Library of Medicine

I wasn't—I mean, I joined this whole information exploration after the Consolidated Health Informatics, CHI, recommendations, I think. To the point that was made about historical systems, I know CVX, MVX, and lot number goes back pretty—pretty far, I think, 2004 of systems working with that. And I know it was ongoing when I started working in this area.

So, I think that maybe has been addressed, but I just, if we are migrating from that, I think we need to really attend to the migration path.

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

Yeah, you know—this is Eric. One of the things, to Betsy's comment and the idea of RxNorm as perhaps the direction of migration, one of the things that is a problem that really does affect health care today is that most EHR systems will not be able to provide a drug allergy alert notification for immunizations, because the way the master file for which immunizations are, where they're recorded, isn't linked to the medication master file which drives drug allergy alerts.

Now, allergies to vaccines are pretty rare, but they can occur, and if somebody has had, you know, some kind of prior serious adverse reaction to a vaccine and it's recorded on their allergy list, most EHRs won't warn the provider when they order or enter the, you know, information regarding administration of a vaccine, and using RxNorm for that could potentially provide a way around that, a solution for, for that very real problem.

So that would certainly be, you know, if we're, if we're gonna disrupt all the work that implementers have done to, to build artifacts around a CVX and require migration of data and so on and so forth, which I think is, should be done with a lot more lead time than this, than this NPRM would allow. It would seem that RxNorm would make more sense.

Female

Sorry, Tricia, [Cross talk].

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

Was there follow up related to—this is Tricia—was there follow up related to RxNorm that would be needed to, I mean, if we're—I don't know. There was, Mitra, I heard a recommendation to consult someone about RxNorm. Is that on the table?

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

Yeah, that is a good idea, yes. That is what Betsy asked me, and Betsy, I was going to reach out to John Kilbourne if he _____ vaccine or thought of RxNorm or not.

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

I did look at the browser and, and I see vaccines represented in RxNorm, but I—I'm not sure of the population on the axes or the, you know, extent of coverage, so that would be, yeah, something for an expert to identify.

Betsy Humphreys – Deputy Director – National Library of Medicine

I will—this is Betsy—I will follow up with John and see if we can't determine whether this makes sense or not and get back to everybody.

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

Thank you, Betsy.

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

This is John Carter. From the perspective of the, of the discussion we've had in our workgroup, I can see how an RxNorm based solution could end up as a win/win/win. RxNorm codes include links, in a whole lot of cases, to NDCs, and it probably wouldn't be that difficult to make sure that there are links to CVX codes as well and so that saying one of those things allows people who want or need to do cross walks to do all of those cross walks, so that might be a really elegant way out of this thicket.

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

I agree with John's solution. That's a great idea.

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

It is 10:49—yeah, go ahead.

Male

So I was gonna say, I would caution against that being in the, you know, whatever edition this is gonna be, the 2016 certification edition, I think that the burden, the burden on implementers is to make any transition that's gonna be substantial—which doesn't mean that it shouldn't be done, but it has to be, I think, weighed with everything else that they're gonna need to do for the next stage of meaningful use. And again, it's unclear whether the advantages are—to me, anyway, such that they weren't this change in the short term.

Male

By the way, the other thing to be considered is that there are many state immunization registries that are maintained at the state level and so this would have an impact on—you know, all of the state immunization registries might need to adjust how they ingest and process data in order to be able to continue to function.

Betsy Humphreys – Deputy Director – National Library of Medicine

I—I think NLM would agree that this is something that may make sense, but I, on the time frame we're dealing with here, I, I agree with the comments that were just made.

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

This is John Carter. I also agree with those comments, and on that positive note, I apologize, I am gonna have to sign off early today.

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

Thank you very much, John.

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

Michelle, this is Tricia. I am happy to craft proposed language. I do think that—I would propose that we meet on Monday to resolve these concerns. Becky, what is your decision on that?

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

While we wait for Becky to respond, Tricia, would it be possible to try and get something out to the group by the end of the day today so they have the weekend to look at it, and we can see if we get any comments back?

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

Yeah.

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

I think it would be great to be able to discuss that during the call on Monday if we do have it.

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

Yes, I'll send out revisions—yep.

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

It sounds like we might have lost Becky, so why don't we touch base and see if we should keep Monday's meeting, depending upon the feedback that we get back?

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

Okay. Well, it's still an open question, then, and we'll have the weekend to review. I'll get them by close of business today.

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

Thanks, Tricia. So, with that, are we ready to open for public comment? Okay—Lonny, can you please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes. If you're listening through your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you're on the telephone and would like to make a public comment, you may press *1 at this time. Thank you.

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

Hi, Lonnie, this is Michelle. I had to restart my computer so I won't be able to see if there is somebody.

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes. We have no comments at this time, Michelle.

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

Thank you, Lonnie, and, as we just discussed, Tricia will try and get something out to the group by the end of the day today for you to review over the weekend.

So thank you, everyone, we appreciate it.

Male

Thank you.

Female

Have a great evening.

Female

You, too—thanks.

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

Thank you.