



**HIT Standards Committee
Semantics Standards Workgroup
Final Transcript
May 18, 2015**

Presentation

Operator

All lines are 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. 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

Here.

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

Hi, Jamie. Becky Kush?

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

Here.

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

Hi, Becky. Andy Wiesenthal? Asif Syed? Betsy Humphreys? Eric Rose? Harry Rhodes? John Carter?

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

John sent his regrets.

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

Yup. John Speakman? Margaret Haber or Larry Wright?

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

Present.

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

Mitra Rocca? Hi, Larry.

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

Yes, here.

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

Hi, Mitra.

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

Hi Tricia, yes, hi.

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

Hi, this is Michelle.

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

Michelle, I'm sorry.

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

Michelle, did I hear Larry?

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

Yes, we heard Larry. Rosemary Kennedy? Stan Huff?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Here.

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

Hi, Stan. Steve Brown?

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

Here.

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

Todd Cooper?

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

Todd sent his regrets.

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

Tricia, you don't need to say that, thank you, during the roll. I just...we need to just know who's here and who's not.

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

Okay, thanks.

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

Tricia 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

I guess I'm here.

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

Anyone else from ONC on the line?

Mazen Yacoub, MBA – Healthcare Management Consultant

Hi, Mazen Yacoub is here.

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

Hi, Mazen.

Mazen Yacoub, MBA – Healthcare Management Consultant

Hi, good morning.

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

Okay, I'll turn it back to you, Jamie and Becky.

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

Hi, Asif's here, too.

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, thank you. Thanks everybody. So I think as many of you know, Becky and I have not been able to connect with these two subgroups to a great extent and so I'm looking forward to the discussion today on the various issues about the use of CVX versus NDC codes. And look forward to hearing about the discussion that has happened in the subgroups. I think that's actually, is that our only agenda item for today?

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

This is Becky and I was on on Friday and we tried to go through all the slides, but I think we were preparing those recommendations and we didn't make it all the way through so, I believe that we might need to make sure we know what we're recommending for Wednesday; is that correct?

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

Right, okay. So should we do...

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

So I had...

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

...yeah.

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

...made a recommendation that we may not be able to start at the beginning again, so I think reviewing the comments we made on the general comments from last Friday. And then asking people if they have any other recommendations on the slides, we might be able to make it through today.

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

That sounds great. Umm...

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

So I do think the first was to go ahead and have Mitra report out on all the research she's done on the NDC codes and CVX. Mitra, are you willing to go through that with us?

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

Yes, of course. Sorry, I was printing the slide I sent you on Friday. Okay, so on Friday afternoon after our call, I reached out to CDC because I think the question came from them that is in the NPRM. And then I also reached to FDA Office of Commissioner and the group that manages NDC. So I know in workgroup 1 they had a discussion about NDC, but it wasn't NDC and...no, workgroup 2, sorry, the one led by Eric. But our workgroup that was led by John Carter, we had exactly like; I guess ONCs question to prefer to use NDC for vaccine versus CVX.

So then I found out that actually FDA has an NDC database and it was last updated on Friday, May 15. And then the process is that FDA, oh actually, I don't know if you are sharing slide; okay, slide 2, sorry. So there is an NDC Directory and then FDA assigns the first portion of the NDC code, which is the labeler code. Then a biopharmaceutical company assigns the second and third portion of the NDC which are the product code and package code and then the firm reports the NDC to FDA when it eLists. And they are all linked to that HL7 SPL, Structured Product Labeling standard.

And then FDA knows how many NDCs have been eListed, but if a firm assigns an NDC and chooses not to eList or that means not to be compliant with eListing regulation of FDA, which is an exemption, then FDA doesn't know that, has no knowledge of those assigned NDC. But all of them go through that eListing process.

And then I asked them about recycling or reusing the NDC, like when Pfizer acquired Wyeth and then what happened to medication from Wyeth that had Wyeth's NDC code? And they told me that FDA doesn't allow reuse of NDC codes, even when one company acquires the other one. And this is I did the link to the NDC database or the Directory. Any questions on this slide? No, okay.

Then I reached out to CDC and this is the group...next slide please, okay. So this is the group that actually developed CVX and MVX and I learned a lot because I was unfamiliar with CVX myself. So in 1999 the CDC published an implementation guide for messaging immunization history and two value sets were defined that allowed specification of the vaccine used at the vaccine administration level. And that is the CVX code and MVX; CVX is a numeric string which identifies the type of vaccine product used, for example, a CVX code of 43; this will represent Hepatitis B, adult formulation.

And then there is MVX code that is alphanumeric string, and that identifies the manufacturer. So for Hepatitis B there are two manufacturers, GSK and Merck and MVX code for Merck, for example is MSD, for GSK is SLK; so then it would be combination of those two for the...so the code, a CVX code of 43 is Hepatitis B plus the manufacturer code. And that is also maintained...similar to NDC that is maintained by FDA, this CVX and MVX are maintained by CDC and it is built into HL7 version 2.x, I think 2.5, 2.3-2.5. Next slide, please.

And then CDC, as I mentioned, maintains the CVX and MVX codes, which are updated weekly. And then the CVX codes are intended to identify vaccines that are currently or recently in use in the US. Oh, they also mentioned that if the vaccine's for not in use in US and developed outside of US, then they don't assign CVX code. And only in extreme situations, like the...like with Ebola, for example, then they...if they are used in US, then they get assigned a CVX code in US; otherwise it's just US vaccines only. Next slide, please.

Okay, so then I tried to compare the two; the NDC codes will become important ways of identifying recently administered vaccine and they are used in ordering vaccine from manufacturer and they are part of that GTIN, the 2 dimensional barcode sca...the bar code that is on the side of the vaccine packaging. And then NDC codes are found on the outer packaging or on the carton and on the unit of use or syringe for many vaccines.

CDC, I didn't know that CDC maintains a table mapping between CVX and NDC codes; so CDC maintains a table of both unit of use and unit of sale NDC for vaccines. And CDC provides a mapping table for linking unit of use and unit of sale and CVX code. And this is the link to where they have the table that maps the two.

And then they said they do not, and they put the not, this is exactly from the email I received from CDC, they do NOT favor using NDC-like codes for the historic doses where exact formulation are not know. So on Friday we had some confusion around historic; I thought historic is like similar like we are using ICD-9 then October 1 we move to ICD-10 then ICD-9 would be historic; but their definition of historic is where exact formulation are not known; that is like historic doses.

And CVX and MVX should be required for all administered doses. And then they also said the systems, the health IT systems should support NDC for administered doses. And then CVX is the code of choice for historical doses. And that was their recommendation that they have provided when NPRM, we actually came to all the HHS agencies for comment, before it went public and that is what CDC provided comment to this NPRM. So, this is what I found out on Friday afternoon; any questions?

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

Well, yeah, I mean frankly this looks confusing to me because it says the systems should support NDC and CVX and MVX should be required; so I'm not sure...

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

I know. They said they want to use it for...they said that it should be required for administered doses, but then they say they should support NDC.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah, this...well, I guess it's, I don't know if I would call it confusing. The tricky part here is that...is the tie-tie between NDC codes and umm, you know, ordering from companies and for, you know, knowing the exact, yeah, well, knowing the manufacturer and the other information. And then the CVX stuff is, you know in this case I would guess I would say that historical means that, you know, you don't have the primary record of the injection so...

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

That's right.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

...a mother comes in and says, oh, yeah my baby was given that MMR a month and a half ago at a clinic. And anyway, you don't have the information so you can't provide an NDC code in that case so that's when you'd use a CVX code. So, I mean, what it...I guess, yeah, what you're really saying is you would

require the CVX and the MVX codes in all cases and where they're available, you would like the NDC code. And the NDC code really is more not for the science so much as just for the...to integrate with the typical kind of billing and ordering, supply chain sort of organization part of the stuff. So...

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

Um hmm. That's right. Yeah, because the manufacturer of vaccine use NDC code, they don't know actually what CVX are.

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

I think we're conflating two different use cases here, right? I mean one is...

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

Yeah.

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

...medication administration and supply chain stuff and that's always used NDCs for better or worse to manage packaged products, right? And then there's this population health and naturally even individual health level stuff which has been bumping along using CVX as a sort of...as a sensible aggregation, not unlike like RxNorm codes, for example, I mean really like things are coming together in ways that are useful for managing people's health with these higher level groupings; it's just hard to order product. And I think that's why those, I mean, they're coming out in that fashion, of course.

From our per...I think from our perspective, and we're...every time we administer stuff, we're kind of doing this anyway, but I think it's important to remember that there are very different use cases here and that's pr...I think that's how to make the best sense of it. I think that if we were to not continue on with the sort of higher level aggregates, keeping up with the rate of change of NDC codes is really a problem. I mean if there's a great reliable source, okay, but there's probably not all that many truly new vaccines in a year, but last I looked, NDC codes change at the rate of 4000 a month. Because, I mean, just different numbers of doses per bottle or whatever it happens to be; so I think that's the real issue here is different use cases and getting them sort of tied up in knot.

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

That's right. Yup, that's right. Okay. And then, yeah, I agree with that. So then the other...the use case that FDA and CDC have in common is the vaccine adverse event reporting. And that is the Center for Biologics Evaluation and Research and they share theirs, which is Vaccine Adverse Event Reporting System together with CDC. And I looked at the form and they don't capture CVX or NDC code on that form, on the MedWatch form for FDA we have a field for NDC code and on Adverse form, they only had manufacturer name, lot number, dosage, so that is...

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

So it's not and so I guess what we're facing is not necessarily a question of whether to replace CVX with NDC but rather whether we should recommend augmenting the...

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

Augmenting...

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

...CVX requirement with an additional requirement on EHRs to also have the ability to capture and maintain the NDC.

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

Yeah, that's right. I agree. And then Betsy in our...on one of our calls, she asked me if RxNorm captures all the NDC code and I didn't know the answer. So I reached out to John Kilbourne and then he said all the NDC codes are included in RxNorm that they receive from FDA; but the CVX codes are not in RxNorm. That's what he just responded to me today. And then he said that we pull the NDC from labels; we also receive them from First DataBank and other databases and then when no label comes in through SPL, we get the NDC from a label that the manufacturer has not submitted to FDA. We have all the NDCs that we know about, what he wrote back.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

I think he stated it exactly right, Jamie and actually that's what I would recommend, too is that we essentially do what CDC says; require CVX and MVX and...

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

Augment it.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

...then augment that with NDC codes.

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

Yes.

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

Yeah and so then I guess it does bring up another question of do we actually want the NDC or RxNorm?

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

Oh, yeah.

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

RxNorm is already required elsewhere.

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

That's right. Yeah, that is what we were discussing on Friday, but we didn't make a decision.

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

All right, so now I feel I'm up to speed on what the question is, umm...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Well the, I mean the, yeah and essentially it's a different organization and sort of a different methodology, but the combination of the CVX and the MVX codes are serving the same purpose as the RxNorm codes.

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

Yeah.

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

Um hmm, that's right.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

But they haven't been correlated and so you would be...yeah, you could argue that if you move the CVX and MVX codes into or did the mapping and then required the RxNorm codes that that would serve the same purpose and that would unify things in the long term. But it implies sort of an unfunded mandate for the RxNorm guys to take on sort of the new work of...that's been being done, in terms of maintaining the manufacturers and the types of immunizations so, I don't know. Maybe make that a suggestion; I mean it would be...I think it would be premature to mandate that now; it's not in place and...

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

No, that's right.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

...maybe...so mandate it the way that CDC has said and make the suggestion that investigate merging the CVX and MVX work with RxNorm.

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

Into RxNorm, yeah.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah.

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

(Indiscernible)

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

To what extent is it really our role to be jumping into the pharmacy supply chain management arena anyhow? Maybe it is, and maybe because of med administration, bar code or whatever, that's what we want to do; but is that really what we're supposed to do?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Well, we're supposed to be standardizing this; I guess I'm not sure what you mean by...

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

I gue...well, yeah, I guess the question is what's the role of certification in this case? So, should, I mean, is there a part of meaningful use to take the more trade...I guess in ONCs terms traditional narrower purpose of certification. Is there an appropriate role for certification to require tracking of NDCs, I guess is the question.

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

Yeah I mean for the pur...for purposes that are largely related to like product ordering and those different use cases. Maybe it is? I mean, I'm fine with that.

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

Yeah, well I was wondering if that was, you know, could be more of a safety reporting use case or something of that nature.

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

Ah, okay. This is Mitra, actually I am working with ONC on the structured data capture and trying to work with Duke to do a real world pilot on adverse event reporting but I work at CDER so I am focusing on adverse drug event reporting from electronic health record that Duke is using. And then so the physician can just press a button and it populates the MedWatch form and sends it to FDA.

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

And is that what...

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

And that has...

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

...and that would require the...

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

...that has NDC. Yeah, it has NDC on the form, but I haven't looked, like I looked at the vaccine form, but that didn't have an NDC code, it didn't have any code, actually.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

And just has a text field, is that what it has?

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

Yeah, it has a text field, it was a table with manufacturer name, lot number, dose and the data administered.

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

So what is the actual language of the NPRM, what does the NPRM propose exactly?

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

...the question to us let me bring it up. Okay, pharmacogenomic...ah, okay, this is the language. National Drug Code for administrative vaccinations, page 170; in the voluntary edition proposed rule, we I guess our comment for future editions on whether we should replace CVX code for representing vaccines with NDC codes and an option for recording historical immunizations, and that is from another 79FRN...

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

So it proposes replacing and I think...

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

Yes.

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

...we would say, from this discussion, we would disagree, our workgroup would disagree with that because we would say, no, it should not be replaced, it should be potentially augmented, right?

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

Augmented. Okay, yeah and then the last sentence is NDC codes offer a number of benefits compared to CVX codes.

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

So...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

They do a different thing, yeah.

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

...it's a different thing, yeah.

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

Yes.

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

Yeah.

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

That's right.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah, so...

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

So, yeah, benefits for one thing, but a different thing, right.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah.

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

So it does sound as if we are, I'm not hearing any disagreement with actually dis...with the workgroup recommendation being to disagree with the language in the NPRM and to say that CVX codes should not be replaced by NDCs, but that ONC should consider possibly augmenting CVX codes with NDC codes, depending on the use case that is intended for certification.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah, I agree.

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

And I don't know if we should explain you know if we can explain concisely the two use cases or if we need to.

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

CVX is designed precisely to fulfill on those times when the, you know, it's...I hesitate to say historical, when the precise manufacturer and...

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

When the manufacturer package and lot number aren't known...

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

Such as in shot records.

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

Yeah.

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

Or just not needed, right? I mean...

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

Not...yeah, not known and not needed; right.

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

If you want to give...make sure that everyone eligible got a flu shot, you really don't need to go through all those complicated queries.

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

Yeah, you don't need the NDC.

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

Um hmm.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yup. So what's next?

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

Umm...

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

War and Peace?

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

So Becky...

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

Yes.

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

...do you want to take us back to the, I guess the overview of the recommendations?

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

Sure, let me get to those slides. I think that, let's see...the general themes had a little bit of a review last time, so when we went through the Semantics Standards Workgroup stuff last Friday, we basically looked at the general themes and just got started on a little bit of the rest. And that's what I was concerned about; I'm not sure what the most efficient way to go through this would be today because I think we have a placeholder for the NDC and we have 16 slides from the two workgroups. So, do peop...have people had a chance to look through these or should we go through them very quickly and see if there's anything people can't live with. Or...that was one of the things we need to do is to prepare for the meeting on Wednesday...

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

Okay.

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

...and then decide who's going to present those; is it going to be one of the leaders from one of the workgroups or, I don't know if you're going to be there, Jamie, I'm going to have to be on the phone for that meeting.

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

Umm, I will be there, but as you know, I unfortunat...I just haven't been able to participate in these discussions, so, umm...

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

Well I would think that somebody from the workgroup, if we could have them volunteer to present their workgroup findings and then maybe you or I could present the general themes.

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

Sure; that makes sense.

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

So...

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

So one thing did stand out to me on the general themes here and that is the third bullet, the NPRM should specify minimum version of vocabulary. You know, we have tried that recommendation I'm going to say at least three times in the past 6 years and it doesn't work. So I don't think that's really, frankly, a useful recommendation. I think that instead of that, I mean, so in other words, the regula...if the regulation's going to cite a standard; it has to cite a specific version is the answer that we've gotten very consistently. I think that, you know, maybe there's perhaps a different way to do it, to say that the NPRM might require the...something like the most current version, you know, minus two or within...you know what I'm saying? Something...I'm searching for a formula that could allow it...

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

Well the FDA has a way of doing that in regulation because they're going to begin to require CDISC standards for...

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

Um hmm.

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

...electronic submission and what they've done is make an overall guidance and then make a standards catalogue. So if we're going to have the Standards Advisory, I'm not sure why the specificity needs to be in the rule.

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

Well right, but the point is that so then the...it's about a rule versus guidance. And so, I guess, you know and they ha...as I understand it, they have...they're different requirements and if it's in a rule, you can't have, umm, I mean we've tried to say, I don't know, Stan help me out here, I think something like HL7 version 2, you know, 2.x; well, you can't do that. You can't say, you know 2.5.1 or later; you have to just have a specific version if you're going to name it in the regulation itself. And I think that's different from a guidance document.

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

Well no, I'm saying this is actually binding guidance, this is pretty much regulation and what they do is point to a catalogue which is a separate document. They say...

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

Yeah, but...

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

...you must follow the standards in this catalogue.

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

I understand that guidance is not a regulation...

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

...yeah well, it's required. So this is a...it sounds like an oxymoron; maybe Mitra can explain it better than me, but it is required.

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

Yes. Yes, you had...in the past we had just guidance's but now they are binding guidance's, so that is required from Biopharma companies to submit to us their results of clinical trial studies using CDISC standards.

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

Yeah, so, I don't know, maybe Michelle or Patricia you can...

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

I'm not sure we're the ones that need to figure out whether they go...

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

Yeah.

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

...into a guidance or a rule, but maybe the general theme is that if you want to change bullet number 3, maybe it should say something else other than what it says.

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

Yeah, so, I mean I think I would be more comfortable if it said something like the Certification Program should allow for versioning of vocabularies...

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

Yeah.

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

...without changes in regulation; that would be great, right?

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

I think that's good.

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

Oh and...but not to say how to do it in the rule, I think.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah, I think that's more useful.

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

So who's holding the pen on this, Tricia, is that you?

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

Yup, um hmm.

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

All right.

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

So instead of the NPRM should specify the minimum version it should say, the Certification Program should allow for versioning...

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

Without changes in regulation, right.

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

...without changes in regulation. Okay.

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

And then the sub-bullet is fine.

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

I don't see it on here, maybe it got in the last round but I think we also were clear that that common data set needs additional vetting. Did that get into the last round or is that still a comment that we wanted to make?

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

I think it's very much a comment we still want to make.

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

Because I saw the latest version of that and it hasn't had sufficient vetting or analysis to...

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

Right.

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

...be declared a common data set. I think that the second to last bullet is a specific request that goes along with the fact that it needs additional vetting.

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

This is Larry; would it make sense to make that as the general point and then the second to last bullet...

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

Yes.

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

...the sub-point?

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

Yeah...

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

Yes.

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

...that would be the best. 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

So...

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

Yeah, it also seems to me that the first bullet on this slide could be sort of tightened up or maybe it's multiple points. Actually I like the second part of that where it just says...

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

Yeah.

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

...more attention should be paid to the broader range of standards and requirements essential to learning health system objectives; maybe that's all we need to say for that first bullet.

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

Well I think without...the first part would lose a lot of the rationale that...

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

Well maybe the first part is a sub-bullet then.

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

Um hmm.

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

That would work.

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

Just rearrange it.

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

Okay. This is Tricia; so if I make those changes, I can route this slides and we can get email confirmation.

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

Yeah.

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

Yeah, that seems good to me.

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

So I'm wondering are there people on the phone who feel comfortable leading us through groups 1 and 2 and possibly presenting these.

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

This is Michelle. So Eric Rose is a Standards Committee member and he led group 2, so I would recommend that he do the group 2 presentation.

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

Thank you. And group 1?

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

Group 1 is John Carter and he's travelling today.

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

John Carter.

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

Yeah and Todd isn't on the line either.

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

Well maybe Michelle and Tricia can you follow up and see if they're comfortable with that?

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

Or Mitra, I wonder if...

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

Oh yeah, I am in group 1; I was in John Carter's group.

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

So if John is not available to present that to the Standards Committee, Mitra could you do that?

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

Yeah, I can do that. What time is your, I don't have this on my calendar, like the Wednesday one. I can ask Becky to send it to me and then I can come in-person; it is in-person meeting or telephone?

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

Yes, it's in-person.

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

It's in-person.

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

Oh, okay. Yeah, I can drive to the meeting. Yeah, okay.

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

Okay, so do we want to just quickly go through these slides for groups 1 and 2 and see if there's any...

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

Yes, yes, let's do that.

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

...additional comments or if we can live with them?

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

Yes.

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

So I'm, let's see, I need to get back to that. Patricia or who's driving the Adobe?

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

I think they're queued up now, group 1.

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

Yeah.

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

So Tricia, do you want to just kind of walk through the slides and anybody on the line who has a comment...is now...

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

Okay. Umm, I g...there was a concern about the maturity of the pharmacogenetics or genomics; excuse me...

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

Um hmm.

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

...the pharmacogenomics for any recommendation about standards, umm...

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

Well there is a pharmacogenomics standard now that's been worked on for about 4 years, but is actually part of the FDA's requirement, so it might be worth looking at that.

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

So perhaps that was misander...there's probably a misunderstanding there about what's available.

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

It's actually a vetted, matured standard, it's a domain within the Study Data Tabulation Model for submission to FDA and it's now going through ballot at HL7 and CDISC in terms of putting it into the bridge, but the actual submission piece is finished; so that's pharmacogenomics.

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, umm...

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

Maybe we need a bullet that just said somebody should look at that before we say there's nothing.

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

Well, this falls under the heading of adopting in regulation standards that are not mature.

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

It's mature.

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

...mature.

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

The regulation standard that I hear you saying Becky is the Study Data Tabulation Model. It is in ballot related to bridge...

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

No, no, no, no stop.

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

Okay.

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

The SDTM is finished; it's already balloted; it's going to be required by FDA.

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

Okay.

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

Okay, so what's going through ballot then; I don't understand.

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

The representation in bridge is going through ballot in HL7...

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

Ah, okay.

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

...but the other one is a CDISC standard that's already mature and being required so it should at least be on the list to look at. It's had about 5 years of work on it and it's finished.

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

So it just sounds like the members of group 1 were just not aware of that.

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

Ah, maybe not. Maybe Mitra wasn't on that phone call, because it is...

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

Okay.

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

Okay, so we can add it to the...to this and then on Wednesday, if John can't make it, I can present that, the domain within SDTM that focuses on pharmacogenomic domain.

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

Yeah, that's right.

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

Okay.

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

Okay.

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

So, great. So the common clinical data set definition, vocabulary standards; we could probably...this is probably a place where we can express the concerns we have on the general slide, uhh...

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

Yeah, I think repeating that general bullet...

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

It's all there.

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

...that more vetting is needed, this would be a good place to repeat that.

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

Yeah. But I think these three bullets are still accurate, too.

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

Yes.

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

Just lead with the general comment that more vetting is needed; okay.

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

Yeah, vetting and harmonization across the...especially across federal agencies.

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

Okay.

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

So maybe just in the interest of time we can just go through these quickly and see if there's anything we can't live with.

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

Yeah.

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

And then if we have little wordsmiths, we can send them back later. So...

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

Very good.

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

So right. The next...on slide 7, if we can go to the next slide.

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

Slide 7, I think.

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

That top one; so we just disagreed with that workgroup 1.

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

(Indiscernible)

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

So, I think we want to change number 1 on slide 7 to disagree with the NPRM but to recommend considering augmenting CVX with NDC for potentially different use cases; but not replacing CVX with NDC.

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

Well it's augmenting the record to include NDC as opposed to augmenting...

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

Yeah.

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

...CVX, which would be...

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

No, you're absolutely right.

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

Yeah, okay.

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

Absolutely right.

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

So, we're good?

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

Jamie, do I need to talk about specific use cases on Wednesday or just say it?

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

I don't...I think just, you know...

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

...okay.

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

I don't think so.

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

Okay.

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

It's possible that the committee will ask questions.

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

Okay.

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

And then the immunization history and forecast, last one, also just needs to be harmonized with what we were saying.

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

Right. And so, and again, I'm not familiar off the top with what the NPRM says on page 174; does it say NDC should replace CVX there also?

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

...74...

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

Because that would be another place, particularly for the history where we would disagree with using the NDC.

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

Ah, okay. They say they are looking for comment on the maturity of bi-directional immunization data exchange activities and whether we should propose to include bi-directional immunization exchange in our certification rules? Commenters supported inclusion of bi-directional immunization data exchange...understand that HL7 version 2.5.1 implementation guide for immunization messaging release 1.5, they are proposing to adopt for this criterion provides improvement that supports bi-directional exchange between health IT and immunization registries; including segment...the segments for querying a registry, receiving information and sending a response to the registry. Additionally we received comments specifically recommending that immunization forecast information and clinical decision support guidance provides results in accordance with the Advisory Committee on Immunization Practices or ACIP recommendation.

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

Yeah.

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

Okay.

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

So this is more focusing on data exchange, the HL7.

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

And so I guess for that purpose then, we would support using CVX with the ability to augment, in that case the...potentially augment the registry with NDC.

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

Okay. That's right.

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

So if we just incorporated all those changes into this slide, do we need this number 4 placeholder?

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

No.

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

No.

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

Okay.

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

So, are we good to go to the next slide?

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

Yeah, so I guess...

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

So is that it for group 1?

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

Yup.

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

That's it for group 1.

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

Okay. Thanks for agreeing to support that Mitra on Wednesday.

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

Oh, you're welcome.

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

Yes. Thank you.

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

We forwarded you the invitation.

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

Ah, you're welcome. Yeah, I received the invitation. And when I get up, Michelle and Tricia, I get the updated slides before Wednesday?

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

Yeah, that...

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

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

Okay, next slide.

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

And workgroup 2, if Eric isn't here, is there anybody on the phone from group 2?

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

I think Asif and Dr. Brown are both...

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

Well, I'm...

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

Yeah, I'm...

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

...hearing none, maybe we could just go through them and see if people on the slide have any comments.

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

I'll remember certain parts, I don't think I'll remember enough to actually lead this, so, I think going through would be probably the best thing, honestly.

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

Well and I...this is Jamie; so I remember numbers 1 and 2 on slide 9 and agree with both of those. And I also, I would agree with the sub-bullet on pedigree, but I'm not sure if that's exactly the way we'd want to say it. I guess we can leave it.

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

So we're okay with this slide?

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

Yeah...

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

Next slide.

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

And so I know Eric has said he was out because of some family issues, I hope he's able to make the meeting on Wednesday. I guess we probably need a back-up person to present if Eric's not able to...

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

Well let's check with Eric and then we can follow up and see who...

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

Yeah. Okay. Okay.

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

All right, next slide, please.

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

So it would seem that some of these, I don't know that we need to include all these concerns about NDC I think because what we're actually recommending now is to augment the CVX with NDC rather than replace.

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

Um hmm.

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

Yup.

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

Yes.

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

Tricia's got the overarching comment to this whole slide or, that's...

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

Yeah...

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

...what that whole slide is on NDC.

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

Yeah. Umm, so, maybe there should be a top bullet above this whole...above all the current comments on this slide that just says, you know, the workgroup disagrees with the recommendation to replace CVX with NDC; however, for different use cases it may be useful to augment CVX in the record with NDC.

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

Okay.

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

And then just leave the rest of this, but, I don't know that we really need to go through it.

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

All right, slide 11, please.

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

Isn't the...isn't this part of that data set, the common data set?

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

Yes.

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

Yup.

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

Which means that race should be harmonized across agencies, because I know we keep running into the fact that we have FDA's race list which doesn't agree with another one from CDC and that doesn't agree with some other from other agencies.

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

So the overarching recommendation is that the federal agencies...

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

Get a race list for all the federal...

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

...should harmonize.

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

Yes.

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

Okay.

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

That's the overarching recommendation.

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

Yeah and that would go above the CDC race list bullet on slide 11, I guess.

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

And it goes for all the demographics, not just race.

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

Yeah.

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

Yes.

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

So actually, maybe that goes above this whole green box.

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

Um hmm.

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

On this slide.

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

It would really make it easier for standards organizations if all the federal agencies had a common set of demographics.

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 just wondering, you know the Federal Health Information Model, Federal Health Architects seems to me like that was part of the aspiration of that effort was...

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

Well aspiration is your key word.

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

Um hmm.

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

Yeah, it would be great if that works.

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

I think it kind of continues on the next slide, too; vital signs, body mass index...

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

Slide 12.

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

Yeah, both of those slides.

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

So, you know, in fact maybe the idea here would be to insert a new slide, in fact before slide 10, to say that the workgroup would like to recommend the federal agencies coordinate on demographics and then...

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

On the whole common data set.

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

...I mean, sorry, I mean before slide 11, yeah, between 10 and 11 insert a new slide that recommends that a greater interagency coordination on these standards. And then, so that...I think that certainly applies to the current slides 11, 12 and 14; I'm not sure about 13. And 15, so, yeah.

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

But aren't those part of the common data set?

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

Yeah.

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

So, I mean we have things for smoking status in CDISC for FDA and it would be nice if all of those would be common. So that seems to be the common theme for all the rest of the slides. Are there any other comments that...should we go through them specifically or is it just a moot point?

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

Can you show me the slide for the military history? Let me make sure I can live with that.

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

Umm...

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

Slide 16.

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

Next, we could advance.

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

Fine. Gee, umm, you know, I think that this reflects some of the discussion; I don't know that it reflects any conclusions. It was sort of my job, which I didn't do, to try to express my guarded optimism for the use of CT, I think, for collecting this sort of information. Umm, and honestly, the language isn't al...is not so bad in the proposed...in the proposal. No, no, I guess it's just unclear why...it's pretty clear to me why it's separate from traditional occupational history, I have to say. Either that or you have a bad job, holy cow.

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

So maybe that's supposed to be...umm, yeah.

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

You know and I think the second bullet is, you know, it's not...I mean surely the NOAA and the like are not...the same category as folks with boots on the ground, I suppose; but I don't know that, I mean, I think the real, the thing that I would agree with is that there needs to be, you know, SNOMED C...further vetting of the utility of CT and if it would...could be augmented in the US edition, then great. But I don't think it's...yeah, I mean I think the wording as we see it in the original proposal is probably okay.

And anything that...where there's a need for additional granularity, I mean, as we've looked into it there's been, umm, just doesn't get down to the level of detail I think that we would hope for. And they extend, you know, additions to the US extension I think could be proposed, you know gainfully and I'd be okay with that. And I think...worrying too much about public health service and NOAA when there were however many millions of folks involved, but, you know, it does apply to. I don't need to worry about that too much.

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

Would you like that removed; that reference?

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

Well I mean, I think it's true, but I don't know that it's a top level bullet; I mean I think a top level bullet is, we'd like to...we'd support the use of SNOMED CT, you know, and it's augmentation as necessary in

the US extension. And then, you know, we can surely contribute between the VA and the Department of Defense and as we come upon the need for new CT terms in the extension then great.

The third bullet I think is right, and that's something we're all pretending doesn't exist, but I mean the number of contractors that were in Southwest Asia is huge and we're not paying attention to that, I don't think as well we should. So we can leave that. So I think it's just changing the order and putting cautious optimism for the use of CT for occupa...you know relevant occupational history and the like and with exten...additions to the US extension and I could be happy with that.

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

When I make the edits and turn these around, we can have them redistributed.

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

Okay.

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

Do we want to promise to, you know, have a...just want to make sure everyone gets a chance to review them; we're on a very tight timeline.

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

So materials were supposed to be due today; so I think we need to get any comments back by end of day today.

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

Okay.

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

Okay.

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

So I will make the edits and turn it around by 2 p.m. Eastern...

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

Okay, great.

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

Okay.

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, you know all comments and edits at that point are welcome; I will do my best here to capture this, so.

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

Okay, so are we ready to open up for public comment?

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

Michelle, I had one question on the last slide. So the recommendation is to add the MOS, the Military Occupation Specialty as extension to SNOMED CT?

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

Is that a question for Steve Brown?

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

Yeah, that was a question for Steve, yeah, he was talking. Yes.

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

Steve, are you on mute?

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

I think it's going back to the, wouldn't it be nice if we could get this altogether. I don't know that...so it would be nice if CT would cover the MOSs.

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

I see, okay.

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

Right? And we don't know the extent to which it does or doesn't, honestly.

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

Okay. Okay.

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

Right; I mean...because, you know most of th...many of the MOSs I'm sure have a lot to do with other types of jobs, you know, like truck driver or something like that.

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

Yes...

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

And so, we just don't know.

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

Yes, yes. Yeah, I used to work on DoDs EHR and we had to add a field MOS into the demographic page and they are like, what do you need, like infantryman is 11B and indirect fire is 11C, and infantry enlistment option is 11X; completely different codes.

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

Historical designation, or not historical, they're in use, the designations in use and they aren't represented in any code system other than a coding system you find in the military.

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

Yes, yeah, and it's a two digit number and an alphanumeric code. And like the whole infantry is 11 and 11 then it starts with a letter after it; like corps of engineers is 12, so it is 12 and like then they have 22 MOS all assigned to different types of engineers.

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

Okay, were there any comments on any of the other intervening slides? I think we kind of skipped vital signs on slide 12 and smoking status. I mean, I guess we have the overarching comment about, you know better vetting and coordination. But I guess is there anything on those other slides that no one can live with?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No, I think they looked okay. And I need to drop off, unfortunately, but yeah, I'm okay with the rest of...

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

Okay, thank you Stan.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Thank you. Bye.

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

Okay, so hearing no other comments, are we ready to open up now?

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

I think so.

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

Yes.

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

Okay. Caitlin or Lonnie, can you please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator - 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 telephone 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

So while we wait for public comment, we are going to confirm with Eric to see if he can lead group 2; if not, we'll have to find somebody else. Tricia's going to do her best to send out updates from today's conversation as soon as possible and then hopefully we can get any responses back by the end of the day today. End of the day, who knows what that actually means, but hopefully we'll have slides in time to share them tomorrow with the Standards Committee.

Okay, so it looks like we have no public comment, but we did have a comment from Dr. Richards, in the public comment body. He had two comments; the first was, in order of increasing granularity which is the most comprehensive? This was in regards to Mitra's conversation; so it was early in the call. And then his other question is, another one...I'm sorry. If RxNorm is only a republished version of CVX and MDX there will be a potential for discrepancy. So I can share those with the workgroup as well, but those were his two comments.

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

Thank you.

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

Okay. So, we'll be in touch soon.

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

All right. And so I'll see you Wednesday and Becky, I guess you'll be on the phone?

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

I will, yes, I'm sorry to say; I've been gone for too long.

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

Yeah, I resemble that statement. Okay, I guess we're adjourned for this call; thank you very much everybody.

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

Thank you everyone for your hard work commenting on this; it hasn't been an easy process. Thank you.

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

Bye.

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

Yeah I appreciate it everybody.

Public Comment Received During the Meeting

1. In order of increasing granularity, which is the most comprehensive?
2. If RxNORM is only a re-published version of CVX and MDX, there will be a potential for discrepancy
3. Do we want to target only the 'low bar' of recording CVX only, not more granular with MDX or NDC?
4. Will that have any impact on providers?
5. Mention of where and how an implementer shall get an authoritative, always-up-to date set of codes (either downloadable, or via REST URI)
6. Vital signs: what is meant by 'calculated'?