

Vocabulary Task Force Workgroup
Draft Transcript
June 24, 2011

Presentation

Operator 1

All lines are bridged.

Judy Sparrow – Office of the National Coordinator

Thank you, operator. Good morning, everybody, and welcome to the Vocabulary Task Force call. This is a Federal Advisory Committee, so there will be opportunity at the end of the call for the public to make comments. And if workgroup members could please remember to identify themselves when speaking...

A quick roll call: Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente

Present.

Judy Sparrow – Office of the National Coordinator

Betsy Humphreys?

Betsy Humphreys – National Library of Medicine

Present.

Judy Sparrow – Office of the National Coordinator

Stuart Nelson?

Stuart Nelson – National Library of Medicine

Present.

Judy Sparrow – Office of the National Coordinator

Marjorie Rallins? Stan Huff couldn't make it today. Chris Chute? Marc Overhage? Daniel Vreeman?

Daniel Vreeman – Regenstrief Institute

Present.

Judy Sparrow – Office of the National Coordinator

Floyd Eisenberg? Donald Bechtel? Patty Greim? Jim Walker?

Jim Walker – Geisinger Health System

Here.

Judy Sparrow – Office of the National Coordinator

Chris Brancato?

Chris Brancato – Office of the National Coordinator

Here.

Judy Sparrow – Office of the National Coordinator

Andy Wiesenthal? Bob Dolin?

Bob Dolin – Health Level Seven International

Here.

Judy Sparrow – Office of the National Coordinator

Kevin Brady?

Kevin Brady – U.S. House of Representatives

Here.

Judy Sparrow – Office of the National Coordinator

Ken Gebhart?

Ken Gebhart – National Institute of Standards and Technology

I'm here.

Judy Sparrow – Office of the National Coordinator

Good. Lynn Gilbertson? Nancy Orvis? Marjorie Greenberg?

Marjorie Greenberg – Centers for Disease Control and Prevention

Here.

Judy Sparrow – Office of the National Coordinator

Anthony Oliver? Did I leave anyone off?

Asif Syed – American Medical Association

Asif Syed, AMA.

Judy Sparrow – Office of the National Coordinator

Asif, OK. Thank you. All right, well, thank you, and I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente

Well, thanks very much, Judy, and thank you, everybody, for joining the call today. We are continuing our ONC summer camp activities now. Now that it's officially summer, welcome to summer.

We have just a couple items on the agenda today. We did receive a letter from NCPDP outlining some recommendations in terms of our selection of vendors to be recommended for allergy and allergen information, both drug and nondrug. And so, we can take, I think, a short while to go through that and review that letter. One of the key recommendations in there is that, in addition to RxNorm and UNII that we had talked about, we should also include SNOMED and free text capabilities. And so, we'll certainly want to take a look at that letter.

I think that most of this call is going to be focused on one of the core issues that we've really been grappling with, which is having to do with the implementation of vocabulary subsets that are used both in certification and in the meaningful use program. So some of the issues there are that if we specify a particular fixed subset, an enumerated list of codes to be used for certification testing, then how can it be ensured that the EMR systems that are certified can handle other codes or other terms from the whole vocabulary that is the actual adopted standard? And so, how do you make sure that the system doesn't break if it gets something out of that inoriented list that was used in certification? And then also, how does that work with updates to subsets that are needed and so forth? And so we're going to have a good discussion there and understand from Ken Gebhart at NIST their approach to certification on the vocabulary side.

So those are our two agenda items for this call. Is that acceptable to everybody, or does anybody want to add something?

Clem McDonald – National Library of Medicine

This is Clem McDonald. I just got on. I just want to note that I'm here.

Jamie Ferguson – Kaiser Permanente

OK, thanks, Clem. So let's see. Betsy, I'm not sure who is the right person to lead us through the NCPDP letter review.

Betsy Humphreys – National Library of Medicine

I'm not sure either.

Jamie Ferguson – Kaiser Permanente

Is Stuart on?

Stuart Nelson – National Library of Medicine

Yes, I'm here, but I don't think that I should lead the discussion.

Clem McDonald – National Library of Medicine

I saw this letter a long time ago (this is Clem), and I didn't see anything controversial about it, but maybe I'm not aware of what kind of [indiscernible].

Betsy Humphreys – National Library of Medicine

Well, this letter was sent to us on May 24, which probably seems like a long time ago, but it isn't all that long ago. I think that it's interesting, because the measure developer—when we were talking with the Quality Group about the measures and what was required there, they also brought up the issue of the use of SNOMED for designating some of the allergens, although here I don't know whether they're referring to (let me look at it) the use of SNOMED or—

Clem McDonald – National Library of Medicine

I thought they were saving UNII for the nondrug things.

Jamie Ferguson – Kaiser Permanente

Yeah, no, that's correct. I think they're saying that free text may also be needed. And there's a comment in here about reporting the reaction in SNOMED CT terms, descending from clinical findings.

Betsy Humphreys – National Library of Medicine

Yeah, I recall the issue about the reaction was also the—on the quality measures side, they were also recommending SNOMED for the reaction. And in looking this over and thinking about it, I think that the issues that we're going to have to discuss, again, around these allergens—and particularly because, in the context of measures, we're concerned about allergies to other things besides just drugs—we're going to have to go through this over there as well.

Jamie Ferguson – Kaiser Permanente

In my mind, the key recommendation is the first bullet on the top of page 4, which is, "Allergen and drug sensitivity concepts not found within RxNorm and NDFRT sources should be expressed in interoperable exchanges using free text. And along with free text, systems may include an interoperable code reference to SNOMED CT, UNII, or a proprietary code set as appropriate."

Betsy Humphreys – National Library of Medicine

Yeah, and I think that where we have otherwise been headed in our own discussion is that the requirements use UNII. So that would be distinction between what they're recommending here and what we had discussed prior.

Stuart Nelson – National Library of Medicine

This is Stuart. I would like to make a comment. One is that it may seem obvious to everyone, but it doesn't seem obvious to me that it's—we're talking about allergy classes as classes of allergens, and then all of a sudden we keep popping up this idea of SNOMED as the type of allergy. And I think it's important to clearly distinguish the two of these things: the type of allergy or the type of reaction and the causative agent for the reaction. In the discussion earlier this week, I also got a little bit confused there,

because it seemed like both things were being talked about at the same time, and I think it would help if we tried to make that distinction.

As far as entering free text is concerned, I think it's important that we always recognize that there may be a need for exception handling. And I think that that's something that NIST wants to address in dealing with it, but I don't think it's useful to designate free text as a standard—just saying that free text can be used in an exceptional circumstance when the appropriate terminology of a standard vocabulary cannot be found.

George Robinson – Medi-Span

Excuse me; this is George Robinson. I'm available to discuss points in the letter if that would help the group. I'm one of the primary authors.

Jamie Ferguson – Kaiser Permanente

Oh. Well, what did we miss in the discussion so far? Let's start there. [Laugh]

George Robinson – Medi-Span

Well, as a backdrop, the big impediment to the industry moving toward interoperable terminologies in the domain of allergy is the confusion that, in some circumstances, you're supposed to go to NDFRT for classes; in others, go to UNII for substances (and there's ambiguity in what a substance is) and then RxNorm for medications. And the intent of the group was to say, "This is impractical for an implementer." Overall, we suggest that RxNorm, the code, be used to represent the interoperable exchange. And the constraint is that the concept itself must be integrated in RxNorm for that to happen. And the idea was, if there's a concept that's not a member of an RxNorm source vocabulary or, in the case of the VA, a concept that's integrated in RxNorm, that rather than requiring someone to go to a UNII or to a SNOMED code, that would be optional. But what we thought was a good, pragmatic step in the right direction was to encourage the use of RxNorm as the primary vocabulary for allergy exchange, just in the context of medication.

Clem McDonald – National Library of Medicine

So it sounds like you've gone further and said the UNII code is needed; it should get an RxNorm CUI.

George Robinson – Medi-Span

Yeah, and the complexity from an implementer perspective is, if you go into the domain of foods or environmental agents, they're actually captured in a different way in the UI reporting. And then, as Stuart pointed out earlier, the current requirement in the clinical document architecture definition of medication allergies and drug sensitivities is a requirement to send the SNOMED type of it being a drug allergy, a food allergy, an environmental allergy or intolerance. And right now, there's not a defining attribute in UNII, for example, that tells you that. It's more the context of how that UNII is associated to an entity that tells you if it's a food or if it's a drug.

Clem McDonald – National Library of Medicine

But is the prime focus of the allergy world to intercede before somebody gets prescribed something? And we don't usually prescribe oranges or peanuts.

George Robinson – Medi-Span

Yeah, that's very astute. So it's nice to exchange information regarding the environmental agents and foods, but from a screening algorithm, I'm unaware of systems that actually (based on a diet, for example) assert a particular substance associated to that diet so you can actually screen for allergies. It's more a text-based presentation of that information to the end user.

Clem McDonald – National Library of Medicine

You may want to make some separation, because the use case, I think, is strictly to control—don't prescribe something that they're allergic to, right?

George Robinson – Medi-Span

Yeah, and an allergy lies in the eye of the beholder. I mean, that's part of the complexity of it. And I'd think the intent of the model for the allergy and drug sensitivity is that if you know that something's an intolerance versus an allergy and you know the reaction, you certainly may look differently at, for example, aspirin that's known to cause shortness of breath or bronchospasm. You're going to look at that much differently than if it caused an upset stomach in deciding to go with an alternative non-steroidal and -inflammatory drug, for example.

Stuart Nelson – National Library of Medicine

This is Stuart. I have a question. If somebody is allergic to egg as a food, does that mean that they need to avoid vaccines that are made with egg?

George Robinson – Medi-Span

Sometimes. The American Academy of Pediatrics, for example, says that's not necessary in their expert advice for MMR, I believe. On the other hand, I think it's a warning, a precaution at least, for influenza, but there are test dose protocols for even getting beyond that. But it's historically a trigger, and I think, for example, one of the leapfrog tests would test for the presence of an egg allergy documented to trigger an alert when an influenza vaccination is ordered.

Stuart Nelson – National Library of Medicine

But I think that's not [indiscernible] sort of a nonactive ingredient, in some sense, rather than, if you eat an egg and then take a flu shot, you're going to get in trouble.

George Robinson – Medi-Span

Right, so part of the complexity right now is (my understanding) the only FDA unique ingredient identifiers, or UNII, that are currently assigned RxNorm identifiers are those that are therapeutically active ingredients. So part of the difficulty in the current state is that an implementer would need to get UNII codes directly from the FDA, which range in the tens of thousands, and would have to independently figure out which of them are relevant or not, versus—we would really like to see implementers have the opportunity to go to a single source for all allergens. We believe firmly that RxNorm is the best publication process to do that. So I think, where we're going, our suggestion is, if we're really looking at this from a pragmatic perspective, and if you were trying to write a certification requirement, you start with the idea that if the patient is allergic to a medication, let's require that that's captured and exchanged in an interoperable manner using RxNorm.

Clem McDonald – National Library of Medicine

Stuart, are there barriers to that?

Stuart Nelson – National Library of Medicine

Well, I think it's reasonable to talk about having the active ingredients in RxNorm. I'm not happy about thinking of how to incorporate things like cow's milk or goat's milk into RxNorm.

Clem McDonald – National Library of Medicine

Well, isn't it yellow dye and that kind of stuff you've got to worry about?

Stuart Nelson – National Library of Medicine

Well, we've got to worry about all of these things.

Clem McDonald – National Library of Medicine

Well, I mean, of course we're going to have to [indiscernible] there are allergens, just billions of allergens, but most of them don't relate to prescribing. So is there a way to constrain those ingredients that are not active that are part of prescribing and they'll be contained in RxNorm?

Stuart Nelson – National Library of Medicine

Well, part of the problem is really knowing what the inactive ingredients of all these medications are, and I don't think we have a really good source of information on that.

George Robinson – Medi-Span

I think the FDA does catalog that. It's contained within the structure product label. I think they even have an inactive ingredient database. Our recommendation as a group was that the FDA really be charged with creating the subsets, and if that was done, then they could approach the National Library of Medicine for publication and integration in RxNorm. We just think it's too much of a burden for the industry to independently got to the thousands of concepts in UNII and make that determination.

Clem McDonald – National Library of Medicine

Are you saying the same thing about the RFT—that they should be police, too?

George Robinson – Medi-Span

We took the approach of “NDFRT is already integrated in RxNorm; in the attribute file, there is a way to identify which class domain a concept spans.” From a pragmatic perspective, we surveyed seven different enterprises, and we came up with a short list of approximately 30 very common classes that would actually represent the majority of documentation opportunities for class-based allergies, and that's listed in the letter as Attachment A. Our recommendation is that a subset of NDFRT classes could be used, but in interoperable exchange, we would recommend the RXCUI for that concept be used, not the NDFRT NUI or a code that starts with an N.

Clem McDonald – National Library of Medicine

And they already exist, it looks like, at least in your Attachment A.

George Robinson – Medi-Span

Yes. And a key thing from an implementation perspective is, we're suggesting that when you have a source system in focus and you're sending an interoperable exchange in the human-readable section of the CCD, for example, the text associated to how that allergen was documented in the source system is the description that should be exchanged so there's no ambiguity. We're also suggesting that the concept level that's chosen for interoperable exchange should mimic the level that's documented in the source system. So for example, in our discussion, we understand in the VA system, typically it's a clinical drug that's captured. So in that context, we would suggest that it would be the semantic clinical drug of RxNorm that would be sent. Many other systems may actually capture just the ingredients. In that situation, there are RxNorm ingredients that are around excellent interoperable touch points. But the common theme is that we're looking for concepts that already have been integrated in RxNorm, because then implementers have a single place to go to from a data perspective to translate those concepts.

Clem McDonald – National Library of Medicine

It makes sense to me.

George Robinson – Medi-Span

There was discussion earlier about SNOMED in the context of reactions. We were simply endorsing the previous recommendations that had been made for HITSP in that space. But descendants of the clinical findings of SNOMED would be very appropriate for that. I don't think we're at the point to comment as to industry readiness for that, but certainly we would endorse the usefulness of a SNOMED CT for that purpose. And some of the earlier work I did at Partners while I was there, in pooling information with UMass, is that we identified a fairly reasonable subset of SNOMED (I think less than 100 codes) that really would represent the vast majority of reaction documentation opportunities.

Clem McDonald – National Library of Medicine

Is that also available?

George Robinson – Medi-Span

It could be. We felt it was a higher priority as a task group to get medication terminology recommendations to the Committee. We would need to spend more time vetting a collection of SNOMED values. I think we can certainly share what's been collated between Partners and UMass. I believe John [indiscernible] may be on the line as well, if he's OK with that. But we can't represent it as being vetted to the same level as, for example, these allergy classes were.

And finally, I think we have an industry plea that we would really like to see some type of governance process that is applied to the maintenance of the quote-unquote “Federal Medication Terminology subsets” that clear use cases, at least in the context of interoperable exchange, are established and that the named Federal Medication Terminology subsets are actually created in a cohesive manner to meet those use cases. I think the way it’s been is, we’d identify these different Federal Medication Terminologies, and we’d identify particular certification use cases. And we’re suggesting that a terminology may be appropriate for this, but it was never built from the ground up to satisfy that requirement. And I constantly am a bit frustrated. I talked to individual members of the FDA, the VA, National Library of Medicine, and they’ve done an outstanding job in each of their domains in bringing forward the vocabularies. But I don’t see an empowered governance process to make sure that all these things work together. I don’t know where that oversight needs to come from; I don’t know if that would come ultimately from Health and Human Services. I know, from a regulatory perspective, it’s confusing. But from those of us in the trenches trying to make things work, it’s complicated.

Betsy Humphreys – National Library of Medicine

George, this is Betsy Humphreys. Thank you very much for going through this for us, and also to you and the whole group for this very useful input and all the work you put into it.

George Robinson – Medi-Span

You’re very welcome.

Betsy Humphreys – National Library of Medicine

So Jamie, I think that we need to obviously discuss all of these points, but perhaps today we want to get on to the presentation about the testing aspects.

Jamie Ferguson – Kaiser Permanente

Yes, that’s good. Let me just ask if there are any further comments and—

Clem McDonald – National Library of Medicine

Whether we can [indiscernible] thoughts on this from the members—I don’t know how many are paid folks on the Committee, but it sounds like the two focal points on this letter—is that RxNorm CUIs would carry everything, that there’d be an effort foisted on the request of the FDA to provide UIs that would be nonactive ingredients related to medication therapies, and then you have to put in text in there. Most of those things sound very reasonable. I don’t know whether we can get that to the FDA. Does anyone have a sense? Or, Stuart, would it be less of a barrier burden if they did do that to the original proposal?

Stuart Nelson – National Library of Medicine

I’m not quite sure I understood all of your question.

Clem McDonald – National Library of Medicine

My question is, if the FDA delivered this subset of UNIIIs that were inactive ingredients of medicine, would that make it feasible to wrap them into the package?

Stuart Nelson – National Library of Medicine

Well, at an ingredient level, we could wrap them into the package. I don’t think it would help just having them in the package. That’s probably not going to be very helpful in prescribing until we can actually link them to products.

Clem McDonald – National Library of Medicine

So it was your expectation that they would link to the products?

George Robinson – Medi-Span

No, right now we’re talking about a documentation exercise for allergy. So what I would expect would be the inactive ingredients that are—the subset that would be provided by the FDA would be brought in likely as a precise ingredient concept or a substance concept, whatever terminology type would make sense.

But in the attribute file, perhaps it could be given an attribute name of “inactive ingredient” or “incipient ingredient” or something that would uniquely identify it as being that subset so then implementers could present that as a subset by using the attribute file and the concept file.

Clem McDonald – National Library of Medicine

And George, does anyone on the Committee think it might be better that we don’t talk about these as allergies in the grand sense, because it’s such a daunting space to call them “medication” or “medication/immunization allergies” or—I mean constrain it to those things that are going to be prescribed or dispensed?

George Robinson – Medi-Span

If you’re trying to do this step by step, I would suggest therapeutically active ingredients contained in biologic immunizations and drugs are probably the subset you’re talking about.

Clem McDonald – National Library of Medicine

Yes, yes. But we also wanted to get the inactive ingredients in case those allergies come.

George Robinson – Medi-Span

That’s correct, and with the primary understanding that that’s a documentation exercise, we do not expect RxNorm to reflect the relationship, for example, of a branded product to those inactive ingredients. I think that’s beyond the scope of RxNorm. You’d be able to find that type of information in a structured product label of the FDA.

Clem McDonald – National Library of Medicine

OK. So thank you, George.

George Robinson – Medi-Span

You’re very welcome.

Jamie Ferguson – Kaiser Permanente

Any further comments on this subject?

Jim Walker – Geisinger Health System

Jamie, this is Jim. In terms of the quality data model, it sounds to me like we’ve identified six buckets: therapeutically active agents, inactive agents, and then nondrug substances; and then for adverse effect type, allergic and nonallergic; and then a third dimension is severity. Is it possible to summarize this discussion with what the recommendations are? It sounds like the therapeutically active agents—is it the consensus that it would be RxNorm CUIs?

Jamie Ferguson – Kaiser Permanente

Yeah, I mean, I think, as potentially expanded, the way we discussed.

Jim Walker – Geisinger Health System

Right, and for inactive ingredients, it would be also RxNorm CUIs, granted that UNII could be...

Jamie Ferguson – Kaiser Permanente

Well, with an exception capability, let’s just say.

Jim Walker – Geisinger Health System

OK. And for nondrug substances, the consensus is that that’s out of scope right now?

Clem McDonald – National Library of Medicine

I would suggest that we’ll get drowned in toxicology and every other darn thing.

Jim Walker – Geisinger Health System

Yeah, no, that makes perfect sense. And then for adverse effect types, allergic and nonallergic, is it the consensus that SNOMED is the code set for both of those?

Clem McDonald – National Library of Medicine

That's what it sounds like to me.

Jamie Ferguson – Kaiser Permanente

Let me come back to the question of the nondrug allergies. I mean, I think that for purposes of the quality measures that have been defined that are under discussion today, those may be out of scope, but they still may be required both in certification and in meaningful use reporting for other purposes in terms of summary records, information made available to patients for download, and things of that nature. So it's not that we're not going to make a recommendation of UNII, I think; it's that it may not be used in the framework you're describing for the current set of quality measures.

Clem McDonald – National Library of Medicine

Well, I mean, there's two [indiscernible] jumping. So you've got things like latex gloves, which everybody worries about, and then you have—in the allergen world of the laboratory, there's, like, 5,000 allergens. Chocolate to various kinds of leaves from the tropical jungles are all allergens, and it seem like it'd be good to find a boundary somewhere. We're not managing the whole allergists' problems, but maybe we are.

Jim Walker – Geisinger Health System

This is Jim. That is one of the questions: Do we need to be able to represent latex gloves and other nondrug substances?

Jamie Ferguson – Kaiser Permanente

Well, I mean, Doug, I don't know if you're still on the call, but my impression of the intent of summary reporting for patient summaries is, yes, you want to be able to represent whether it's food allergies or latex allergies or what have you. There needs to be some standardized way of representing this.

Jim Walker – Geisinger Health System

And for right now, would that also be UNII and RxNorm CUIs?

Jamie Ferguson – Kaiser Permanente

I think so, but I don't know. Stuart, you may want to speak to that.

Stuart Nelson – National Library of Medicine

My mind is just reeling with thinking about how I'm going to do all this, including allergens in RxNorm. I really don't see that, without an infusion of a lot of cash, we're ever going to approach anything outside of the recipients.

Jim Walker – Geisinger Health System

So this is Jim. Does that mean, Stuart, that you're recommending that inactive ingredients and nondrug substances would just be—the recommendation would be UNII for the code set?

Stuart Nelson – National Library of Medicine

Well, I think I can manage inactive ingredients from a list provided by the FDA. But getting outside of that arena into the leaf allergies and so forth, I'm just very, very timid about that. I don't think I can do that.

Jim Walker – Geisinger Health System

So you think, for the nondrug substances like latex gloves, we'd need to use UNII.

Stuart Nelson – National Library of Medicine

Yeah, I think you need to use something....

Clem McDonald – National Library of Medicine

Well, can I suggest that maybe we need a subgroup or something to think about this a little more?

Betsy Humphreys – National Library of Medicine

Yeah, this is Betsy. I also think that another issue is [indiscernible], because it may well be that just as we're phasing in things in other areas, this is not something that we're going to expect people to implement—I mean for nonstandard representation of nondrug allergens for phase 2. So I mean, we need to think about what would make sense. And then the issue is, I think we do need bigger understanding of the trajectory for UNII and what it will cover and when before doing it. So I think that's worth a discussion at another time.

Clem McDonald – National Library of Medicine

So just to clarify, once we get away from treatment-related or medication-related things, I think people have a simple-minded idea. If somebody says, "I'm allergic to strawberries," OK, we can put in strawberries. But when you go further, there's excellent proteins that are described, and there's another code system from Pharmacia which describes the distinct allergens that are at the base of the protein level. That's already something that patrons will know [indiscernible] into the testing area, and they almost got the allergen shot. So it's a very big space and maybe not the—

Jamie Ferguson – Kaiser Permanente

OK, so listen. This is Jamie. I need to cut in at this point, because we're going to spend this entire call talking about this and not get to the other topic.

Clem McDonald – National Library of Medicine

Go for it.

Jamie Ferguson – Kaiser Permanente

So is there anything that folks feel is truly urgent for this call to talk about, recognizing that we're going to come back to the subject? [Pause] Then in that case, Ken Gebhart, thank you for holding on through this discussion, and what I'd like to do is ask you to jump right into your slides and discussion if that's OK with you.

Ken Gebhart – National Institute of Standards and Technology

Oh, sure, and I've enjoyed the conversation—wasn't surprised at all at the longer conversation, for sure. So can we get the slides up?

While the slides are coming up, let me just mention—let's go to slide 2—just what we're going to talk about. I'm reacting to the earlier conversation at the last full call, where we started talking about how would you test some of the things that we were discussing. So what I'm doing today is to give you some initial thoughts about that. And the frame of reference here that I like to actually keep in mind is that I'm really trying to give you thoughts about the testability of the requirements as you've been talking about them, recognizing that you're still sorting out what those requirements are. And we'll try to be helpful today to sort of give you some ideas, but at the end of the day, NIST is primarily focused on how to test to a fairly well-defined set of requirements. And there's a bit of a gap here that somehow has to get addressed of sorting out what those requirements are. It's not NIST's responsibility per se, but we'll try to be helpful today. So we'll talk about how that applies specifically to LOINC, since that was the focus of the conversation the other day, and then we'll start a conversation about what does it mean for other vocabularies. I would like to emphasize this is a conversation about initial thoughts, not a proposed approach. I think there's a lot more we all need to understand, particularly NIST needs to understand, before we could get to the stage of something as refined as a proposed approach.

So let me go to slide 3 then. I don't think this is news, but you were talking at the last call about subsets of codes. You asked for some NIST input. We're here to do that. So let's go to slide 4.

Now, slide 4 is, I'll say, my best translation of what I thought I heard in the last full call. It's entirely possible that it's not complete and it's not correct, and your thinking may have matured since then, too, or matured as a result of some of this here. So I'm not suggesting this is an accurate statement, but this is

what I got out of the conversation the other day. So let me just read it briefly and look for reactions, and then, in the subsequent slides, assuming this holds up, we'll talk about what are some ideas about how you would test these kinds of things and what are some of the unknowns we'd have to sort out. So we certainly were talking about "An EHR needs to be capable of understanding a subset of roughly 2,000 of the most commonly used LOINC codes for lab result reporting." We've talked about the Regenstrief LOINC mapper's guide as part of that framework.

And then, what I thought I heard essentially came down to three kinds of requirements. The first was to be able to have an EHR need to be capable of performing computable activities on received LOINC codes, so the EHR would need to be capable of storing LOINC codes received in the lab results message in such a way that the EHR can perform computable activities on the received LOINC codes. We'll spend more time talking about what "computable activities" might mean. And then the second one was "Don't break if you receive an unknown LOINC code," and that was mentioned earlier today. And the conversation seemed to go along the lines of "Even you don't know the LOINC code, display the text description if the LOINC code is not recognized by the EHR." And the obvious implication is the text description has provided in the received message. Then the third one, which we've certainly been dealing with already, is in [indiscernible] stage 1 is transmitting LOINC codes, so directly instantiating LOINC codes and messages and documents being generated and sent from the EHR.

So maybe I should stop there and say, "Are these on target? Are there big departures from what you said you were talking about?"

Doug Fridsma – Office of the National Coordinator

Ken, this is Doug Fridsma. The only friendly amendment to R2 would be "Don't break if you receive an unknown code."

Ken Gebhart – National Institute of Standards and Technology

Right, so in general, while we were talking about LOINC's right now, this can apply and should apply to the other vocabularies as well.

Doug Fridsma – Office of the National Coordinator

Well, I guess what I mean by that is that somebody may have a proprietary system for some rare test that they're going to do, for which either a LOINC code doesn't exist or for which they haven't mapped their systems into LOINC for that. They may only have a textual description of that. And so, it isn't so much that it's a LOINC code that they don't recognize, but it's any code that they wouldn't recognize—try to provide at least some sort of textual description of that.

Jamie Ferguson – Kaiser Permanente

Doug, this is Jamie, if I could just butt in for one second. And sorry, Ken, but my understanding is, I think R1, R2, and R3 basically are generally accurate for—and we've talked about these capabilities beyond LOINC. And I'm not meaning that we have to have a broader discussion today, but I think that in talking about this for the LOINC codes for lab results reporting, this discussion or rather these capabilities that are listed here, I think, should be more generalized.

Clem McDonald – National Library of Medicine

I think we probably all agree that it would apply to most codes that we pick.

Jamie Ferguson – Kaiser Permanente

And Ken has some slides coming up that actually ask that question of generalizability. But it isn't so much they receive a LOINC code, and if they receive an unknown LOINC code, it's different than receiving just any code. That's still a laboratory test code; it may be a proprietary system code. But I don't want to quibble about it. I think we understand where we'd like to go with this.

Ken Gebhart – National Institute of Standards and Technology

[Indiscernible], and I certainly understand that [indiscernible] will be working with some HL7 code tables the other day, and there's actually a long list of possible code tables you could drop into that standard for

this. So I'm not suggesting you worry about this today, but I understand what you're saying, Doug. So thank you for the comment that—yeah, I am asking the question toward the end of the slides about generalizability. Does this say requirements work for everything or not?

Clem McDonald – National Library of Medicine

Could you talk a little about how you'd decide with the correct one code, what you're thinking is there in R3?

Ken Gebhart – National Institute of Standards and Technology

Would you mind if we get to that in the test slides that follow?

Clem McDonald – National Library of Medicine

No, I'm fine.

Ken Gebhart – National Institute of Standards and Technology

OK. And that's a good question, and it's a tricky one. But OK, so I'm going to move on then. Jamie, I see we've got about 10 minutes left here, so we may not get through everything, but you can guide me.

So going on to slide 5, I said it already; I'll just repeat again: I can give you initial thoughts. We've assembled a team inside of NIST to help develop the guidance I'm sharing with you today. But fundamentally, there's more work to be done about defining the requirements before you can actually figure out what is a conformance test to meet those requirements. It's not unusual; this is always what goes on in any software development life cycle, in your requirements definition life cycle. So I'm just trying to acknowledge where you are in the process.

So for requirement 1, we started this conversation during the last call: What does "computable activities" actually mean, and what EHR functionality would you test to do that? I've listed several ideas here; we talked about one of them. But before we go into them, let me just mention that I'm approaching this from what testers call a black box testing approach, which means we give an EHR input and we look at its output. It's a black box to the tester; the tester doesn't become concerned with how the black box does what it does to take the inputs and create the outputs, so we can only give it inputs and look at outputs.

I want to contrast that with what's generally called white box testing, where you actually look inside the EHR and see what it's doing and how it's doing it. And inside the EHR, you might look for a master file table that contains all these LOINC codes and verify that it's complete and it's maintained. You might look at the technical architecture diagrams and documentation of the product to verify that it actually handles the data internally the way you expected. You might look at the database design and verify that the data architecture provides the place to store the LOINC codes.

I'm not going into those kinds of tests today. That's generally not what we've done in meaningful use stage 1. And so, what I'm suggesting at this stage is the black box testing, where you get the EHR inputs, it does outputs, you try to evaluate whether or not it did what you expected based on the inputs.

So I asked this question at the last call: What would represent a computable activity? One of the comments was perhaps the flow sheets' display of received lab results perfectly mingled. So you have the CBCs end up together regardless of where they came from. Others, too, that are possibilities [indiscernible] support role against the received lab results maybe identified a reportable lab result based on the LOINC codes in the lab test. Certainly there'll be things EHRs need to do with clinical quality measures, which rely on LOINC codes for inclusion or exclusion decisions. And it's certainly possible to suggest that patient summary records containing local lab results would be appropriate LOINC codes with the consent of the EHRs as a possibility.

I think this list goes on, but I really wasn't clear about was what you considered computable and whether or not an item or two or all of these resonated with you or whether there's something else you had in mind. That's a question.

Jamie Ferguson – Kaiser Permanente

Well, Doug, I'm very glad that you're on the call, because isn't that a question for you? [Pause]

Doug Fridsma – Office of the National Coordinator

I'm still here on the call. I got pulled into a side conversation. Can you repeat the question?

Jamie Ferguson – Kaiser Permanente

The question is being asked, "What comprised computable activities for which the EHR functionality should be tested against these LOINC codes?" And so, we're talking about the possibility of flow sheet display, firing clinical decision support rules, and other functions.

Betsy Humphreys – National Library of Medicine

On the slide 5, and I think Ken's question is the kind of thing that...

Doug Fridsma – Office of the National Coordinator

So when I think about the testing, one would expect that you could send a LOINC code and then have something come back that required recognition that that LOINC code was—do something with that LOINC code that represented that it was executable. And so, a clinical decision support rule might be one that, if we sent a laboratory test result that was abnormal or something like that, it would come back and say, "This particular test is maybe contraindicated in this particular patient," or whatever. I think this group can think through—in fact, I was pulling up my meaningful use grid to see if there are some elements that are drawn from the meaningful use grid that could be used as a model to help us determine that. So, for example, there is a notion to implement drug-drug and drug-allergy interaction checks. There's physician order entry. There's an e-prescribing activity. But it may be that we need to go through the objective measures from the HIT Policy Committee and identify one of those that might be useful to test this notion of doing something computable with it.

So I envision that you would receive a laboratory test result and, rather than simply displaying it, actually demonstrate that the computer understood what that code meant and then was able to do something with it. And that means that there's a derivative product that comes out of that. Reportable laboratory results, clinical decision support, quality measures—all three of those things would be something computable, I think. And I have to think through whether patient summary records or flow sheet display would be the same thing. I mean, obviously, if you take the information and you're able to graph it or display it in a different way other than displaying the code in free text, it would seem to me that would require some understanding of what the test result was and how to display that effectively.

Clem McDonald – National Library of Medicine

Well, could I just comment on some of those things, given the initial statement of your random subset? You may have trouble getting hits, except for something like a flow sheet, where you'd really land on something that has a decision support rule. So maybe the alternative—you don't do random subsets for those.

Doug Fridsma – Office of the National Coordinator

Well, I think that as we move from stage 1 to stage 2 in terms of meaningful use, stage 1 was about conformance to a standard, being able to create a conforming C32 or to be able to create an NCPDP prescription. As we move to stage 2 and stage 3, we're starting to do things that—we have to string together functionality to provide behaviors, if you will. And so, the fact that testing computable activities strings together the ability to receive that LOINC code—and then a second thing is, once you have that LOINC code, do something with it—it may be that we can tie some of those other objective measures. And I haven't gone through it with sufficient detail to know where that might rest, but—

Ken Gebhart – National Institute of Standards and Technology

But I agree, Doug. And on slide 7, actually, is an example of some of that possibility.

Doug Fridsma – Office of the National Coordinator

It's very similar to what we would hope we could get to with some of the interoperability testing, which is the notion that I can send a laboratory test result using a LOINC code and that I can also receive back an acknowledgement that that was properly sent or that it was properly formatted or that it was received, stringing together the different tests to make a conversation, if you will. And I think NIST is particularly strong with figuring out ways to create those testing environments. And so, I think those are the kind of things—this particular group may be able to provide some input. And certainly the Implementation and Certification Working Group out of the HIT Standards Committee has been charged to look at not only a conformance testing but how you would create the script that would help you test multiple requirements and setting up that conversation.

Jamie Ferguson – Kaiser Permanente

OK, I know we're at time for this call, and I think it's pretty obvious we're going to have to come back to this topic.

Clem McDonald – National Library of Medicine

Does anyone know if most medical record systems can do flow sheets today?

Jim Walker – Geisinger Health System

This is Jim. I would think almost all could, but I don't know that.

Clem McDonald – National Library of Medicine

I would hope so. I have to read those emails from people that really threw me off. They sounded like they'd take and throw the medical record into a shoebox.

Ken Gebhart – National Institute of Standards and Technology

This is Ken. I just want to mention that when the flow sheet conversation came up, it did occur to me that that might be a new certification requirement that's not in meaningful use 1, so we'd be [indiscernible] possible about that.

Clem McDonald – National Library of Medicine

I think that space could be a way to broadly test our ability to manage LOINC codes—the idea that it would insert it along with other ones like it. There's that host of other little issues that we could maybe talk about online, Ken.

Ken Gebhart – National Institute of Standards and Technology

Yeah. So Jamie, I'm available whenever you want to resume this conversation.

Jamie Ferguson – Kaiser Permanente

OK. So it seems to me from this call, Betsy, that we're going to have to have more calls of this group than we have currently scheduled. And does anybody on the call disagree with that? [Pause] So I think, Judy, we're going to have to then look at identifying some additional times for other calls.

Judy Sparrow – Office of the National Coordinator

Right, I'll work with Kay. And you did have a joint call on the 29th of this month. OK, you want to do public comment now?

Jamie Ferguson – Kaiser Permanente

Yes, please.

Judy Sparrow – Office of the National Coordinator

Operator, can you see if anybody wishes to make a public comment, please?

Operator 2

Yes. If you are on the phone and would like to make a public comment, please press *1 at this time. 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. [Pause] We do not have any comments at this time.

Judy Sparrow – Office of the National Coordinator

Thank you, operator. Thank you, Jamie and everybody. [General thanks and farewells]