

**Clinical Operations Workgroup
And Vocabulary Task Force
Transcript
October 10, 2012**

Presentation

Operator

Ms. Robertson, all lines are now bridged.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good afternoon everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a joint call of the HIT Standards Committee's Clinical Operations Workgroup and the Vocabulary Task Force. This is a public call and there will be time for public comment at the end, and the call is also being transcribed so please make sure you identify yourself before speaking. I'll now do the joint roll call. We'll start with the Clinical Operations Workgroup. Jaime Ferguson?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jamie. John Halamka? Martin Harris? Chris Chute? Cris Ross? Donald Bechtel? Elizabeth Johnson? John Klimek? Joyce Sensmeier? Kevin Hutchinson? Becky Kush? Wes Rishel? Jay Crowley? Karen Trudel? Nancy Orvis? Terrie Reed?

Terrie Reed – Food & Drug Administration

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Terrie.

Terrie Reed – Food & Drug Administration

Jay's also on the call.

MacKenzie Robertson – Office of the National Coordinator

Sorry, who was that?

Terrie Reed – Food & Drug Administration

Jay is also on the call; he's probably on mute.

MacKenzie Robertson – Office of the National Coordinator

Oh, okay. Vocabulary Task Force, Jamie, we have you. Betsy Humphreys?

Betsy Humphreys – National Library of Medicine – Deputy Director

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Betsy. Andy Wiesenthal? Bob Dolin? Chris Chute? Dan Vreeman? Don Bechtel? Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Present,

MacKenzie Robertson – Office of the National Coordinator

Thanks Floyd. Jim Walker? John Halamka? John Klimek? Marjorie Rallins?

Marjorie Rallins, DPM – American Medical Association – Director of Measures, Standards and Informatics for the Performance Improvement Division

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Marjorie. Patricia Greim?

Patricia Greim, RN – Department of Veterans Affairs

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Patricia. Becky Kush? Stan Huff? Clem McDonald?

Clem McDonald – National Library of Medicine

Here, present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Clem. Marjorie Greenberg?

Marjorie Greenberg – Health and Human Services – Center for Disease Control

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Marjorie. Stuart Nelson? Are there any other members on the line that I may have missed or joined late?

Amy Gruber - Centers for Medicare & Medicaid Services

Amy Gruber, CMS.

MacKenzie Robertson – Office of the National Coordinator

Thanks Amy.

Daniel J. Vreeman, PT, DPT, MSc – Regenstrief Institute

Dan Vreeman from Regenstrief.

Anthony Oliver – Health Resources and Services Administration

Anthony Oliver from HRSA.

MacKenzie Robertson – Office of the National Coordinator

Thank you. And are there any ONC staff members on the line?

Farrah Darbouze, MPH – Office of the National Coordinator

This is Farrah Darbouze from Office of Science and Technology.

MacKenzie Robertson – Office of the National Coordinator

Great. Okay, with that, Jaime, I'll turn it back to you.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay, great. Well thanks very much everybody for joining the call today and apologies for the late notice. We did want to have a discussion about recommendations we were going to bring to the committee before the October committee meeting. Now, we previously had a review of the actual UDI rule, and so what I'd like to do is today, to jump straight into potential comments that we might make from the combined workgroups to the Standards Committee. Is that acceptable to everybody?

M

Yes.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay, great. Now, Betsy you just noted that you had sent an email to ... I'm sorry, did someone else just join? Betsy, you mentioned that you had just sent an email with a few ideas to the entire group, and actually, that might be a very good starting place. In fact, your point number one is one that I was going to propose that we talk about, in terms of the inclusions and exclusions for the UDI. And as context for that, from the clinical operations perspective, something that we had previously noted was that all devices that are going to be prescribed, or that may be prescribed using standard transactions, should have the standard identifier. But, I'm not sure if that is exactly the same as your comment Betsy, I hope it's acceptable to start on that point of discussion.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes. It seems to me that ... and I'm glad we have the experts on the rule on the call, but as I read it, the exclusion of retail devices, except those that are only available under prescription when you go to the retail place, you know, where you would have to go to the equivalent of the pharmacist or whatever to get them. It seems to me to be quite problematic because of the fact that other types of devices, which are then just generally available from the pharmacy or from a store or something, are often the subject of prescriptions, even though the device itself is available retail. Even if somebody may be recommending that you get a glucometer or you have an X or a Y or a Z, so it really seems to me that, and FDA is soliciting comments on this very point in the rule, and it does seem to me that it would be very reasonable for the Standards Committee to comment that the exclusion of such devices means that we won't have a unique identifier ... public unique identifier in the database for a lot of things that are routinely prescribed.

M

I support that because all the blood pressure cuffs and the home glucose monitoring, lots of those things are not, don't have to be prescribed.

M

Even drug testing.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Right, things that don't have to be prescribed, but things, but they may be prescribed and they may also be paid for through standard claims transactions.

M

Well, that certainly goes for the glucometers. That might also be true for blood pressure cuffs and the like, thermometers and those kinds of things.

Betsy Humphreys – National Library of Medicine – Deputy Director

The other issue, of course, is that if you imagine a wide variety of care and things taking place in the home and then the results being reported up the line in some way, the inclusion of the unique device identifier in that context would also, it seems to me, to be very helpful. Plus, there's the recall issue, obviously, what do you care whether you bought it retail if now it's being recalled. You would like to be able to use the same system.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. So what's the comment that we might consider making on this?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

This is Floyd. I think what I'm hearing is that non-prescription devices should be included, is that correct? Is that what I'm hearing from Clem and Betsy's comments?

M

Well, I think you might want to hold back on things like tongue blades and gauze pads, but they might be prescribed ...

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Right, it's a matter of defining devices because I was thinking of even things like braces, like a back brace, to see is it effective, has it worked, has that been tried before you do something else. But, some of them may be prescription and some are not. But, you're right, so how deep does device definition go?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, I think that the rule, the proposal as it is written, although there is, as I say, there are explicit...there's an explicit request from the FDA for comment on this particular issue, just excludes them all. And so I guess the issue is, how do you frame a recommendation that seems reasonable? I think the exclusion of all of them is going to really limit...be a significant limitation of the utility of this.

M

Definitely. Is there any way to know how they think of as non-prescribed, that is never prescribed or can't be paid for by somebody or...

Jay Crowley – U.S. Food and Drug Administration

This is Jay Crowley from FDA. Devices are determined by the agency, prescription or over-the-counter. Occasionally people write prescriptions for over-the-counter devices, but the Agency has a very clear determination about whether the device itself is actually an over-the-counter device or a prescription device. I really have to agree with how the device ... what the device is being used ...

Betsy Humphreys – National Library of Medicine – Deputy Director

So it's like ... I would assume that the distinction is like a prescription medication versus an over-the-counter medication. You might ... a physician might tell you to use either one, but you would...you obviously would have to go through a different process and deal with it differently in order to get one that was only available under prescription. And I guess ...

Jay Crowley – U.S. Food and Drug Administration

... that's right.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, I still feel that it would be reasonable, in the context of Health IT Standards Committee to make some comment about this, because I really think that the exclusion of devices which are probably, are pretty integral to health care and even more so when more care is provided in the home and can be paid for by Medicare, is a problem.

M

I would agree. Is there some way to find, is there another cleavage plane in the definition that devices used to decide ... to adjust therapy or follow treatment, which would be measurement devices, or warn, in some way to improve as a therapy. Is there some way to find to include more of them, and not include every little tiny thing? So we wouldn't – the boundary of prescription seems too blunt.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Is there some way to define it based on devices that are, for which patients are reimbursed, although I don't know if that's the best definition, but does that help?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well patients are probably reimbursed for crutches, too.

M

Well those and back braces and heating pads and – there's a lot of things you'd like to know about probably.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah.

M

So I'm actually hoping the person from the FDA might have some insight, if there's another cleavage plane besides prescribed, non-prescribed.

Jay Crowley – U.S. Food and Drug Administration

Unfortunately, not an easy one at this point. Jay Crowley from the FDA again. I mean, it's something that we struggle with, so, if you can sort of qualitatively describe the kinds of devices that you think should or should not fit into this category, we can try to create a regulatory construct around those. But at this time, we don't – our problem is we don't really have one that allows us to do as you're describing, but we might be able to come up with one if you describe the qualities that you're looking for.

M

Well those things that patients would use to measure their qualities – laboratory or biologic qualities to help decide on success or failure of treatment.

M

That would be one. That would be the measuring devices. But then there are also the treatment devices, and I'm having more trouble with that, but they range from heating pads, back braces that might be harder. Can I get help from anybody?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah, one of the examples that has been present in some measures was compression stockings, for instance.

M

I mean, there may not be any boundaries because 4 x 4's and gauze pads and bandages, kind of get into there in some ways, but probably less urgent, less important to track.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well it seems that there are different ways to tackle this question on sort of inclusion exclusion. One is, I think, sort of, what Clem had just referred to of looking at existing definitions of measurement devices and treatment devices and then describing sort of the parameters for those that would cause them to need to be identified. But another one is what I had mentioned earlier, which is essentially things that are prescribed, that in an electronic prescription transaction have to be identified. And I think, you know, so there are problems with all of those, which probably Jay is why you don't have a clean definition. But it would seem to me that in terms of maybe the right way to think about it is come at it from a different angle of what's in the EHR. So if the, if data in the EHR about devices that were used in treatment, if that then may have an impact on surveillance, recall processing, etcetera, then maybe there's a different way of defining what it is that really needs an identifier. Or is that just saying anything that's in the treatment device category needs an identifier?

M

Well the pharmacist, pharmacies dispense some things, certainly glucometers and needles and syringes and, but, is there anyone on from the pharmacy industry who could say whether that's a, there's a big list with some definable boundaries in that? I mean, there's urinary catheters, there's TENS devices, again, I don't know if those are prescribed through pharmacies, but there are a lot of, there are devices and supplies that are, you know, bags for colonoscopies, no, colon – well, never mind.

Betsy Humphreys – National Library of Medicine – Deputy Director

We know what you mean. So, but in terms of, it seems to me that we need a little more, it seems to me that ...

MacKenzie Robertson – Office of the National Coordinator

Hi, I'm sorry, this is MacKenzie. Can I just ask whoever is typing, if they could just please mute their phone, because we're getting a lot of interference. Thanks.

Betsy Humphreys – National Library of Medicine – Deputy Director

I guess my point would be. This is Betsy. My point would be, that would we all agree that there are some categories of these devices which are currently excluded because it's difficult to narrow down in the proposal, that we really ought to figure out a...or try hard to figure out a way how they could be included. Then it seems to me that that would be sort of the general recommendation and then maybe we could come up with some suggested approaches or ideas about how this would be done and without necessarily feeling that between now and next week we have to come up with the world's definitive definition of how to do this.

Marjorie Greenberg – Centers for Disease Control and Prevention

This is Marjorie Greenberg. Hello?

MacKenzie Robertson – Office of the National Coordinator

Yup, we can hear you. Go ahead.

Marjorie Greenberg – Centers for Disease Control and Prevention

Yeah I generally agree with the discussion. I'm thinking about the, I think it's the provider ID, I can't remember now whether it's the provider ID or the plan ID where CMS actually came up with some other kind of number for things that really didn't qualify as a provider or a plan – I think it was a for maybe a third party adminst – that's in the plans, I know, third party administrators, whoever, but that it was good to be able to track them, and I don't know whether the FDA would be receptive to something like that. But I certainly agree that a lot of these types of things that you've mentioned, I mean glucometers is a real obvious one, but it would be good to be able to track, because of, you know recalls and use and as Betsy said, they're a pretty integral part of home management of your health condition. So, perhaps as you suggested Betsy, we need to identify this as a limitation of the standard and to say that we think it needs, there needs to be a way to capture at least some of these more significant over-the-counter, non-prescription devices and throw it back to them to have them think of how they can do this.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, I think that probably we could be a little more helpful than that by identifying some categories like where Clem started, with those that are actually measuring something...

Marjorie Greenberg – Centers for Disease Control and Prevention

Right, it's just that, you know, when you start going down that route, well, then some things work and some things don't. But, I defer to you all, who have more clinical information. But, I agree with you, that that leaves out a significant amount of types of devices or products that you would ideally want to be able to track. And they might want to distinguish between things that are prescribed or require prescription and things that don't, so that changes also over time.

Betsy Humphreys – National Library of Medicine – Deputy Director

But the rule specifically covers prescribed devices and I'm – and based on what Jay just told us, I assume that those refer to devices that are just not available for you to pick off the shelf. I mean, you have to go to ...

M

But at the same time, what I was focusing in on Betsy, were the devices that may be available at retail, but that may also be prescribed.

Betsy Humphreys – National Library of Medicine – Deputy Director

That is, that they're the subject of health professional orders.

M

Correct. So, anything that's the subject of a professional electronic prescription that then needs to be identified not only for the prescription transaction and the tracking of the dispensing of the device and so forth, but also through to the payment system, like other things that may only be available by prescription. It seems to me that we should have a consistent identifier standard for anything that's electronically prescribed by an authorized professional for treatment purposes.

M

Yeah, and certainly a lot of things, including crutches and wheelchairs and those things that are prescribed. I just, you know, the CPT, I mean, not CPT, HCPCS has codes for some of these and I've been trying to find them just now on the computer, I can't. Whether that would be a helpful category.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

My concern, this is Floyd, is it possible also to order gauze dressings and do we want to include those.

M

It certainly is, I did. But, maybe that's not that bad, I don't know.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Now, I just found the – it's the Global Harmonization Task Force from May, 2005, which I assume – I imagine the FDA may be familiar with its definition of medical device, that might be helpful; that does extend beyond prescribed devices, it doesn't talk about prescription at all, as something on which we can model a definition. Or they can.

M

Can you read it?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Well, I can read a bit of it and I can forward it. It's basically the, get back to the statement, medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software material or other similar or related article. It could be too expansive, but I'll happy to forward it and see what you guys think.

Terrie Reed – Food & Drug Administration

This is Terrie. We are familiar with that. I guess, like Betsy and a couple of you have referenced, it probably would be very difficult to come up with an exact regulatory definition for you on the phone, but if you write down maybe what your concerns are, exactly what you want to get out of, meet the criteria, and we could work through that based on comments about the criteria that you want devices to be included for UDI.

M

Well I think a measurement device isn't, I don't want to say no-brainer, but is a fairly well bound thing, which puts out a number reflecting some patient's state. The treatment devices we may get into trivia if we don't find the right boundary.

Terrie Reed – Food & Drug Administration

Okay.

M

I guess it cou – and if there is some insurance – I mean, the insurance companies decide what they pay for, if someone has access, there might be some good hints but just saying an enumerations of what they pay for as devices, we might then be able to deal with the treatment devices in a rational way.

Terrie Reed – Food & Drug Administration

That's a little tricky because it's hard to put – we're having a lot of discussions about claims data and what insurance companies pay for, which is hard to do because they don't have UDIs.

M

Well, even looking at names, you know, might give us – it might galvanize sort of an idea about what we really mean by treatment devices, if one could see the spectrum.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, or, this may be a place where HCPCS could be used to identify essentially the classes of things that would be included in this ...

Terrie Reed – Food & Drug Administration

That's true, that's true.

M

I just, glancing at what I can find in HCPCS, it's mostly exotic things that probably are prescribed, glue for joints and things like that.

Betsy Humphreys – National Library of Medicine – Deputy Director

So Jaime, I think where we are is we want to formulate a recommendation that says what we hope to include and then provide some suggestions of helpful ways forward to define that subset, right.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. I think that's right.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, I think the overarching statement of what we'd like to have is what you said, anything that would be prescribed, right?

M

Yeah, I agree.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, we would have an even system and then we could then sort of under that comment on some of the categories that are frequently prescribed, but are over-the-counter and are important devices and see what FDA can deal with that, too. And of course, I think that the Standards Committee can always say that they'd be willing to help, you know, further on in terms of interaction of developing input to revisions to address these comments or something.

W

Um hmm.

M

Yeah.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. That seems like a useful way to go for this comment. Okay, what other comments are top of minds for those on the call?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well of course, near and dear to our hearts here at NLM, is the fact that it would really be great if the UDI database, whatever was submitted to the UDI database had to include the LOINC code for every test that was generated by...that was done by the device or the test case. That would, in my opinion, be very helpful by moving the coding way upstream to the source of the data, and in terms of generating...having LOINC codes available for it.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. So, I'm not disagreeing with that, but how would that be maintained?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, the manufacturer has to update, is required to update when things change. And if they – if the device is the same, it would seem to me that if a device that generated test A suddenly becomes a device that generates the result of test B, then this is going to be sort of a significant difference that is likely to be a different device, isn't it?

Clem McDonald – National Library of Medicine

Well I could actually give an answer. So the labs, the instruments now have to, at least for certain class of instruments, have to report a 510K, I think it is, form to the FDA. And they have sort of essential equivalents, some test kit to test kit, and those things would define – if there was a difference in equivalence, it would be a different set of LOINC codes. Now the difference is, there would be more than one LOINC code for a lot of devices. The laboratory – this year have gotten very heavily onboard and I know that all of the eight large IVD, what do they call them, the device manufacturers, international manufacturers, have internally, at least, mappings from their codes and we've talked with a lot of them. So, they kind of know what the codes are, it would just be a matter of reporting in ahead of time, before the device came out would be when you're doing it through the UDI.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

So are we talking about a versioning in a sense of devices, does the UDI stay the same but there's some versioning?

M

Well, the LOINC code doesn't relate to that. The LOINC code might, will be probably more stable than the UDI, depending what the rules are about slight changes in the device.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

And that's, I think, a topic for another comment, perhaps.

M

Yeah.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah, maybe it's related to this and it might be different, you can let me know, but one of my concerns is two manufacturers making a similar device, each has a different UDI, but how do we classify them rather one is to just create another value set, but classify them all as the same kind of device ... I guess similar to RxNorm versus NDFRT for meds.

Betsy Humphreys – National Library of Medicine – Deputy Director

That's supposed to be taken care of by the requirement to submit the GMDN codes ...

Terrie Reed – Food & Drug Administration

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

... so that is a requirement and that's exactly why it's there, so that you will have a more general classification of groups of devices as well as the specific UDI.

John Halamka, MD, MS – Harvard Medical School

Hi, this is John Halamka. I've just joined late, sorry about that.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Hi John.

Betsy Humphreys – National Library of Medicine – Deputy Director

Hi John.

John Halamka, MD, MS – Harvard Medical School

Got my mother recovered from her hip fracture and headed home. So, this is the other great role I get to play, not just Standards, but health care navigator.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

So John, just to catch you up. We had a, I think, a very good discussion first on the inclusion and exclusion criteria for the scope of coverage of the UDI. Specifically, a comment on the exclusion of devices really proposing a comment against the exclusion of devices that are really integral to the care process, that can be paid for by CMS, specifically anything that's prescribed, including frequently prescribed over-the-counter devices, should be included. And there's some sort of fine-tuning on that comment that we're going to have to do.

John Halamka, MD, MS – Harvard Medical School

Great.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

And now we're talking about a comment to include the LOINC – in the UDI database, to include the LOINC identifier for all tests that are performed by the device, and things related to that one.

John Halamka, MD, MS – Harvard Medical School

Very good.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

So I think Clem, you were still talking about that.

Clem McDonald – National Library of Medicine

Well I think it's just, I think I said what I meant to say and, I said basically the LOINC codes would be also a generalization because there are fifty glucose tests, all which would ... in serum, which may likely have the same code. And then most instruments put out more than one...most devices put out more than one value.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. So one of the things that came up in that discussion was talking about the criteria for changing the UDI, and I know Betsy you, in your note this morning or in the discussion, you had talked about some of the conditions under which a labeler can essentially voluntarily change the UDI for an unchanged device. Certainly something else that I've heard a number of comments on is the – if the device itself doesn't change, but the labeler changes due to corporate ownership or something like that, having the ability to essentially track substantially similar if not exactly similar devices in registries and for clinical operations purposes. If that's a desired outcome, then figuring out how to do that when the UDI is changed is certainly a concern that I think the committee might want to comment on. So, who wants to start on that one?

Betsy Humphreys – National Library of Medicine – Deputy Director

Let me make a couple of comments. One is that it's clear in the rule deal with the case where a UDI is changed and the labeler, and I think Terrie will correct me if I'm wrong, but it actually covers the case where the labeler of the device, usually the manufacturers change, like one manufacturer buys another's product or another manufacturer. And, under the system that we have here, they're required to change the UDI if one labeler takes over the device from different one, because the UDI includes an identification of the labeler. So they're required to change it. They're also required to indicate the previous UDI when they do that. And then the rule states that within the UDI database, there will be linking of the records for the previous UDI and this one. So, depending on how that is handled and displayed and presented, you should end up with a situation where there could be multiple UDIs historically for exactly the same device, but in fact, there will be a connection among all of them, so you should be able to find out all the UDIs that ever were in place for a device.

What struck me, however, in reading it was that I gather that the same labeler, the same manufacturer, can change the UDI for any reason they want to. They just have to, when they submit the new one, connect it to the old one. And I guess my view is that having fifteen valid UDIs for the exact same device does not strike me as the ideal situation, although maybe workable if they're all very clearly linked and available as alternatives to each other. The same thing occurs, however, because of this issue of having multiple agencies accredited to issue UDIs, and you as the manufacturer of a particular device, can get a valid UDI from each accrediting body and use them all. And again, I guess theoretically this could all work, as long as we always can find all the UDIs that are valid for a particular device. So, I was trying to figure out in my mind what would be a recommendation, or what would be a statement from the Standards Committee about what the conditions or how this would have to be treated in the UDI database, or by the FDA, so that it actually works.

Clem McDonald – National Library of Medicine

Could I ask a question Betsy? The UDI will be attached to the label, correct, something a little bit analogous to the package insert.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, and we should be asking Terrie this, but ...

Terrie Reed – Food & Drug Administration

It's okay, I'm monitoring, you're doing great Betsy.

Betsy Humphreys – National Library of Medicine – Deputy Director

...but I think that yes it is, and that was the question that I had Terrie, if in fact I go to GS1 and get one and I go to the UPC Agency or somebody and get one, if I have two valid UDIs, do I have to put them both on the packaging?

Terrie Reed – Food & Drug Administration

We actually have a concept, primary DI number.

Clem McDonald – National Library of Medicine

Well, that's what I was kind of getting to. You wouldn't want to have, if you ended up with thirty UDIs to have thirty different package labels that people could stumble across to see what was really true now. So there is a general upper level number that applies?

Terrie Reed – Food & Drug Administration

Right. There, primary DI number.

Betsy Humphreys – National Library of Medicine – Deputy Director

So my question in all of this was if that's the case, I really wondered the value of having multiple records in the database for the same, exact product or whether instead of having that, you should have ... you should basically update the single record and have a history feature.

Terrie Reed – Food & Drug Administration

Well, that's what we're ... so the database is developed in that way, in the latter way.

Betsy Humphreys – National Library of Medicine – Deputy Director

Oh, that's kind of not clear from the way ... or wasn't clear to me in reading the preamble, but I must have missed it.

Terrie Reed – Food & Drug Administration

A lot of the database design is not in there, you know ...

Betsy Humphreys – National Library of Medicine – Deputy Director

Again, then maybe that reduces those concerns ...

Clem McDonald – National Library of Medicine

And what's the primary ID called, is it another UDI that's just picked out or is it a different thing?

Terrie Reed – Food & Drug Administration

I can read you our definition. An identifier that is the main look up for a medical device product and meets the requirements to uniquely identify a device through its distribution and use. So a secondary is an identifier that is an alternate look up for a medical device product issued from a different issuing agency than the primary DI. Those are, I'm looking at our vocabulary list from our database. And one of the things to note though, is that we are right today, in the middle of our external ... acceptance testing of our database, so we have sponsors and some other folks testing and actually looking at this vocabulary and how we have designed this, and giving us feedback. So what I say today may not be just like the proposed rule, how it all ends up.

Betsy Humphreys – National Library of Medicine – Deputy Director

So Terrie, on that point though. I understand that if I have one device and I happen to get two UDIs then I put one in the primary thing, I put the other one somewhere else, and I make that choice myself?

Terrie Reed – Food & Drug Administration

Yes.

Betsy Humphreys – National Library of Medicine – Deputy Director

Okay. So, that's one case. Now we go forward from that and I sell my device to another company. And the other company ... but it's still the same device. So the other company now has to issue its own UDI and I guess it would have to get two more, right, if it wanted to do the same things. So then I would pick one of the two new ones, which would now show up in the UDI record as the primary ID and the other three now would be listed as alternate IDs, is that how it goes?

Terrie Reed – Food & Drug Administration

Wow. There are use cases, it's possible. You know what might be useful, I don't know, is for you all to have a copy of this vocabulary.

Clem McDonald – National Library of Medicine

Yes. Because, but you know it gets back to what the public would like to look at, I think, and users would like to look at would be the label.

Terrie Reed – Food & Drug Administration

Right. I mean, what ... one of the instructions, and what we try to emphasize with the manufacturing who's submitting is that the information that you put on the label should match what you submit to the UDI database. That's often not clear to them, and, even though we make definitions here on our vocabularies, we emphasize that principle a lot. Because again, the notion is, when you look at that label and you use the information in that label to look up things in the UDI database, they should be the same, it shouldn't cause ...

Betsy Humphreys – National Library of Medicine – Deputy Director

But it's going to be different if they sold the device.

Terrie Reed – Food & Drug Administration

Exactly.

Betsy Humphreys – National Library of Medicine – Deputy Director

And I've got one at home and I've had it for ten years. It's going to be different.

Terrie Reed – Food & Drug Administration

It will.

Betsy Humphreys – National Library of Medicine – Deputy Director

So when I look it up, however, for me there should be something that is telling me, you know, previously used ...

Terrie Reed – Food & Drug Administration

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

... previous manufacturer, it should all be there, in the same record, in my opinion. But is that what you're planning on doing or are you having successive records which I guess would still work, as long as it was explained well ... as long as the ...

Terrie Reed – Food & Drug Administration

We are working on the base level and working on enhancements, so any ideas you have on that would be ...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I think ... this is Jaime, if I can cut in for a sec. Because I think, based the discussion here, our suggestion would be that when the UDI changes for any reason, but the device stays the same, then there really should be essentially the primary, as I think Betsy was explaining, the primary and alternate UDIs in the record for that device. So if you think about it as rows and columns, if the device is a row, then every alternate UDI, just becomes another history column, rather than having to separately link different historical rows.

Terrie Reed – Food & Drug Administration

Right, which is true.

Clem McDonald – National Library of Medicine

And getting back to the labels. When Betsy was talking about the LOINC code, that's what they would be attached to, not every single UDI that might be defined for that ...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. It would be attached to that record which might have a primary as well as historical or alternate UDIs.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah. See, because some of the characteristics of the device ... well, if it's an unchanged device, then all the characteristics except the manufacturer and the UDIs should remain the same, right. Otherwise, it would be a different device, in which case it would need its own UDI anyway.

Terrie Reed – Food & Drug Administration

Right.

Clem McDonald – National Library of Medicine

Well, that raised the other questions about what...how tiny a variation creates the generation of a new label or how big does the variation have to be?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, it's pretty well spelled out in this proposed rule, but it's just about anything.

Clem McDonald – National Library of Medicine

Because, I mean, in terms of people finding what they want to find, they may be hit by a blizzard of choices and not know ...

Betsy Humphreys – National Library of Medicine – Deputy Director

I know, but if you're going to recall the device, you want the version, the model, the size...

Clem McDonald – National Library of Medicine

Yeah, yeah.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. So I think that it sounds like that's a comment we could make that would in essence reinforce the intent of what we believe FDA intends and perhaps we can clarify how it would be useful for that to work operationally.

Terrie Reed – Food & Drug Administration

Those are good comments as well, that we're going in the right direction or...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Um hmm. Yeah.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, they do ask the musical question, does it really make sense for there to be more than one accredited issuer of UDIs. And I think the justification for doing it that way is that that reflects what's on the ground and unique identifiers that have already been assigned to existing devices. And so, it would be practical to continue to allow that to happen.

Clem McDonald – National Library of Medicine

Could someone mention how many there are and who they are, just a short list.

Terrie Reed – Food & Drug Administration

Well right now there's three major ones, TS-1, HIBCC and ICCBA.

Clem McDonald – National Library of Medicine

Okay.

Betsy Humphreys – National Library of Medicine – Deputy Director

So I had one other idea about an additional thing, that should...that I think we might recommend be included as ... within a required submission to the UDI database, and that is there's a part of the rule that states that once the UDI goes into effect and you have to label your device this way; any previously used national health related item code, or national drug code, because some of these combined things had them I gather, is rescinded and you can no longer use it on the label. But it seems to me that these also should be required to be in the record, so that if I've got my previous version and I actually have an NDC code on it, or an NHRIT code in my system, for whatever reason, I can get from that code to the information that's currently in the UDI database.

Terrie Reed – Food & Drug Administration

That's a good idea.

Betsy Humphreys – National Library of Medicine – Deputy Director

So I think that maybe that would be a reasonable recommendation for us to put forward.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

That's a great idea.

Farrah Darbouze, MPH – Office of the National Coordinator

Hi, this is Farrah. I'm sorry, could you repeat that so I can make sure I get that?

Betsy Humphreys – National Library of Medicine – Deputy Director

Okay...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Let me try to read it back the way I got it. When a UDI exists for a device, when it comes into existence, then previous identifiers such as an NDC or NHRIC code are rescinded, but must be inserted and updated...or must be made available in the UDI database.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Would one want to go as far as saying indexed?

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah. Included and indexed, and retrievable.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Um hmm.

Betsy Humphreys – National Library of Medicine – Deputy Director

This relates specifically to section 801.57 of the rule, proposed rule.

Farrah Darbouze, MPH – Office of the National Coordinator

Okay great, thanks.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. That's good, thank you. Other comments or comments from others that we want to consider.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Well the comment that Betsy initiated about LOINC, I never heard a conclusion on it.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Oh, okay. So the idea is to have a comment that very simply proposes a requirement for the UDI database to include the LOINC for tests that are performed by the device, and that that's a requirement for putting a device into...or to have a UDI for a device is that if it performs a test that is identified by a LOINC that the LOINC is...or multiple LOINC's are included in that device record.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yes.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, the other issue that relates to GMDN. So Terrie or Jay, in your wildest dreams, when does this rule get published?

Terrie Reed – Food & Drug Administration

Sometime in 2013.

Betsy Humphreys – National Library of Medicine – Deputy Director

Um, okay. So, we'll have to follow up on where we are now in terms of access to GMDN content, public access to GMDN content ...

Terrie Reed – Food & Drug Administration

Um hmm...

Betsy Humphreys – National Library of Medicine – Deputy Director

... is that a sizeable amount of GMDN content has been integrated initially into a separate section of SNOMED for medical devices...

Terrie Reed – Food & Drug Administration

Really.

Betsy Humphreys – National Library of Medicine – Deputy Director

... and the first issuance of this occurred this summer. And in that integration, we have the GMDN names for the devices and we also have SNOMED IDs attached to the devices and extant is a mapping between the SNOMED IDs and the GMDN IDs, although that is not publically available, it is available to the FDA...

Terrie Reed – Food & Drug Administration

... really.

Betsy Humphreys – National Library of Medicine – Deputy Director

... and to manufacturers, I mean, to other regulators. So, at the bare minimum, whenever this rule comes out, there will be in SNOMED, as I understand it, there will be in SNOMED names and SNOMED IDs for all the devices that are covered in the early phases of...phasing in of this. So, whether we have gotten to the point where there is a generally publically available source of the GMDN code would be another story. However, clearly the UDI database could have both ...

Terrie Reed – Food & Drug Administration

... SNOMED ID and GMDN ID.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, right. So, I could imagine that the comments from the committee could note that fact of where we are now, and say that that would be another approach to doing it. But of course, the issue is really, that is that the SNOMED code alone connected to the GMDN name would really solve the problem from the point of view of health care.

Terrie Reed – Food & Drug Administration

... because the SNOMED IDs are used in electronic health records.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, because all the health care providers in the United States have access to them ...

Terrie Reed – Food & Drug Administration

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

... and the vendors do as well.

Terrie Reed – Food & Drug Administration

So that would be a comment, that ...

Betsy Humphreys – National Library of Medicine – Deputy Director

That could be a comment and ...

M

Isn't the complimentary thought that the GMDND is not available to everyone?

Betsy Humphreys – National Library of Medicine – Deputy Director

It isn't yet, I mean, there's still all these discussions about it.

M

And that's a problem that could be alleviated by the SNOMED codes.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay, is there any objection to developing a comment that the SNOMED CT ID should also be included in the UDI available. And what are the constraints around that Betsy, is that as mapped by NLM or how should that be described?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, the situation would be, it really is...it's a little complicated. But given the manufacturers that have to submit to FDA, may or may not use the SNOMED CT in any way, shape or form. So if you say, you have to submit it on your end, then I could imagine the FDA currently getting a lot of negative comments, we don't use this, we use GMDN, whatever. Given that any manufacturer submits a GMDN code, it would be a tiny matter for the SNOMED code to be added, you know, on this end. Then the issue becomes whether the FDA wants to have anything to do with any piece of information that's in there, or...

Terrie Reed – Food & Drug Administration

Is that file available to us? It was, right?

Betsy Humphreys – National Library of Medicine – Deputy Director

That was definitely in the requirements of the agreement that was put together between the ICF DO and the GMDN agency, so ...

Terrie Reed – Food & Drug Administration

Is it available now?

Betsy Humphreys – National Library of Medicine – Deputy Director

I can certainly find out.

Terrie Reed – Food & Drug Administration

The reason I ask is, we're running a pilot on some cardiovascular devices with real UDI information and we're trying to get every aspect of this, so, to see that information would be helpful.

Betsy Humphreys – National Library of Medicine – Deputy Director

All right. I will see where that is, but I think it has to exist.

Terrie Reed – Food & Drug Administration

The same is true for the LOINC codes, as a data management person at FDA, I'd be interested. I've had discussions with Steve Gitterman about this whole LOINC code testing process. Sorry to divert the conversation, but that I'm interested in as well.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, we should have a separate...you should probably have a separate conversation about that because the LOINC codes, of course, are absolutely available to everyone right now.

Terrie Reed – Food & Drug Administration

Okay.

Clem McDonald – National Library of Medicine

If there's any, if you want to call or meet, or whatever, we could do that and...

Betsy Humphreys – National Library of Medicine – Deputy Director

And Dan's on the phone, too, isn't he?

Clem McDonald – National Library of Medicine

Yes.

Daniel J. Vreeman, PT, DPT, MSc – Regenstrief Institute

Yeah, I could, too.

Terrie Reed – Food & Drug Administration

Thanks.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

So, I'm trying to understand perhaps a little more precisely how would the SNOMED CT IDs be in...how would they become included in the UDI database if the database had a place for them, when they're correlated with the GMDNs?

Betsy Humphreys – National Library of Medicine – Deputy Director

It is something that would have to be worked out, so I can understand why you are confused.

Terrie Reed – Food & Drug Administration

I mean, right at this moment, when manufacturers, they have to pay for those GMDN codes.

M

Right.

Terrie Reed – Food & Drug Administration

So, it's hard to just ... so we cannot make those codes available. We can make the description available in the GMDN, but we can't make the GMDN codes available, because the idea is then no one would buy them, right?

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, exactly. So the thing is, that we could change this whole situation as Jay and I have talked ... rapidly, so the issue is how we address it in this ...you know, how it should be addressed here. I think it would be perfectly legitimate for the Health IT Standards Committee to make the statement that they understand that the GMDN content is being integrated into SNOMED and they think it would be very valuable from the health care side to have the SNOMED ID in the database. That would take care of what is a rational recommendation from the Standards Committee next week.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah.

John Halamka, MD, MS – Harvard Medical School

Jaime, this is John. Unfortunately, I have to drop off again. But I will follow up.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay, good. Thank you John. Okay, well, it seems to me that that's another useful comment. So I think really I've got five, I've got recommendations for five comments at this point; one on the exclusion criteria, one on LOINC, one on SNOMED, one on how the primary and alternate UDIs should be used and, or how they should be made available and another one about the previous identifiers for a device when they've previously been identified by other identifiers. What other ... so, is there any disagreement on those five comments? And then what other comments might be useful for the Standards Committee to make, and Floyd, I want to call on you in just a sec, because it seems to me that the use of the UDI, particularly in quality measure value sets is something that needs to be considered and so if and when the SNOMED CT ID is made available, I know that some of those things may be underway that we actually use the SNOMED IDs but where would you actually use the UDI instead.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

So is that a question now or you're coming to it?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah, well, I guess it's a question, I'm not, sorry, I should have been clearer. Yeah, that's a question now I think.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

So that's actually a big...do we expect that the devices will be identified only by their class, meaning the SNOMED, or by...just a minute, I have to turn that off...only by their class, which would be the SNOMED, or by their actual device identifier. Because there might be some differences in measures comparing a patient on, even though they're in the same class, one device versus ... a series of devices versus a series of others. So there still may need to be, to evaluate the measure, a value set. But the question is, are EHRs going to be expected to maintain the UDIs, and that's clearly not required now, in Stage 2.

Clem McDonald – National Library of Medicine

I would, you know, because we can't predict the future, I would predict that they will, just because they'll be sort of loaded in when they buy the stuff, but it might be like NDCs where they shift and they don't change them. But it seems like we could deal with that as things evolve, wouldn't constrain it to only those, you know ...

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

So I would agree and I think that most systems do deal with devices, probably using their charge codes right now, because that's how ... especially in hospitals, where they purchase and provide them, but they don't necessarily have a standard identifier. So, that is something that could be done. Ambulatory is a little bit different though.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, let me turn it around to a different discussion and then come back to that, and that is, there's been a conversation among members of the Standards Committee about possibly recommending that the discharge summary, the standard electronic clinical document, the CDA template or combination of templates for a discharge summary, should be updated to include a requirement to use the UDI for implants, so that consumers could have a truly unambiguous way of identifying what was implanted in them when they download those discharge summaries or other clinical summaries that would include that information, through the materials that are made available by the provider. And so it seems to me that's sort of a clear use case for actually now including the UDI, at a minimum for implants in the EHR. So now back to, so Floyd, you had said there's no requirement for EHRs to store the UDI, and I think there may be a recommendation for the UDI for EHRs, at least inpatient EHRs to be capable to have UDI identifiers in the near future, at least in that way.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

I would actually support that strongly, especially since when you're talking about implantable devices, at least for joint prostheses, it can take up to 6 months to identify some infections or other complications and so by maintaining information about that device across settings, is going to be really important to be able to track and do even post-market surveillance on those devices.

Terrie Reed – Food & Drug Administration

This is Terrie. This is a journey I'm on to try and work on the implants and one of the things that I've come across in the last few weeks is that there may be a Joint Commission requirement for identifying devices in the operative note. I don't know if anyone on the call...

M

I think there has been, I think they have to keep records of a lot ... at least many kinds permanently.

Terrie Reed – Food & Drug Administration

And so, the operative notes are included in the consolidated CDA, that's what I understand, and so it's possible that through that connection, the UDI could be in the summary of care document.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah, I think that one thing about that Terrie, is, my understanding at least, is that that's not required to be a coded entry for an identifier of that kind, it would just be in the text.

Terrie Reed – Food & Drug Administration

Right. So, could ... is that a place to make a comment in the ... I have the Consolidated CDA document in front of me.

M

Well, since hospitals have to keep sort of device, I think tables of devices for some purposes, it may or may not...it may fit better in its own table, I don't know, you know, in the ... just like a drug, this is a list of devices that have been implanted. But, I've not been involved in that discussion. Jaime, do you know better?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

I do not know, sorry.

M

But it might actually be easier to just go their database and jam it into another table than trying to insert it into a note that was dictated at a particular point in time.

Terrie Reed – Food & Drug Administration

Oh, I see.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah.

M

Just keep tuned I guess.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

And at least the discussion item, I think, around the discharge summary is that it should be...implanted devices should be added as a coded entry, which would be different from the op note.

Terrie Reed – Food & Drug Administration

Okay. All right. I was just, I was verifying.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

So, at least for implants then, Floyd, I think back to your question. If, for example, if that were accepted into meaningful use 3, then that would give measure developers the ability to use that information. I'm not sure if there's a clear comment here or not. What is the comment?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

The UDIs are good.

Terrie Reed – Food & Drug Administration

Rah, rah.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Well I guess it's a comment that UDIs are, especially with implantable devices, are important for inclusion in interoperable documents. That may be going too far, but I thought I'd put it on the table.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

No, I don't disagree with that personally. How do others feel?

Betsy Humphreys – National Library of Medicine – Deputy Director

Fine with me. That reminds me, however, that I do think that the comment from the Standards Committee should start out with, hey, it's a great idea to have UDIs and a UDI database.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. So that's the first comment. So Floyd, could you say that again about...so UDIs are important, especially for implantable devices ...

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

... for use in interoperable documents that refer to them.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Um hmm.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

I was afraid you were going to ask me to repeat word for word what I said.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

That's pretty close.

Terrie Reed – Food & Drug Administration

And just because of that interoperability word, what do you mean by interoperable documents in that case?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Well, what I was referring to was a summary of the patient moving from one provider to another electronically.

Terrie Reed – Food & Drug Administration

Oh, okay.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

And it doesn't just – that expands beyond just the discharge summary, but if it were included say in a clinical summary that the patient has a device out of an office visit, the way that's worded, it means that the UDI should be included with it. That's why I questioned whether that was going too far.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I think that it's a good question to bring to the committee. My sense is that the committee members are completely supportive on the discharge summary and it'll be interesting to see how folks feel about ambulatory summaries and transition of care documents.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

So – and it really leads to the question of, what kinds of data provenance should be required and so if you're ever referring to a device, should it always have the provenance of the UDI along with it, or not. It's a provenance issue in my mind.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Can you say a little more about that please?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

In other words, when you're dealing with certain kinds of data from knowing the information about how that data was derived originally may be helpful even though it's passed through five different documents along the way. To know that a blood pressure, for instance, systolic and diastolic came from a specific blood pressure device, and when you're graphing it, you're – if you wanted to actually look at are they really from the same device or different devices, and you're looking over time and trending, it might be helpful to know that these were different devices. The reason that the numbers seem lower and then rose was the patient bought a new device and has used it and it's not related directly to their clinical response, it's device related, perhaps. And that needs to be considered. But how would you know that, if you were just looking at trending over time. So, having that information stay with the data may be helpful. That's just one example.

M

That's true across all kinds of measuring devices or instruments in labs and test kits, too.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah. And that's the issue, how much metadata needs to come along. I may not need to know every document it's been in, but I need to know where it originated.

M

Well I mean, in that case, I think it would be so easy to just carry it with the result, you know, if the lab knows what it is. You know, the challenge there is like – they load it when they first put a drug into the drug database, they don't necessarily adjust it. So, there might be more labor to keep track of which machine was doing what; it may not work as well.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah, and hence the controversy over how much to ask for.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, it seems to me that implants are a pretty clear case of something that I think everybody could agree, whether it was implanted during an inpatient encounter or outpatient surgery or otherwise, but, and then I think how much beyond that is really a question for the committee to discuss; that's my sense of it. Does that sound right to folks?

M

Yeah.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah, I would agree with that.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Okay, good. Well, we're down to about 15 minutes left for our scheduled call. I now have seven comments including the first one that is just enthusiastically supportive of the UDI rule and the UDI database, in particular. And what other comments do we want to make, or what other comments do we want to recommend to the committee?

Betsy Humphreys – National Library of Medicine – Deputy Director

This is Betsy. I think we've covered the ones that had occurred to me, plus some others.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Stuart, are you still on the call? I thought I heard Stuart on the call.

Betsy Humphreys – National Library of Medicine – Deputy Director

I don't think he was on the call.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Oh, okay. All right. Well, he had previously brought up an issue that I wanted to ask if it was appropriate to make a comment on, about how to ensure appropriate maintenance and updates on the database and in terms of the importance of that maintenance. And it's actually come up a few times here, such as when the LOINC's would have to be updated – so generally, I think there's a great deal of support for the rule overall, but I think that there's been an expression of concern. I think Stuart had a valuable way of expressing that over how to ensure comprehensive, complete and timely, especially timely, updates in the database.

Betsy Humphreys – National Library of Medicine – Deputy Director

I think that I'm recalling his comments and I think one of the issues is the notion of what is available in the market today. And some requirement for manufacturers to actually update the database, to say that the thing is no longer in the market.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Yeah, that would be very valuable. But some of the other attributes, like say if you had an RxNorm code inside, I don't know that you'd want to press them to have to change that if there was a recoding, because that can be done through the RxNorm translation capability. I mean, they have a way to tell people when you want to update, make it simpler.

Betsy Humphreys – National Library of Medicine – Deputy Director

I do know – yeah, and I’m trying to remember the context of Stuart’s comments, but I do know that there is a tremendous amount of analysis – you know, sort of work that goes on to try to figure out whether something is still in the market, as far as drugs are concerned. And I think he was hoping that we might avoid some of those issues ...

M

... with these devices.

Terrie Reed – Food & Drug Administration

Are you asking...we have marketing status in the database.

Betsy Humphreys – National Library of Medicine – Deputy Director

So are they required – how often are they required to update it? Is there a requirement that they update it as soon as it changes?

Terrie Reed – Food & Drug Administration

I don’t think that’s in the proposed rule ...

Betsy Humphreys – National Library of Medicine – Deputy Director

Well ...

Terrie Reed – Food & Drug Administration

... most things are through guidance and...

M

Well if there’s some ability to say within some period of time, instant might be hard.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Perhaps we could recommend to the committee that the committee would say that marketing status changes should be updated on a timely basis and then leave it to FDA to provide guidance on what timely – how timely is defined. Does that sound like a reasonable approach on this?

M

Yeah.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, I do think that there’s a lot of – there has been, I mean and we’re sort of getting to the bottom of it now, but there has been a lot of time and effort and wasted whatever put in over, you know, people having tons of NDCs hanging around for drugs that are no longer in the market.

Terrie Reed – Food & Drug Administration

Well, there may be things that are, no longer marketed, but still out ...

Betsy Humphreys – National Library of Medicine – Deputy Director

No, we’re not suggesting ... absolutely not suggesting that you delete anything ...

Terrie Reed – Food & Drug Administration

Right. But, but, you may have a source or something that’s out there, no longer marketed ...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

... so this ...

Terrie Reed – Food & Drug Administration

... you would like to know that it is no longer marketed.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah, exactly. So when marketing ceases that should be known in a timely manner.

Terrie Reed – Food & Drug Administration

Right. And we do have the date the device was discontinued, as part of the database.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay.

Betsy Humphreys – National Library of Medicine – Deputy Director

I'm looking through my notes here to see if I had another one that I wanted to bring up, but, I can't seem to find it, so, I guess it wasn't important. Oh, wait a minute ...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, while Betsy is looking for that, let me ask if there are other areas for comment, aside from these eight that we've talked about here. And I'm going to suggest that if there aren't, then we should call time on this meeting in just a minute and then ask for any public comment.

Betsy Humphreys – National Library of Medicine – Deputy Director

I found my other comment.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay.

Betsy Humphreys – National Library of Medicine – Deputy Director

It was just that it says that if you discontinue manufacturing a device, and then you resume manufacturing the device, then you can use the same device identifier as before, you're allowed to but you're not required to. And I guess that's okay since you could change it for any other reason and as long as we end up with what ... we will describe what we've got, you're all right.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

It sounds like, Betsy, that is also covered by the comment that we're going to make reinforcing the intent of the FDA to link primary and alternate UDIs in the same device record. So, they may in fact choose to use a new UDI for a new manufacturing sequence of that device, but it would be linked in the same record.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yup, that's right.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. So, is there anything else from the workgroup members for this call? Okay. So, MacKenzie, let's turn to any public comment then.

Public Comments

MacKenzie Robertson – Office of the National Coordinator

Sure, before we go ahead and open the lines, I just wanted to touch base in terms of bringing these forward to the Standards Committee meeting next week. I just wanted to let everyone know that it has been made virtual, it happened today, so there won't be an in-person committee meeting. You'll all be able to join in through the webinar. I have currently 40 minutes on the agenda to present the comments and to allow discussion. Do you think that's enough time?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, to me that sounds like plenty of time. How do others feel?

Betsy Humphreys – National Library of Medicine – Deputy Director

I would think so. I mean, the goal would obviously be that at least they would have the list before they sat down.

MacKenzie Robertson – Office of the National Coordinator

Yeah, that's kind of part two of our conversation is just having – I know Farrah's been taking notes during the meeting today and having a plan for if those notes need to be sent back out to the joint workgroup for one final review before they go forward to the Standards Committee ...

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, what I was going to suggest is, I've also been taking notes and so why don't I...MacKenzie why don't I first send my notes to you, which I can do later today. And then you and Farrah can update or augment as necessary and send that out to the workgroup members, so we have a chance to review them and then out to the committee. How does that sound?

MacKenzie Robertson – Office of the National Coordinator

Okay. So if you send yours to me, I would just copy Farrah at the same time. If you send them to us by COB today, she can then compare them to her notes and if we look to get a turn-around tomorrow to the full workgroup and task force then we can get comments back by Friday and that way we can have it sent out to the committee for advanced review on Friday. Does that work with everyone?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Sounds great. Good for me.

MacKenzie Robertson – Office of the National Coordinator

Okay. And then, do you think forty minutes is too much time?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Umm ...

MacKenzie Robertson – Office of the National Coordinator

I'm not sure how much discussion the committee might have. I mean, I've heard just say from listening, there will probably be some discussion.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah, I think there will be some. I think that particularly the inclusion of UDI in various clinical documents. Well, I don't know, maybe I'm wrong, maybe something else will generate discussion, but I think a half an hour is a good minimum.

MacKenzie Robertson – Office of the National Coordinator

Thirty minutes, okay.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

But you can always ... if you have forty, you can always quit early.

MacKenzie Robertson – Office of the National Coordinator

That's true. All right then, we'll settle on the forty and that will be the presentation with discussion and Jaime, do you plan on presenting as Chair of both?

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

I do.

MacKenzie Robertson – Office of the National Coordinator

Okay, great. All right then, operator, can please open the lines for public comment?

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you are listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

MacKenzie Robertson – Office of the National Coordinator

Thank you.

W

Okay, well, thank you very much for being able to get on this call today and I'll be waiting for your notes Jaime.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

That's a good call. Thank you very much everybody.

MacKenzie Robertson – Office of the National Coordinator

Thanks everybody. Bye.

Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay, bye.