



Interoperability Standards Priorities (ISP) Task Force

Transcript
September 24, 2019
Virtual Meeting

SPEAKERS

Name	Organization	
Kensaku Kawamoto	University of Utah Health	Co-Chair
Steven Lane	Sutter Health	Co-Chair
Andrew Truscott	Accenture	Member
Anil Jain	IBM Watson Health	Member
Arien Malec	Change Healthcare	Member
Clement McDonald	National Library of Medicine	Member
Cynthia Fisher	WaterRev, LLC	Member
David McCallie	Individual	Member
Edward Juhn	Blue Shield of California	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Google	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Ricky Bloomfield	Apple	Member
Sasha TerMaat	Epic	Member
Scott Weingarten	Cedars-Sinai Health System	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Tamer Fakhouri	Livongo Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Tina Esposito	Advocate Aurora Health	Member
Valerie Grey	New York eHealth Collaborative	Member
Victor Lee	Clinical Architecture	Member
Cassandra Hadley	Office of the National Coordinator	Designated Federal Officer

Operator

Thank you. All lines are now bridged.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Great. Thank you. Good afternoon, everyone or good morning, everyone. Welcome to the ISP Task Force meeting. Today, we're going to continue discussing the draft accord that will be presented to the HITAC in October on recommendations. But first, let's get started with roll call. Ken Kawamoto?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Steven Lane?

Steven Lane - Sutter Health - Co-Chair

Good morning.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Good morning. Anil Jain?

Anil Jain - IBM Watson Health - Member

Good morning.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Good morning. Arien Malec? Andrew Truscott? Clem McDonald? Cynthia Fisher?

Cynthia Fisher - WaterRev, LLC - Member

Yes, present.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. David McCallie?

David McCallie - Individual - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. Edward Juhn?

Edward Juhn - Blue Shield of California - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. Terry O'Malley?

Terrance O'Malley - Massachusetts General Hospital - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. Leslie Lenert? Jack Po?

Ming Jack Po - Google - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. Raj Ratwani? Ram Sriram?

Ram Sriram - National Institute of Standards and Technology - Member

Present.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thanks. Ricky Bloomfield?

Ricky Bloomfield - Apple - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thank you. Sasha TerMaat? Scott Weingarten? Sheryl Turney? Tamer Fakhouri?

Tamer Fakhouri - Livongo Health - Member

Here.

**Cassandra Hadley - Office of the National Coordinator for Health Information Technology-
Designated Federal Officer**

Thanks. Tina Esposito? Valerie Grey? And Victor Lee? All right. Steven?

Steven Lane - Sutter Health - Co-Chair

Well, good morning, everyone. Welcome back to I think what is going to be our penultimate meeting of the taskforce prior to presenting our final recommendations to the HITAC. What we're going to be doing today primarily is discussing additional feedback that we have received, both during our very lively discussion with the HITAC last week as well as additional input that has come from those of you on the taskforce. Clem McDonald actually submitted some late input this morning, which we'll see if we can get to.

So, we're going to work through this input today. We then have another meeting coming up in two weeks and then we will hopefully be ready to present a final set of recommendations to the HITAC. So, put on your roller skates here because there's a lot of feedback that we've received and some of it quite substantive and I think warranting our careful attention. Ken, do you have anything to add to that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

That sounds good. I'm also just going through Clem's comment and real time putting it in here. So, it will be available in the online version as we talk.

Steven Lane - Sutter Health - Co-Chair

Oh, fabulous. That's great, Ken. So, would you rather that I start in on the document?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah, that sounds good. I'm just going through – we just received the comments.

Steven Lane - Sutter Health - Co-Chair

Great. Thank you to Clem for sending those in. All right. So, why don't we go ahead, then, and switch over to the document itself. What we'll do is we'll just go down and look through the comments and try to reconcile them and address them as best as we can. We'll see how well that works today given the time available.

Some of the comments people have submitted have just been kind of simple edits and clarifications. A few of them we've just accepted as we've gone along as opposed to bringing them to the committee. We want to make the most use of everybody's time. There are obviously a lot of people on the call, both taskforce members and members of the public.

So, these comments at the top, I'm a little unclear what they are doing. My tendency would be to skip over those. I'm not quite sure what to do with those. Working our way down here, there are some editorial comments that Ken, I think mostly you have submitted. Maybe we can come back to those. Ken, why don't you come back here? A lot of these comments when I'm looking on the early pages do have your name on them, and it might be easiest if you walk us through them. I think on page four, there are a bunch of comments.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Oh, this part was completely at a new section, I think. I'm going to look at my copy. Whoever is controlling the screen, if you could, click on my comment on the right. It's hard to tell exactly what

section it's for. If you could click on the first add comment, on my name on the top one. It will say where it's coming from. So, it's talking about –

Clement McDonald - National Library of Medicine - Member

Could you make the text just a tad bigger, about 5% or 10% bigger? Some of it, especially in the comments side, is hard to see.

Kensaku Kawamoto - University of Utah Health - Co-Chair

So, I'll look at it on my screen. Don't worry about it. The first comment was just I added, "In addition, overarching recommendations are first provided for issues that cross multiple parties." I think that's fine because we said we would do it. So, I just added that text. The next one, I added, "Pending HITAC review edit approval," in yellow. I think that's true.

The next set of comments is a new section I had added. This was before we went to HITAC. This was there from before. We added a cross-domain recommendations section. The first section was moved over the public availability of health IT standards. And then I highlighted in yellow – before, it was really just referring to NCPDP. Why don't we all look at these overarching ones and just go through them from the top? Some of them have been reworded a little bit. Do you want me to read it? How do you want to review this?

Steven Lane - Sutter Health - Co-Chair

I think probably a quick read is worthwhile. There are often people on the phone that are not on the web.

Kensaku Kawamoto - University of Utah Health - Co-Chair

All right. So, the first cross-domain recommendation was public availability of health IT standards. Observation – some HIT standards required by federal programs are not publicly available. There is a strong benefit in public availability of health IT standards required by federal programs, including EHR certification to ensure public review and compliance.

NCPDP standards, which support the interoperability of medication and pharmacy data, should be freely available to the public, including providers, pharmacists, and technology developers. It has been NCPDP's business model for the past 20 years to allow only members access to NCPDP standards. This has an NCPDP tent because we took it from the pharmacy part. Many NC-accredited SDOs and other organizations such as the AMA for CPT either charge for their standards or only allow them for access.

Clem added here, "This seems to be an unnecessary rationalization. I believe NCPDP also gets money per message." That is, I think, true. Or I don't know if that's true. So, the question there is do we keep it? I think it's a true statement.

Steven Lane - Sutter Health - Co-Chair

Are we going to do the hand-raising thing?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Let's do the hand-raising thing. Clem, since this is your comment, do you want to comment on your comment first?

Clement McDonald - National Library of Medicine - Member

Which part of it? I think that was maybe gratuitous. I don't know for sure about that. I understood they got income per message. But I don't know that as a fact and it should probably be taken off. But I do think we should try to encourage that the standards be free, period, and then find other ways for them to get income. So, the [inaudible] [00:09:07] get income, the education gets income – it's a tough issue because it's got to be funded. It makes it really hard to review a standard if you've got to review it and you can't read it.

Steven Lane - Sutter Health - Co-Chair

Yeah. We had an extensive discussion about this at the HITAC meeting. There was general agreement that this was a good idea. As you'll see, we separated out two different sections, the section that discusses access to the standards themselves and the next section, which discusses access to the code sets that the standards call for. Really, I think, in the case of CPT, it's the code set access and use that is being charged for. But again, I'm not sure how much value there is in calling this out, mentioning these particular SDOs since we are making the point more generally.

Clement McDonald - National Library of Medicine - Member

Yeah. Okay.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We could just delete the bullet points here. Some HIT standards required by federal programs are not publicly available. There is strong benefit in public availability. We can just remove the bullet points, if you wish.

Steven Lane - Sutter Health - Co-Chair

I would take out the yellow text. I think the other bullets are clarifying in a helpful way. David, did you want to add to that?

David McCallie - Individual - Member

Yeah. I'm sort of in agreement that the principle is what matters here, not the details on any particular standard. The policy lever discussion might mention that in some cases, it may prudent for ONC to fund the standard directly. We might want to say something like that. There's nice precedent with SNOMED, probably CMS. I think the principle is they must be freely available. Otherwise, they're not going to really serve as standards. Don't go into detail on how they support themselves.

Clement McDonald - National Library of Medicine - Member

Yeah, I'm okay with that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

So, the suggestion is just delete. Is that okay?

Clement McDonald - National Library of Medicine - Member

Yeah.

Steven Lane - Sutter Health - Co-Chair

Again, Ken, my preference would be to simply delete what you have highlighted in yellow.

Kensaku Kawamoto - University of Utah Health - Co-Chair

But if we talked only about NCPDP, it might have been appropriate in the medications round, but it's no longer appropriate when we're talking about all health IT standards. Now that it's a general section and only talk about NCPDP standards, it seems a little bit off to talk about just one of the many standards.

Clement McDonald - National Library of Medicine - Member

I'm happy to get rid of it and move on. We've got a lot to talk about.

Steven Lane - Sutter Health - Co-Chair

Okay. That's fine. Any objection from anyone else.

David McCallie - Individual - Member

No objection. I'm curious how you guys would summarize the discussion in the HITAC. Was there a general agreement with our point here? Was there pushback?

Steven Lane - Sutter Health - Co-Chair

No. There absolutely was. It extended to the free availability of the code sets as well. That's what we have here on the next page. Before we go there, let's deal with this disclosure statement. We had some back and forth in the comments about that. Ken had it when he initially entered this, had put in an acknowledgement that he was an unpaid board member of HL7 and drafted the recommendation. It seems to me that now that we've discussed it and agreed upon it, the relevance of who initially drafted it is minimal. So, I had suggested we take out the disclosure. Does anyone object to that?

Clement McDonald - National Library of Medicine - Member

Yeah. I agree. A lot of us are active in HL7. They don't pay us. We pay for that privilege of working with them.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We pay several thousand dollars per trip for the privilege of going to HL7.

Clement McDonald - National Library of Medicine - Member

Yeah.

David McCallie - Individual - Member

This is David. I don't think it needs to be noted, but I'm a member of the HL7 Advisory Board, also unpaid. So, I have a similar situation.

Steven Lane - Sutter Health - Co-Chair

No, it's not unusual. And then as I mentioned, there was this discussion about the availability of the code sets themselves. To me, that was a little bit of a shift from our earlier discussion about access to the standards. So, I really wanted to bring that here to see if people were comfortable. This is largely a mirror of the notes above with a slight change in the language.

Again, I'll read it for anyone who may not be on the web. The observation is, "While some code sets required by health IT standards are freely available, others require users to pay the associated standards development organization in order to utilize the codes in HIT systems." The recommendation was to develop and support a standard method to ensure free public availability of all code sets referenced by required health IT standards with the suggestion of policy levers of ONC, potentially in partnership with federal organizations such as CMS or NLM, consider paying for US license to code sets required by EHR certification.

We should probably say criteria and other federal requirements. And then support not only standards that are not currently freely available, but also those that are publicly available now, especially if not doing so jeopardizes the future availability and maintenance of those code sets.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Steven, my suggestion would be to merge that into the standards part. I view things like CPT, SNOMED – they're just standards. Instead of information model standards, they're terminology standards.

David McCallie - Individual - Member

I think it's worth calling out that fact, that code sets are standards and are critical just like the information model and other protocol-based standards. Whether it's two sections or not, I don't care, but I do think people need to understand that the mere number itself can be expensive. That's what we're suggesting should be changed. There should be a way that that's not a barrier to use of the code set.

Kensaku Kawamoto - University of Utah Health - Co-Chair

If you could scroll up, it's being addressed up –

Clement McDonald - National Library of Medicine - Member

For the record, FHIR forbids the use of code sets that aren't free unless they're required by federal regulation.

Steven Lane - Sutter Health - Co-Chair

Right. FHIR has had to make an exception for this perverse situation that we're in. So, Ken, I think that's a great suggestion, to simply add that language including standard code sets and terminologies and then we can handle it all within one small section. Does anyone object to collapsing those two into one?

Clement McDonald - National Library of Medicine - Member

No.

Cynthia Fisher - WaterRev, LLC - Member

No.

Steven Lane - Sutter Health - Co-Chair

I see no hands up. We can do that. Good. All right. We can move on. Clem had a concern about a sentence, which I think is now resolved. That one is gone. Okay. So, then the next area that we had a lot of discussion about – Cynthia, I think you’re on the phone and you’ve been a stalwart advocate of cost and price transparency. We had a lively discussion about the difference between cost and price and the importance of assuring that all of that information was available.

One suggestion was to just switch the use of the word from cost to price, but I think people use those words sometimes interchangeably and sometimes somewhat differently. So, I tried to add some language to clarify this. Again, just looking at this section, healthcare costs are a major challenge facing many US citizens and households.

Cost and price transparency was a key component of recommendations provided around medication, pharmacy data, but impacts many other domains, including imaging procedures, durable medical equipment, and hospitalizations. Consumers had an interest in understanding the costs of producing individual healthcare products and services. The standard prices of products and services is provided by various sources or vendors as well as the net price they would have to or will pay based on their individual circumstances, including coverage, deductibles, discounts, etc.

Cost and price transparency was one of the priority areas identified by the ISPTF, but which the ISPTF did not have sufficient time to tackle. Recommendation – advance cost and price transparency in all aspects of clinical care with policy levers suggesting the ONC invent standards for cost and price transparency, charge a task force, which could be a continuation of the ISPTF, to further assess and provide recommendations in this area and pursue measures to encourage to require the use of such standards for enabling price transparency. So, there’s a lot in there. I would welcome people’s feedback.

Clement McDonald - National Library of Medicine - Member

So, Steve, I think it’s good. But be aware that it really is a tough issue to really discern what people are thinking about out-of-pocket costs. Costs themselves, like, “How much does it cost the hospital to do something?” are really, really tough. I think it’s good as it is, but I think there will be additional tangles in the future.

Cynthia Fisher - WaterRev, LLC - Member

I’m sorry. This is Cynthia. I’m a phone and I didn’t raise my hand. I apologize for not raising my hand. I’ll try to do that the next time. I do think the way this is written is a little confusing between cost and price transparency. I go back to just sticking with price transparency because there are several prices that are negotiated and you’ve got the chargebacks of price and then you’ve got negotiated rates and then you have a task price that’s oftentimes lower than the negotiated rate because it’s paid on the side of the cash price.

I think what would be really helpful here is to just settle on price transparency and that we would also include what's the cash price for a service as well as those negotiated rates and what standards are used. And Jack Po and I, on a couple of sidebars after we had offered to put forward some illustrative recommendations, have just a rough draft that we could include but we would obviously look for discussion of the group. So, I can send that in now to the taskforce to think through some of the things that we outlined.

But I do think a timely subgroup – Jack Po and I did this together – would look at offering to try to put a framework together because look, we have [inaudible] [00:20:56] of the world now having a nice price list up for their new health clinic, that this, “This is the price.” And this is where things are moving. This is where the industry is moving. I think it behooves us not to just say we didn't have sufficient time to tackle, but I think we could readily tackle because standards exist in the pricing world across the sector and payment already is standardized.

Steven Lane - Sutter Health - Co-Chair

Yeah. Cynthia, I really appreciate those comments. We've got a number of hands up. Before we jump into them, I'll just say I don't think there's anyone arguing against this. The reality is we simply don't have time, as much as you and Jack may want to dig into this, to go deeply and thoroughly through this area. So, what we're trying to do was to really capture the high-level concept and say that this really warrants additional detailed focus. Let's hear the other comments. I think Terry, you were up first.

Terrance O'Malley - Massachusetts General Hospital - Member

This is just to speak in support of Cynthia. I would focus this solely on price and let cost go. I think it's going to be too difficult to nail down. Vendors and providers are not really happy about sharing their actual costs. But the price to the patient, what they're going to have to pay out-of-pocket, whether it's cash or by insurance, I think is the key issue. I would just focus on that.

Clement McDonald - National Library of Medicine - Member

I think Terry is right.

Steven Lane - Sutter Health - Co-Chair

Okay. Is anyone committed to holding onto cost?

Clement McDonald - National Library of Medicine - Member

Except out-of-pocket cost is a nice one.

Steven Lane - Sutter Health - Co-Chair

Right.

Ming Jack Po - Google - Member

This is Jack Po. I think the comments from the other committee members make a lot of practical sense. If the statement was going to be very high-level, like the current paragraph as opposed to a longer doc,

I wonder why it's necessary to then take out cost. If it's high-level, it looks like it would be good to mention cost and price at this level so that potential next taskforce can have the charter to tackle both.

Terrance O'Malley - Massachusetts General Hospital - Member

Jack, this is Terry. I just think cost is not necessary – as a first step, I think price is really the key issue. Cost is going to take us down a whole lot of different pathways. Price is what comes out of the patient's pocket.

Cynthia Fisher - WaterRev, LLC - Member

This is Cynthia. I'm sorry, but [inaudible] [00:23:33] the patient's pocket because their employer is also a payer, oftentimes 180 million people. The employee and the employer share on coverage. So, the entire pricing needs to be known, not just a copay or a deductible or a portion of it. We need to see the entire price. So, I think we're narrowing it way too much if we just say out-of-pocket costs or out-of-pocket prices. We need the entire negotiation rate.

Terrance O'Malley - Massachusetts General Hospital - Member

I'm sorry if I implied that. I think price is what we should focus on, not cost. That's my only point.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Let's go to Anil and then David, who have their hand up.

Anil Jain - IBM Watson Health - Member

Thank you. Yeah. I think we're getting hung up on price versus cost, but it's really two sides of the same thing. If a provider has a price, that's the cost to an employer or a patient. So, where I'm a little hung up on is the first bullet, where consumers have an interest in understanding the cost of producing individual healthcare products and services.

I think that's a little strong. I'm interested in knowing how much it costs to make my car, but that's not something that I'm going to – I know how much I have to pay for it. In healthcare, we need to make sure we know that total costs incurred in delivering the care, I think how much it actually costs to produce a drug or produce a device or to keep the lights on in a clinic is really not what we're focused on here, in my opinion.

David McCallie - Individual - Member

I agree.

Terrance O'Malley - Massachusetts General Hospital - Member

Agree.

David McCallie - Individual - Member

This is David. Since I think I'm next in line, I'll follow that. I agree with that. But I think what might be missing here is what we think is the purpose of the transparency. Maybe this is a much broader discussion. The goal here is for competition and choice. Let me put it this way – transparency doesn't

do you much good without competition and choice. So, we're missing the rationale for why we're calling for this transparency.

Clement McDonald - National Library of Medicine - Member

Good point.

David McCallie - Individual - Member

The principle of, "Thou shalt not be too surprised," is maybe implicit, but that's not sufficient. I think the other points that we should focus on, the delivered product and its price as listed and cost to user as consumed is appropriate, not only internal processes of how you got there. If one car maker makes better use of robots, then good for them, but we don't need to know that as a purchaser of cars.

Clement McDonald - National Library of Medicine - Member

Back to Steve's point, this is a very deep subject.

David McCallie - Individual - Member

Very.

Clement McDonald - National Library of Medicine - Member

It will be contentious for a long time. We need to find a way to say something that we like and get to more of the report.

Steven Lane - Sutter Health - Co-Chair

Cynthia has her hand up.

Cynthia Fisher - WaterRev, LLC - Member

I was agreeing that it's [inaudible] [00:27:03]. The goal is to be able to keep competition and choices as well. Maybe we can state that in there. I think I also disagree that we're not looking for what it costs to manufacture, what it costs to produce, but we are really looking at variability in prices.

As we look at what other standards were doing where doctors refer to specialists or they're referring for a knee brace, for instance, I think across the board, the patients, rather than going blindly to a brace shop, if they can see that brace, see it online, they might be able to save and get it at a tenth of the price or go to another lab where they could get it at a tenth of the price. So, this is really important as patients become in control of their care and their choices.

Steven Lane - Sutter Health - Co-Chair

So, I've made some suggestions in the text that I think most of you can see to strike out the red references to cost and clarify that we're talking about price transparency supporting competition and choice. Does anyone have any objection to striking the red and adding the green? I think we can move on.

Cynthia Fisher - WaterRev, LLC - Member

This is Cynthia. I would just change the word cost to the prices.

Steven Lane - Sutter Health - Co-Chair

We got it. It's right here, Cynthia. If you look at the text, that's what we've got.

Clement McDonald - National Library of Medicine - Member

I like it.

Cynthia Fisher - WaterRev, LLC - Member

You were going to take out the red, I thought you said.

Steven Lane - Sutter Health - Co-Chair

Yes, take out the red.

Cynthia Fisher - WaterRev, LLC - Member

My point is that in the black, you say the standard prices of products. I don't think there is a standard price. So, I would omit the word "standard" and instead, under where it says consumers have an interest in understanding, I would keep that to say the prices of individual healthcare products and services and take out cost of producing.

Steven Lane - Sutter Health - Co-Chair

Yeah. That's exactly the proposal.

Cynthia Fisher - WaterRev, LLC - Member

Okay. Perfect.

David McCallie - Individual - Member

Steven, this is David. I agree. I think that the closure – back to what this taskforce is focused on, which is standards – would be to say that any standard for healthcare should, where possible or where it makes sense, include mechanisms for conveying price. The scope of our purview is standards. So, we're saying the standards should include sufficient mechanisms to convey price so that competition and all of these other benefits can accrue. Does that make sense?

Steven Lane - Sutter Health - Co-Chair

I think so. I'm struggling with the language.

Clement McDonald - National Library of Medicine - Member

Steven, that's pretty broad. You're going to take a lot of things where it won't be possible.

David McCallie - Individual - Member

No, I said where possible – where possible if the standard has nothing to do with price. But we've seen that some of the early prescription standards didn't include a mechanism to convey the full out-of-pocket cost information. Those have been advanced. That's what we're saying is a good thing and that should apply across the board to healthcare standards.

Clement McDonald - National Library of Medicine - Member

I agree.

David McCallie - Individual - Member

I'm just saying that we're about standards in this group, not about competitive policies and healthcare in the US. But to the degree that standards can foster transparency in competition, then I think that's the strength of our – that's the purview that we have to make a strong statement. The good news is the standards are doing it. It's good. It's going well.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I like Steven's suggestion. I think to the extent that we can make more broad statements – it sounds like we might need another taskforce or something to flush out the details, the broader scope that we allow them to be, the better. So, a general statement around standards and how this can be helpful would be really helpful for the next group.

David McCallie - Individual - Member

Sounds good to me.

Steven Lane - Sutter Health - Co-Chair

I think we've reached a consensus. Can we scroll back up? Ken made some additional suggestions in the section above.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I just reworded that section – a little bit lower. It was the standards part – lower, as in page down. There is no semantic change. Clem just said that sentence structure was confusing. So, I just updated it. I'm going to just accept it so it's easier to read and then you can see if it makes sense.

Clement McDonald - National Library of Medicine - Member

Yeah. Good job.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. I wouldn't spend much time on it. Semantically, it's equivalent. I just updated the sentence structure.

Steven Lane - Sutter Health - Co-Chair

Great work. Thanks, Ken. Team, let's scroll down to the Multiple Competing Standards on page seven, I believe it is. Ken, I think you made most of these edits.

Clement McDonald - National Library of Medicine - Member

What header is it under?

Steven Lane - Sutter Health - Co-Chair

Multiple Competing Standards.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. So, I took this from one of our sections and I just moved it. It was the first thing I did. So, observations – somebody deleted that there are many custom interoperability solutions. But anyway, I took what initially said there were many customer solutions and I changed it.

There are often multiple, sometimes competing, standards that may need to be maintained as the industry moves towards single standards where appropriate and as new technologies, such as FHIR or integrated workflow. At the same time, a clear single best approach may not be available. There's a need for a process to retire standards that have been supplemented by such conversions, possibly as part of ISSA.

And then recommendations – I'm going to accept these, but please review and make sure you like them. Basically, this content was different before. I just reworded it a little bit. Recommends – actively seek out and identify opportunities to consolidate, simplify, and render cost-effective health IT interoperability landscape. I don't know what "render cost-effective" means. Let me just say consolidated and simplify because I don't understand what render cost-effective means. So, actively seek out and identify means to consolidate and simplify the health IT interoperability landscape.

Then Clem had a comment on this, saying, "What does this mean?" Like, "We have to pick something." This was from before. We said, "ONC should avoid picking winners prematurely and remain open to potential approaches which may ultimately be superior for a given problem or in a larger context that considers various use cases, e.g. by avoiding the need to maintain separate infrastructure for multiple use cases."

So, I think the point here was the prematurity part. I think ultimately, we do want to pick winners, right? So, I underlined that there. I'm just going to accept it for now and then we can...

Clement McDonald - National Library of Medicine - Member

Well, I don't think that paragraph is operationally implementable. What does it mean? It's sort of saying just keep all the things in play and never get a decision. That part, I think is significant.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't think so. I think the point is prematurely. It's saying don't make a decision before it's clear. So, I think the context of this was in the referrals, where there were direct-based referral mechanisms like 360 and they were FHIR-based. We were talking about pros and cons. Back then, our discussion was –

Clement McDonald - National Library of Medicine - Member

Maybe an example would help, though. Or would that be too complicated? As I look at the rate of adoption of FHIR, I don't know what could be premature.

Steven Lane - Sutter Health - Co-Chair

Well, it might be premature to require it to the exclusion of other methods. Truly, in practice, much is done using CCDa and that has not moved to FHIR. In our meetings, we all talk about FHIR. But in the real world, we're not really using it as much.

Clement McDonald - National Library of Medicine - Member

All right. I accept that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think it's a similar kind of thing for like CCDA/CDA, right? Most records still do move around CDAs. I think it would be premature to say, like, "Everyone, stop using CDAs. Start using FHIR for everything you're doing with CDAs for now."

Clement McDonald - National Library of Medicine - Member

Right. Okay. I take it all back.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Perfect.

Steven Lane - Sutter Health - Co-Chair

Comment? David?

David McCallie - Individual - Member

Yeah. I think this is another fairly complicated space. I'm okay with the words we've got here, but it's just scratching the surface. One thing ONC can do and is doing is to assess the existing standards and rate them, point out their strengths and weaknesses, consolidate access so that people who want to understand the standard can quickly find the right places. That's what the standards advisory document and website does. I think we can endorse that that's a good thing.

But at the same time, the premature optimization on a standard should be reserved or a regulatory focus on a particular standard should be reserved for cases where the market has failed to solve the problem. Really, regulation should address market failure. Now, that's a political perspective. That's what you get into here.

Clement McDonald - National Library of Medicine - Member

None of this is really operationizable, an effective procedure to actually have that happen.

David McCallie - Individual - Member

Yeah. Policies are broad goals. The process of putting that into actual regulatory language is complex. We're not going to solve that. I think we're trying to say be cautious about switching to new standards. It really should be don't do it premature. Wait until there is some kind of market failure.

Clement McDonald - National Library of Medicine - Member

I wouldn't say that. The nature of this is to wait. Medicare didn't wait, nor did we wait about e-prescribing and then it happened. We've been waiting for 20 years.

David McCallie - Individual - Member

But e-prescribing happened before there was a regulatory requirement for it. It happened because markets addressed the problem. I don't think this group – I'm not proposing that we get into that debate. But I think the word premature, is rolling up those complex notions of when is the time to regulate the use of a standard. That's a big decision. That's a difficult decision.

Clement McDonald - National Library of Medicine - Member

Well, I think as stated, it's okay. But I wouldn't go forward with waiting, using that word.

Steven Lane - Sutter Health - Co-Chair

So, I really appreciate the dialogue here. I do think that Ken has captured this as best we can. We're avoiding prematurely picking winners and then down below under policy levers, where appropriate, such as in the case of failure, the industry to reach consensus on its own. The ONC should commission or support efforts to identify functional overlap and identify opportunities for consolidation. That seems like it captures it. Of course, there is a lot of devil in these details.

David McCallie - Individual - Member

I like that language.

Steven Lane - Sutter Health - Co-Chair

All right. Any objections? Being sensitive to the time that we have available, is anyone uncomfortable with where this ended up?

Clement McDonald - National Library of Medicine - Member

No.

Steven Lane - Sutter Health - Co-Chair

Great. All right. Let's move on. I've accepted all those changes. So, those were the overarching issues that we had moved up to the top of cross-domain recommendations and now, we're back down into orders and results, which we've tackled a number of times and hopefully, we're just doing cleanup work at this point. Ken and Sasha have some comments that were included down below on page nine, if we can scroll down there. It was a Clem comment.

Clement McDonald - National Library of Medicine - Member

I think we throw around this information model without much precision. FHIR claims it's an information model. What are we really – I don't want to get too much into it, but I don't know that it's clear what anybody means by that.

Anil Jain - IBM Watson Health - Member

I can clarify. For me, an information model in FHIR for labs is the fact that there is an observation that has a code and a value in a normal range. The terminology standard is saying the –

Clement McDonald - National Library of Medicine - Member

I get it. That's good. I get it. Shouldn't we say that so that people aren't seeing some vague thing? That has to be too hard. So, never mind. We won't get that done. It would be nice if we anchored it in something.

Ram Sriram - National Institute of Standards and Technology - Member

Hello, this is Ram here. Can I say something on the FHIR?

Steven Lane - Sutter Health - Co-Chair

Please, go ahead, Ram. Feel free to use the hand-raising feature also.

Ram Sriram - National Institute of Standards and Technology - Member

I don't know about the hand raising. I'm just trying to figure out [inaudible] [00:42:25]. In any case, FHIR is not – I'm not sure it's an information model, per se. It's a protocol. It's a mechanism to do certain – and ask for services and all kinds of things. So, I'm not so sure I would call it an information model.

Clement McDonald - National Library of Medicine - Member

That phrase is inside of it. When you look at some of their specifics, I think it is, as Ken said.

David McCallie - Individual - Member

I agree. It is. It's a low-level information model, in addition to being a protocol. It's more than one thing.

Ram Sriram - National Institute of Standards and Technology - Member

Okay. Fine.

David McCallie - Individual - Member

I think the goal here is to call out the notion that it's not sufficient just to have a protocol. It's not sufficient to just have name and value code sets. If you want to convey complex clinical information, you need higher layers of knowledge in your standard. That's what an information model gives you. It may be self-evident to anybody who's worked on standards, but there's a naïve understanding, I think, a lot of times that if you have a code set like SNOMED or LOINC that you're done. If everybody would just use SNOMED or LOINC, we'd be done.

I think the point here is no, you're not. You need an additional set of constraints on top of those code sets called an information model, if you want to interchange higher level semantic knowledge.

Ram Sriram - National Institute of Standards and Technology - Member

Okay. That's fine. Thank you.

Steven Lane - Sutter Health - Co-Chair

Sasha, you had some specific comments that you did as a comment as opposed to a suggested edit. Do you want to comment on this and where you think we should put it?

Sasha TerMaat - Epic - Member

So, my colleagues, who have more experience with SNOMED than I do, felt that the highlighted bullet maybe oversimplified exactly when SNOMED should be used versus when LOINC should be used. They recommended the resource I linked in the comments on guidance of using SNOMED and LOINC in conjunction with each other as the appropriate best practice to endorse.

Clement McDonald - National Library of Medicine - Member

That publication is published by SNOMED. I don't buy that. That's very deeply self-interested by the one organization.

Steven Lane - Sutter Health - Co-Chair

Yet, I think we are looking for this clarification of how these two standards and code sets are utilized together.

Clement McDonald - National Library of Medicine - Member

I think it's in ISSA and stated in a number of places, stated in the USCDI, at least in the case that was called out. The other part of it is we've got to be honest – there will be cases, in the case of LOINC for a test and the case of SNOMED for a diagnostic statement or answer – there isn't a good code. So, it's got to be a little bit soft. I don't want to be too soft. I think in FHIR, they do soften it because the code is not always there.

Sasha TerMaat - Epic - Member

I think the language Ken is adding to highlight this as a relevant resource is appropriate.

Steven Lane - Sutter Health - Co-Chair

I agree. I think it's nice to include this. Clearly, deep thought has been put into this.

Clement McDonald - National Library of Medicine - Member

That is SNOMED saying how they want it used. I just think that's very biased.

David McCallie - Individual - Member

Well, we're not picking winning and losing standards in this taskforce. We're identifying issues that should be prioritized. Solving this particular problem is obviously still out there. Clem, you think SNOMED's advice is bad. So, I think mentioning it –

Clement McDonald - National Library of Medicine - Member

I'm not saying it's bad. I don't think it's appropriate any more than having CPT declare what should be used.

David McCallie - Individual - Member

So, who should, LOINC?

Clement McDonald - National Library of Medicine - Member

Neither of them should be making those declarations.

David McCallie - Individual - Member

But I think that's what we're calling for for prioritized development is to focus on solving these problems. If you want to have – there should be an –

Clement McDonald - National Library of Medicine - Member

I'm only saying an independent process, not one that's managed by one of the organizations that has an interest in how it comes out.

David McCallie - Individual - Member

But I don't think we're calling for endorsement of the SNOMED recommendation, but just pointing to that that is the kind of problem that needs to be solved. If there's an equivalent LOINC document that has a different perspective, we could link to that as well. But from a standard priorities development, this is still a gap.

Clement McDonald - National Library of Medicine - Member

It's not an unbiased statement. That's all I'm saying.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I tried to address it. Can folks read it and see if that's sufficient? I do agree we just need to move on. If we say potentially biased perspective, is that sufficient?

Clement McDonald - National Library of Medicine - Member

That helps.

Kensaku Kawamoto - University of Utah Health - Co-Chair

If that's okay, should we just accept this and move on?

Clement McDonald - National Library of Medicine - Member

ISSA already specifies which should be used and not used. That would be a less biased perspective.

David McCallie - Individual - Member

It's not... Neither of these goes nearly deep enough to convey complex clinical information. These are simple name value proposals, which doesn't get you to end game, albeit it's a step forward.

Anil Jain - IBM Watson Health - Member

Should that paragraph be added as the next bullet?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I thought there was something around this. I'm trying to look. There is a whole section on that later about how semantic [inaudible] [00:49:30] requires standards around information models in addition to associate terminologies. So, let's not add it right now. That's one section below this or two sections below this, the notion that our current models only support the simple stuff.

Clement McDonald - National Library of Medicine - Member

Actually, ISSA guidance goes beyond laboratory results. It talks about observations versus the values of those observations in general under many categories.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think if it's okay, we should keep moving.

Steven Lane - Sutter Health - Co-Chair

The next section, where we suggest long-based coding, that probably belongs under – is that a recommendation or is that a policy lever?

Kensaku Kawamoto - University of Utah Health - Co-Chair

That's a policy lever.

Steven Lane - Sutter Health - Co-Chair

I'll move it down then. That's what I thought.

Clement McDonald - National Library of Medicine - Member

This is, again, a case where I think we ought to be a little careful that – there will be cases where neither of them will have the right code, neither LOINC nor SNOMED.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. We run into that now. So, after we move it to the policy lever, let's add a sentence. Basically, there needs to be a way to deal with there isn't a code for what you need to send. Steven, did you already move it? CLIA comes under CMS, right? Should we just keep it under CMS? It's further down under policy levers. You can scroll down about half a page for what's being displayed, down to where it says CMS – another half a page. Yeah. Perfect. So, this section, I moved it.

Clem, you had a comment about this. I think your comment was you might want to provide a small out because FHIR codes don't exist. That's true. I agree. How about I'm going to put it here? There should be an exception, as is done in the case of FHIR US Core profiles, where a relevant code does not exist, e.g. the notion of a home blood pressure reading. Does that work? We were running into things where we're like, "I can't believe this [inaudible] [00:52:48]."

Clement McDonald - National Library of Medicine - Member

It's a very tricky area. I don't know if we can solve it. He probably reported his blood pressure. There are cases where you need an extensible or something like that to say more.

David McCallie - Individual - Member

That's a classic information model problem. Do you separate it into type of measure and location of measure or do you conflate them into a single code? That's an information model decision?

Clement McDonald - National Library of Medicine - Member

That actually will probably be apparent from the other parts of the message.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Does this address your issue, Clem?

Clement McDonald - National Library of Medicine - Member

No. So, Medicare has sentences as answers. They can't go into SNOMED in their assessments. The class is like that. Or they will have a chain of things and that's not allowed in SNOMED. LOINC has other limitations. They just haven't gotten to certain spaces. So, be aware that there may be a need for exceptions. That's all I want to say.

Kensaku Kawamoto - University of Utah Health - Co-Chair

The relevant code, e.g. where a relevant LOINC code does not exist to identify an observation or where a value should not be represented using a SNOMED code, right?

David McCallie - Individual - Member

Cannot rather than should not, right?

Clement McDonald - National Library of Medicine - Member

Yeah. They have rules right now that forbid certain kinds of codes. The important thing is that there should be room for exceptions.

David McCallie - Individual - Member

Which is why it's pretty risky to say that something should be made a condition of practice. Do we really want to say that?

Steven Lane - Sutter Health - Co-Chair

You mean a condition of participation?

David McCallie - Individual - Member

Condition of participation. Are we saying that or not?

Clement McDonald - National Library of Medicine - Member

That's actually why I brought it up. You can be torn by this because if we do something strong, it will happen, but there's some point at which we shouldn't be too strong and we should allow for cases that can't be done. Now, of course, once you do that, then anything they don't do couldn't be done. So, it's tricky.

David McCallie - Individual - Member

But I think that's what standards do is they identify the part that can be standardized and essentially make it mandatory and then identify the parts that can be relegated to free text or other nonstandard approaches. Every standard has those boundaries, FHIR and everything else. There are comments in FHIR, right? You're allowed to do that.

Clement McDonald - National Library of Medicine - Member

Right. I was suggesting some softening. I don't know that we can find the perfect level. We've got to recognize some limits.

Steven Lane - Sutter Health - Co-Chair

Well, thank you, Clem, for that. I think we've captured it about as well as we can in the time allowed. I'd like to scroll back up. Sasha has some really pertinent comments and I really want to thank those who took the time to really read through this carefully. Sasha, do you want to walk us through your thoughts up above? If you can scroll up on the screen, Sasha's comments are on page ten.

Sasha TerMaat - Epic - Member

I'd be happy to. I don't remember exactly what was on page ten. So, I'm scrolling –

Steven Lane - Sutter Health - Co-Chair

Here we go. Go up a little bit more. Perfect.

Sasha TerMaat - Epic - Member

So, the first comment, I think, was just an endorsement of the recommendation that we had. This, the comment I mentioned earlier, came from my sharing of our recommendations draft with colleagues of mine who were experts in all the different areas, labs, medications, different types of interoperability. So, they strongly endorsed the bullet about prioritizing accurate coding as the data source as the best method, which was, I think, what the taskforce had preferred. That's my first comment.

The second comment had to do with under policy levers and requisite responsibilities, the second bullet about working with HL7 for standards-based exchange of textual reports. My colleagues read this as perhaps implying that there was no place for textual reports and that the intention was to convert things that have been historically narrative, like anatomic pathology reports, into structured data.

I didn't think from our taskforce conversation that that was the intention. So, I thought it would be pertinent to clarify that. Our goal was to exchange things that are in text format with as much structured data as possible but not to eliminate the use of narrative reports for areas where it's useful.

Clement McDonald - National Library of Medicine - Member

Well, I'd reinforce it because I think the whole part of the note reports in ISSA – I mean in **[inaudible]** **[00:58:31]** is exactly that. If it's reported as text, radiology reports, let's get it out there. Let's get it sent to them with some labels that you can store it properly.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Does that work.

Sasha TerMaat - Epic - Member

That addresses, I think, my colleagues' confusion. Ken, thanks. And then on the next bullet, I think my colleagues had some specific recommendations on how we could address the concern that LOINC was at here. If you hit show more, they made some specific recommendations. So, there were some

elements that they thought would maybe be using a LOINC code but possibly other metadata like coded units, testing methodology, they thought a hierarchical relationship with respect to how granular or specific a particular LOINC code was would be useful.

That aligned with mention of our conversation. And then their final suggestion was a process for provisional LOINC codes if the concern is that they aren't being developed quickly enough for new tests, having something standard that was not reusable but sort of provisional for that purpose might be addressing the need of our goal as to always use LOINC even as a new test comes on to the market and hasn't been assigned a code yet.

Steven Lane - Sutter Health - Co-Chair

This is obviously very detailed. It's also incredibly helpful. It's a level of detail that we had attempted to get down to when we went through this initially. So, I really appreciate, Sasha, your working with your team to bring this forward.

Clement McDonald - National Library of Medicine - Member

I'd like to indicate that there is a hierarchy and it's been improved recently. So, it sounds like this sort of talks that there isn't. Laboratories actually ask directly, many of them for LOINC codes before they're delivered, but the volume is very high. I think the question is made around resources to make enough capacity to handle the volume as it comes in.

Mayo has coded 80% of the orders in one side of their business and about 60% in another side of their business, which include panels. If all of them do that, the capacity will be limited. I think provisional, just saying people make up their own codes will be sort of a bad path. We'll end up with just a bunch of local codes.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think it is useful, kind of like how SNOMED has the ability to create a local name space with extensions for the notion – we run into this as [inaudible] [01:01:20].

Clement McDonald - National Library of Medicine - Member

Yeah. LOINC could do that. We've got local codes already with their own coding system.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We run into real problems, Clem, like as a practical matter, in some EHR systems, you may only represent a FHIR message using LOINC. I think it would be useful.

David McCallie - Individual - Member

I agree.

Clement McDonald - National Library of Medicine - Member

How do we make local codes be standardized? That's what we're talking about.

David McCallie - Individual - Member

The point is to have a standard way of being non-standard. That's what a provisional code approach does so that you know that this is, in fact, a non-standard provisional placeholder as opposed to something completely unspecified and random. It's a small step forward, Clem. Every coding system supports this, XML, everybody.

Clement McDonald - National Library of Medicine - Member

Let's just clarify what you're saying. You're saying any institution can make up a code and call it provisional. Is that right?

David McCallie - Individual - Member

I'm saying that if they can't find a LOINC code because it doesn't exist yet or for whatever reason, they can't find it, they can flag that this is a placeholder for a LOINC code in the future that we're going to substitute a provisional marker for so that anyone knows downstream this is a provisional code.

Clement McDonald - National Library of Medicine - Member

Well, they can send the local codes now, David.

David McCallie - Individual - Member

But they don't do it in a consistent way.

Clement McDonald - National Library of Medicine - Member

What's consistent about them inventing a new code? It's just like their local code. FHIR says it can be sent local codes.

David McCallie - Individual - Member

You flag it as the intent. You're capturing the intent. The intent is to use a LOINC code. It's not available. This is a placeholder.

Clement McDonald - National Library of Medicine - Member

Without any discussion, without any adjudication, without any to check to see if there isn't one in there.

Sasha TerMaat - Epic - Member

I think the idea was, Clem, that it would enable other possibilities, such as linking provisional codes to the LOINC codes once they are created and having that available on the back end. I think there are possibilities that it would provide, even provided tracking how long provisional codes are used before they're replaced with a formal LOINC code that aren't necessarily possible with local codes. That was, I think, part of the thinking, as David said and Ken of my colleagues in saying it.

Clement McDonald - National Library of Medicine - Member

Well, it would be useful for people that don't want to bother about standard codes or having a – if you see it come in and people just want their own stuff, then why bother? Just let them do what they've been doing?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem, we obviously want things standard. Like taking the specific example of a 24-hour blood pressure or a home blood pressure. LOINC has one that says, “Was the home blood pressure low, high, or medium?” But if you want one that says this was the actual home blood pressure, there is no LOINC code.

If we wanted to use LOINC but only current approaches to petition LOINC wait maybe at best six months for it to be adopted and then another 6 to 12 months before it’s actually available in a health system to start using. Like, I think it really just comes down to at that point, what do we do? In SNOMED, we can create a local extension.

Clement McDonald - National Library of Medicine - Member

FHIR tells you what to do. It says use the general code and then add whatever you want to be more specific. Currently, that’s what is the current guidance.

Kensaku Kawamoto - University of Utah Health - Co-Chair

You say blood pressure, just regular blood pressure – well...

Clement McDonald - National Library of Medicine - Member

Well, there are a lot of blood pressures, but yeah. You use not just blood pressure. You use diastolic or systolic or median, whichever you’re really measuring. Then you can add your local code or some other thing that would specify that it’s a home. But there is also indication because I think if you look in the bigger part of the message, there is stuff in there that says this is done in Clinic A or B or C. The encounter is going to be specific to that.

You have other ways to show that. To make the stuff work, you’ve got to have a discussion of all the stuff with a larger group. Otherwise, you’ve got what we have now. Local means local. We’ve got a file of 7 billion LOINC codes from 14 institutions. It’s working for a lot of stuff. I think the only way to handle the time lag is to help with the volume they have in some resources beyond what’s now available.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Well, all we’re saying is consider at this point. If you look at how we currently specify it – I’m going to just accept these so it’s a little bit easier to read. Why don’t we look at the proposed wording and see if it captures the notion? That’s the bullet point three.

Consider introducing a standard approach developing provisional LOINC codes where new LOINC codes cannot provisioned and implemented quickly enough as new instruments are introduced, perhaps in a manner similar to how SNOMED CT may with local incentives. Note that such an approach risks reducing interoperability. So, it’s really consider – it’s not saying do it. It’s saying consider it.

Clement McDonald - National Library of Medicine - Member

Well, there is already an attribute used that you can use before you can get – but it does take too long. As the volume increases, I don’t know how to avoid that without... It’s a challenge.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It's gotten to the point where we've considered introducing a LOINC code like LOINC SNOMED CT this because SNOMED has the concept but LOINC doesn't. It's like do we wait a year and a half or not.

Clement McDonald - National Library of Medicine - Member

Okay. Go ahead with it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Well, we removed consider. Is that okay?

Clement McDonald - National Library of Medicine - Member

Yes.

Steven Lane - Sutter Health - Co-Chair

I just added a little parallel sentence structure there.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Can we just say standard? Should we say standardizing? Well, I don't know.

Steven Lane - Sutter Health - Co-Chair

Well, we're talking about additional elements here.

Clement McDonald - National Library of Medicine - Member

Well, now, units of measure are already specified standards. So, what are we really talking about?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah, actually, it is.

Clement McDonald - National Library of Medicine - Member

It's required by FHIR and it's required by DICOM and it's required by –

Kensaku Kawamoto - University of Utah Health - Co-Chair

You said UCUM, right?

Clement McDonald - National Library of Medicine - Member

Yes.

Steven Lane - Sutter Health - Co-Chair

How about the testing methodology, Clem? Is that already in there?

Clement McDonald - National Library of Medicine - Member

There are ways to specify them, but there, the challenge becomes how granular you want to get. We've already faced a challenge with the granularity of methods. It's a challenge – now I'm under a different – except for the course ones.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't understand the units of measure one for sure because LOINC specifies you must use UCUM.

Steven Lane - Sutter Health - Co-Chair

Sasha, do you have any insight here? This came from your comment.

Sasha TerMaat - Epic - Member

No. I'll ask my colleagues and I'll put in a comment if I get more clarity.

Steven Lane - Sutter Health - Co-Chair

And testing methodology, should we keep that in or leave it out?

Clement McDonald - National Library of Medicine - Member

I think it would be helpful to have more specifics versus what – there are generic or a large, chunky [inaudible] [01:09:43] X-ray and CT, MRI, and that kind of thing in certain areas and there are also chunky ones in some labs, but mostly a lot of the common labs are standardized across methodologies. Other than that, there is stuff like – [inaudible] [01:10:06] is a specialized way to do one of the albumin tests, but some people complain about that. They don't want the distinction. They've got them both in some cases.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Isn't the testing methodology implied by the LOINC code in most cases?

Clement McDonald - National Library of Medicine - Member

Yes. But sometimes it's not specified because nobody cares about the distinctions or they have to be standardized across the methods.

Sasha TerMaat - Epic - Member

Why don't I ask my colleagues for some clarifications since I don't have the context for some of the questions you're raising now? We can come back to it.

Clement McDonald - National Library of Medicine - Member

The other thing is if you're talking about lab tests, you're not going to get their protocol. They're going to do what they do. They don't have the details in a coded form inside. It's going to be hard to get more specific unless you ask for their protocol. I would guess regarding units, they're looking for a number, a numerated list of all units.

Steven Lane - Sutter Health - Co-Chair

Given our lack of clarity, I suggest we strike this sub-bullet (i) and stick to the (ii) and the (iii).

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. That sounds good. Then we'll just ask for –

Steven Lane - Sutter Health - Co-Chair

And Sasha, if you can bring back any further clarification that would be great.

Sasha TerMaat - Epic - Member

I'll take that as a follow-up. Thanks.

Steven Lane - Sutter Health - Co-Chair

Excellent. All right. We are closing in on public comments. We've got another five minutes. Any other comments? I don't see any hands raised. The active participants have been few in number but deep in their thoughts.

Clement McDonald - National Library of Medicine - Member

Steve and Ken, I want to publicly compliment for all the work that you've done. It's a ton of work and you've done a really good job.

Steven Lane - Sutter Health - Co-Chair

Thank you, Clem. I assure you that all of the taskforce code shares have just been tremendous through this HITAC process in the past year or so. It's a great opportunity to serve. Let's scroll down to the next section. We'll start in here. This is going to be at the bottom of page 12, I think. Level of granularity of standard codes differ according to use. There we go. Good. Ken, you captured some comments here as well as Sasha. Do you want to – I think some of these came from David and from Clem, though. Perhaps we can start in on those.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I'm trying to think what I was thinking there.

Steven Lane - Sutter Health - Co-Chair

The first one here had to do with information model, which I think we've covered up above.

Kensaku Kawamoto - University of Utah Health - Co-Chair

This is actually coming from David, where I just put in his comment.

Steven Lane - Sutter Health - Co-Chair

David, I think you agreed that we had managed the information model issues up above as best we could.

David McCallie - Individual - Member

Yeah. I think so. We're not going to solve it in this document. So, as long as we register that there's more than just code sets...

Steven Lane - Sutter Health - Co-Chair

Great.

David McCallie - Individual - Member

I think it's an unsolved problem as to where information models should come from. There are funding issues and jurisdiction issues. There are some policy level issues. But at a minimum, we should register the need for that work in terms of prioritizing future actions, which is what our goal is here.

Kensaku Kawamoto - University of Utah Health - Co-Chair

The next one is Clem's comment, I believe. Is public comment 9:15 or is it 9:20?

Steven Lane - Sutter Health - Co-Chair

20 after.

Clement McDonald - National Library of Medicine - Member

Should I elaborate on this? So, the blood pressure is a classic example where you need more structure. We proposed that in one of the – maybe the most recent or the one before it. It was rejected for simplicity reasons. These are things that could go into the FHIR model easy because FHIR has a model for blood pressure but there are just two variables in it.

It could use more that could be optional, like cuff size and standing and sitting, etc. That's true of most of the vital signs. There's this tension between we've got to stay simple and dealing with the model as it really is. I think it will evolve in FHIR, honestly. But I think Dave's point is well-taken. I do think it will evolve.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Do we need to change anything in here or add anything to address your comment?

Clement McDonald - National Library of Medicine - Member

I think we should leave a comment that there are models in FHIR. They're just not very comprehensive.

David McCallie - Individual - Member

But there are models in – there's SIMI, there's Open EHR archetypes – there's a bunch of standards for those models that are competing and buying and I don't think there's a winner yet. Ours is too static.

Clement McDonald - National Library of Medicine - Member

Some of those models aren't going to win in the US.

David McCallie - Individual - Member

I think FHIR is the right place to solve it, but it hasn't been solved. Calling out that more work is needed is, I think, the level we're at here. We're not going to solve it.

Clement McDonald - National Library of Medicine - Member

It's ongoing, but you've got to walk before you run.

David McCallie - Individual - Member

All the code sets do that, but it's just not complete. In terms of prioritizing future standards development, this is the next turn of the crank, solving these next level problems for more complex information models that go beyond the existing standards.

Clement McDonald - National Library of Medicine - Member

Well, I just wanted to highlight that there are information models in FHIR and the problem is they're too simple.

David McCallie - Individual - Member

Exactly. There are information models in SNOMED and in LOINC. They're also too simple.

Clement McDonald - National Library of Medicine - Member

Well, you're right. But I really think that – I think FHIR will end up being the source because the momentum is so huge. Resistance is futile, as Schwarzenegger said.

David McCallie - Individual - Member

I personally agree.

Steven Lane - Sutter Health - Co-Chair

Let's hold there. But it's time for public comments, guys. We want to be good to that. So, let's go ahead and read the public comment info.

Cassandra Hadley - Office of the National Coordinator for Health Information Technology- Designated Federal Officer

Great. Thanks. Operator, can you open the lines to public comment, please.

Operator

Yes. If you would like to make a public comment, please press star-one on your telephone keypad and a confirmation tone will indicate your line is in the queue. You may press star-two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key.

Cassandra Hadley - Office of the National Coordinator for Health Information Technology- Designated Federal Officer

Do we have any comments in the queue?

Operator

No comments at this time.

Cassandra Hadley - Office of the National Coordinator for Health Information Technology- Designated Federal Officer

Thank you.

Steven Lane - Sutter Health - Co-Chair

Excellent. Now, we can continue. I just wanted to be sure we respect our public process.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Just as a logistical issue, if we can go back to the Google doc, we need to make a determination probably by the end of the call today, maybe leaving a few minutes, whether we feel we can complete our work in the next meeting or whether we need to schedule another meeting or perhaps look at, for example, extending a meeting, if we need to start earlier and later, that kind of thing.

We're making good progress, but there are a lot of meaty comments here. Maybe let's discuss that at the final few minutes. Clem, does what I added address your concerns? So, potential approaches to defining these more complex information models include the use of more granular FHIR profiles, clinical information modeling, initiative semi-models, open EHR archetypes, etc.

Clement McDonald - National Library of Medicine - Member

I don't think we should bring in players that haven't been players in the US. We're less focused than we really are. The archetypes have had no uptake in the US and SIMI not much. But I would mention it.

David McCallie - Individual - Member

I agree that as a standard, it's unlikely to gain much traction in the US, but as a source of model and information and learning, it's pretty valuable. It heavily influences what Graham does in FHIR anyway. So, whether we mention it or not, it's in the minds of the people that are working on these problems. I don't really care.

Clement McDonald - National Library of Medicine - Member

It sounds like our thinking is cabbaging rather than focusing. It's been around a long time. It's never been mentioned before.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It's been pretty heavily used within SIMI and what not as a source of requirements.

David McCallie - Individual - Member

And it's in use in Europe. It's a relevant standard. We're not endorsing it. We're just saying learn from it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Just as a note, Claude Nanjo demonstrated at the HL7 meeting last week using SIMI models to create and do real time translation of FHIR and execute CQL. These aren't mutually exclusive. You can have a FHIR structure definition without the source of truthing underlying it being the structured definition.

Clement McDonald - National Library of Medicine - Member

Okay.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. If this looks resolved, let's move on. You had another comment.

Clement McDonald - National Library of Medicine - Member

I think the second statement here really is redundant with talking about rollups you've talked about above.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Can we just delete it?

Steven Lane - Sutter Health - Co-Chair

I don't know that we went into specifically this level of granularity, the idea of trending semantically equivalent test results together. Was that copied above? I don't think it was, Ken. From a patient/clinician standpoint, this is incredibly important.

Clement McDonald - National Library of Medicine - Member

All right. Leave it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sasha?

Sasha TerMaat - Epic - Member

So, I have the next two. On the prioritization one, my colleagues and I supported prioritizing the most important order types but in our early recommendations, we actually recommend all. It seemed inconsistent. We would actually recommend going back to the earlier one where it said all and reconciling with like this sense of prioritization.

Clement McDonald - National Library of Medicine - Member

Is this the yellow highlighted one that says cardiac pulmonary?

Steven Lane - Sutter Health - Co-Chair

We point out prioritizing the most common and important results of each order type. Above, we said really all orders. I think the idea here would be to prioritize, to do the most common things first knowing the overarching goal is to get everything semantically interoperable.

Sasha TerMaat - Epic - Member

I think if we amend earlier to say starting with those to be prioritized to be the most common, that would reconcile it well.

Clement McDonald - National Library of Medicine - Member

I think that sounds good. Be aware that some of the big referral labs are submitting all their order panels to LOINC. One of them has got 9,000 orders or 8,000 orders and it's already completed about 6,000. Some of them are redundant and don't make different LOINC codes.

Steven Lane - Sutter Health - Co-Chair

Yes, Clem. We'll get to that comment momentarily here. Sasha, do you want to take a stab at finding the text further up and doing the affiliation? That would be great.

Sasha TerMaat - Epic - Member

Leave that comment in here to remind me and I'll go back and find it all and suggest language in mine. My next comment was just that my colleagues weren't sure in this next bullet when we said clinical conditions if we were referring to diagnoses or results or something else, some combination of those. If they were confused, they thought others would be and maybe we could clarify.

Clement McDonald - National Library of Medicine - Member

I took clinical conditions to be the FHIR claim, like a problem.

Sasha TerMaat - Epic - Member

Like diagnoses?

Sasha TerMaat - Epic - Member

That's too strong a word, but like diagnoses, yeah.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think we're saying it's key like observations related to common clinical conditions.

David McCallie - Individual - Member

I think the injection fraction is an observation. Is that the one we're talking about?

Steven Lane - Sutter Health - Co-Chair

Yeah. That was the example.

Clement McDonald - National Library of Medicine - Member

Which observation should be association with which conditions? And make sure we dealt with them.

David McCallie - Individual - Member

I think I put that example in there. The thought was for common clinical conditions, being able to structure essentially parameters of that condition would be a step in the direction of moving towards more semantic interchange. We're not going to eliminate text. I certainly don't want to eliminate text.

Clement McDonald - National Library of Medicine - Member

Dave, you're right on. You don't need thousands of terms to do this.

David McCallie - Individual - Member

No. It's very few that clinicians actually care about.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think we need to just pause there. We do need to discuss what we're going to do next time. We only have like a minute left. Steve, do you feel like our current –

Steven Lane - Sutter Health - Co-Chair

I think we're going to run out of time. There has been such great input. I suspect some other folks are going to be inspired to go in and do a careful read. I think your concept that we need to consider an additional meeting is a good one. As it stands, our next meeting is on the 8th. And then we're presenting to the HITAC or giving the final for HITAC on the 16th. I would suggest that we add another meeting a week for today on the 1st, appreciating that not everyone will make it, but that we give that a shot. Does anyone object to that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I have a conflict with this time next week.

Clement McDonald - National Library of Medicine - Member

I do too but that's not relevant.

Steven Lane - Sutter Health - Co-Chair

I'd hate to do this without you, Ken. Did you have another suggestion? The 15th is too late.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sometime next week is good. Would potentially something like next Friday work for folks?

Clement McDonald - National Library of Medicine - Member

What's that date?

Kensaku Kawamoto - University of Utah Health - Co-Chair

That would be October 4th. Steven, do you have clinic on Fridays?

Steven Lane - Sutter Health - Co-Chair

I do. That's going to be hard for me. Could you go later on a Tuesday, Ken?

Kensaku Kawamoto - University of Utah Health - Co-Chair

My Tuesday looks really bad. I could potentially do 3:30 Eastern or we could do 3:00 Eastern.

Clement McDonald - National Library of Medicine - Member

Is that Tuesday the 3rd?

Steven Lane - Sutter Health - Co-Chair

Tuesday the 1st. Anyone strongly object to 3:00 Eastern Tuesday the 1st as an attempt to sneak in an extra meeting?

Sasha TerMaat - Epic - Member

No objection.

Clement McDonald - National Library of Medicine - Member

I think that could work.

Steven Lane - Sutter Health - Co-Chair

Great. Let's try that. Let's put it down for 90 minutes and we'll see what kind of participation we have and we'll do the best we can. I really appreciate everyone's willingness to dig deep and invest time in this. I think we're going to have a great product and we want it to be as good as we can make it.

Clement McDonald - National Library of Medicine - Member

This would be what time, again?

Steven Lane - Sutter Health - Co-Chair

12:00 Pacific, 3:00 Eastern Tuesday the 1st of October. Thank you all for your participation. Sorry for running over by a minute. Thank you also to the public who signed on and left some written comments and were here to help us on. We will hopefully speak to most of you next week.

Cynthia Fisher - WaterRev, LLC - Member

Thank you.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Thank you.