Interoperability Standards Priorities (ISP) Task Force

Transcript
September 10, 2019
Virtual Meeting

SPEAKERS

Name	Organization	
Kensaku Kawamoto (Co-Chair)	University of Utah Health	Co-Chair
Steven Lane (Co-Chair)	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
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning, everyone. Happy Tuesday. Again, we're at the ISP Task Force meeting. A quick roll call of the task force members: We have our two co-chairs, Ken Kawamoto, and Steven Lane, Anil Jain, Cynthia Fisher, David McCallie, Terry O'Malley, Jack Po, Ram Sriram, Ricky Bloomfield, Sasha TerMaat, and Sheryl Turney. Are there any members, either on the Adobe or phone, that haven't announced themselves yet? Okay. We'll circle back. I'll let you know if others have joined. With that, I'm going to turn it over to Ken to get us started.

Kensaku Kawamoto – University of Utah Health – Co-Chair
All right. Steven's on the line, but I think he's in transit, so I think perhaps he'll have to leave during the call. Next slide, please. All right. So, this is just a reminder of our charge, and the key thing here is we need to publish a report on our findings, which is what we'll be focused on today. Next slide, please. And then, of course, our task force members. Next slide. So, this is key to our timeline. We're on our September 10th meeting. What we'd like today – we sent out some emails requesting, per earlier discussion, to review the draft report and provide suggestions at it, so we're going to focus on those at this point. And then, we'll summarize those recommendations and provide it to the HITAC for draft recommendations when we meet in person next week. I think we have about an hour and a half on the schedule.

One of the things we'll want to make sure we do today is if there are particular issues that we want to bring to the HITAC's attention beyond the report – particular questions, for example – we'd want to highlight them so we can have them ready for discussion. And then, we have two more meetings scheduled for being able to finalize and revise, presumably also based on feedback we should receive on the 17th, and then we'll be wrapped up. Next slide, please. So, at this point, I'll share my screen. Let me share my screen again. If you can see my screen, let me know. It should be the draft. Can folks see that or not? I hope it's not still blank. Is it visible to folks – the draft report?

Unidentified Speakers
Yes.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay. So, I saw that a number of folks had commented. I went through this morning and reviewed and addressed, and there are still a number of things to be discussed. What I'd like to do is walk us through some of these comments, start with the ones we have, and try to get through those. While we're on those comments, we can certainly address particular issues. Some high-level issues I ran into when reading folks' comments: There were a few places where people commented – and, I think it's true – that we have cross-use recommendations. Do we want to pull those into general, cross-use recommendations? Those included things like how there are clinical legacy standards and FHIR-based standards. We recommended that we come up with a strategy to deal with that. And then, there were also things like how when we reference standards, we should be supporting them and making sure

they are freely available. When we reference something, it's required that it doesn't involve people having to pay a lot of money to be able to use those standards. So, that was one.

And then, another set of thoughts that I came across as I was going over it again was that we should do Tier 1 and Tier 2 recommendations, but there are certainly a lot of Tier 1 recommendations. Another thought that's probably worth thinking about is whether we want to designate some as Diamond Tier or top-tier recommendations. I think that's something to think about if we want to promote certain things as really high-priority.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
[Inaudible] [00:05:11] insofar as we're going to be presenting this to HITAC to seek their input on what might be the very top tier, if that seems appropriate.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, I think so. It's somewhat implied in some of our content, and there were some comments about how these should be put at the top of the Tier 1 recommendations, which is another way of saying these should be our top priorities within these. But, I think that's a great topic for next week. I'm just going to go straight through here, and I think we should just review. Basically, other than typo edits, all the comments are here. I suggest we go through from the top and edit some things.

I just added some content on what we did in terms of approach. We invited subject matter experts to provide input and consultation, we identified issues that could be improved through better use of health IT, formulated recommendations to address the issues, as well as potential policy levers, and find recommendations through feedback from task force members and the larger HITAC. So, I think that's innocuous, so unless there are objections, I'm going to keep going.

Down here, the first content – we reviewed this last time we talked, about this notion of appropriately personalized normal ranges, and there's a discussion thread here between Jack and Ricky. I think the big-picture question is whether we want to specifically call this out here and in the recommendations. I'm okay with it; I just wanted to see if people had any strong thoughts on it, and I'm not sure if I can see hands, so could somebody who has the whole screen as an organizer identify hands that are raised and ask them to speak up?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
There are no hands at the moment, Ken.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay. I'm going to assume that people are okay with it. I'm going to take your silence as meaning it's okay to include. So –

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Oh, correction. There is one hand. It just popped up.

Ricky Bloomfield – Apple – Member
This is Ricky. I just raised my hand. Just to clarify here, I'm fine including it as well. My point here is that if we are going to include it in the use case section, we should call out the specific – since this is a standards and interoperability task force, we should call out the specific standard that we think we are advocating for in order to make this a reality. It's a nuanced issue that may have a little complexity in teasing out how we actually approach personal normal ranges, and I don't know if we did a lot of due diligence in the earlier conversations on how to make that a reality, or maybe we should keep it pretty general and say we recommend further exploration on this topic, which would also be fine.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I added this as a proposal to address that notion, that we shouldn't talk about it if we don't specifically mention how it could be achieved. There was one that said, "Not all results are sent to clinicians in codified format with the necessary metadata about verification and utilization EHRs." I added "optimal utilization" and proposed here, "Such standardized delivery of information could allow, for example, trending semantically equivalent test results together, leveraging the results in clinical distance support, and providing interpretation of results based on the patient's characteristics retrieved through other means, such as FHIR, e.g. age, gender, race, ethnicity, and/or comorbidities."

I think when we talk about how we need to send standardized data and whatnot, one of the things it would enable is things like, "Well, you know exactly what it is, so, other than just displaying it, you could actually make use of it, such as for creating personalized references." So, I think the prior recommendations we had do cover how we would be able to do this. I just suggested this as a way to make explicit how that could be done.

Ricky Bloomfield – Apple – Member
Got it. And, this may be a dumb question, but is there good data on the idea that we can personalize the normal range? I see the value in having the data that's there that will come help you eventually interpret that, but the fact that you could come up with a person-by-person range of normal for you seems to be a little more abstract, and I'm not sure there's been research done there.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, that is true. I think the only places where I'm aware are things like when you calculate things like –

Ricky Bloomfield – Apple – Member
EGFR?

Kensaku Kawamoto – University of Utah Health – Co-Chair
– atenine clearance, EGFR.

Ricky Bloomfield – Apple – Member
That's the only one that –

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, D-dimers that are age-based, but it's pretty few and far between as I'm aware. Not to say that it couldn't be created, right? At least, among people who seek care within a certain age and gender cohort, you could create those, except it will probably be highly biased toward those who seek care.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
Just be clear, in these personalized ranges, we can personalize the patient **[inaudible] [00:10:43]**.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Steven, you're really breaking up.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
Oh, sorry. I can turn it down.

David McCallie – Individual – Member
This is David. I… Steve, are you going to try again?

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
I can try. Can you hear me?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yes.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
Okay. When we speak for personalized data we may be personalizing, is that to the user or to the patient?

Kensaku Kawamoto – University of Utah Health – Co-Chair
I assumed it was patient.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
Okay. There would be a difference for a personalized than **[inaudible] [00:11:23]** patient-specific.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yes. I believe the use case – and, Jack can speak up if he's on – because I'm an Asian male who's 40-something years old, my personal range should be different from a Caucasian female who's 70, or something like that.

David McCallie – Individual – Member
I think the vast majority of –

Kensaku Kawamoto – University of Utah Health – Co-Chair
One suggestion would be to – go ahead.

David McCallie – Individual – Member
I think lab systems today support that kind of age and gender range variation. It's a configuration, typically, in a lab system as to how granular they want to break it out. Are we calling for something new and different beyond that, like genomic personalization or contextualization of a clinical disease that you have?

Kensaku Kawamoto – University of Utah Health – Co-Chair
I think the part was ethnicity that was brought up. I just don't want to get in a – we have so many to go through. I don't want to get too bogged down. I'd like to suggest something that makes it less controversial and move on. Let me see if I can find where that was.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair
I think it's something **[inaudible] [00:12:38]** personalized, and that the source of the personalized ranges is the source system. That's how we can best do it at this point, for the system **[inaudible]** specific range, a gender-specific range, **[inaudible]**.

Kensaku Kawamoto – University of Utah Health – Co-Chair
You're really breaking up and very hard to hear and understand. You may want to put – I don't know if you can put it in chat. It might be easier to see. I think I see that you're typing. So, one suggestion while Steven's doing that – I suggest saying, "Such standardized delivery of information could allow, for example, trending semantically equivalent test results together, leveraging the results in clinical distance support, and providing interpretation of results based on the patient's characteristics," and I just said "age and gender." "Patient-specific range as defined by the source system…" It has to be – I think the key thing so far that Ricky brought up was how basically, a lot of systems might be able to do these for some things, but aren't taking comorbidities and that kind of thing into account, so does this work?

David McCallie – Individual – Member
I'm guessing what Steven is trying to say is that the standards allow for the transmission of such specific normals. The problem is getting them out of the source systems. So, the lab system, which is not a standards issue, has to be prepared to actually produce an age-, gender-, and ethnicity-specific range of normals. Once that's done, the standard can carry it, so it's not a standards issue as much as it is asking the source systems to be more granular in their personalization of the range of normals, which is a policy issue, not a standards issue.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Since you asked that **[inaudible]**, you could have the source system send what it believes to be the normal range for that population, or you could have the interpreting system use the results plus additional data points to define what's normal for this population. So, you can do it both ways.

David McCallie – Individual – Member
Right, but it's not a transmission – it's not a standard issue. That's all I'm saying, which is a minor point, but we are about standards in this group. In other words, you can put it in a FHIR message or an HL7 V2 message what you think the range of normal is, and you can add a comment to your heart's content

about how to interpret it. So, it's a broader point than just enhancing the standard. It's enhancing the use; it's enhancing what we expect to be in those standards – personalization of range of results, which is a policy goal that's laudable, but if you separate it out, it's a policy goal.

Ricky Bloomfield – Apple – Member
Right. It's both a policy goal and a research question because they don't exist at the level of nuance that even labs would be able to fill in the information that we're asking for. I just want to make sure that we're not getting all dressed up with nowhere to go in terms of what we're recommending.

David McCallie – Individual – Member
I agree.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I suggest that we just remove that. Is that okay? I think we're getting stuck in a rabbit hole where it's kind of a niche functionality, and that's already –

Ming Jack Po – Google – Member
This is Jack. I'm happy to just remove it. I did not intend to generate this controversy.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay. Let's just change this for now. Thank you. I think that's good. The standards for reference do allow the kinds of things we talked about here. I think saying that it will be available implies that we really are expecting people to do it, which is perhaps too much. Okay, perfect. Let's keep moving. Here, the first one was, "Meets Tier 1 need for consistent encoding of test results." There was a lot of confusion and comment about which one we referred to, the test or the results, and combining LOINC and SNOMED.

So, I added clarifying text. I said, "Need for consistent encoding of tests in the results laboratory and other tests in the results are not" – so, I differentiated the tests and the results. If you look at this – "and the results are not consistently encoded with appropriate standard codes, limiting ability to exchange actionable results between HI systems, also known as semantic inoperability" – that was an addition. "In this report, "tests" refers to the tests performed, e.g. hemoglobin A1C tests, systolic blood pressure, bacteria identified in blood by culture, whereas "results" refers to the value of those tests, e.g. 7.4%, 140 mm of mercury, *Neisseria*, might initiate that SNOMED CT code 18722-004." I hope that clarifies things. I think this is just a common understanding of what this means, but the idea here was to be explicit about the difference between the code for the test and the code for the results, where appropriate.

David McCallie – Individual – Member
Sounds good.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay. I'm just going to accept these. I don't see a way to accept these, but I'm going to assume it's accepted. So, recommendations – there is a little bit of rewording. "Resulting organizations should

provide blank codes to identify all clinical tests, and send these blank codes with the results when reporting or exchanging the data via messages," which is really clarifying that it's about the identification of the tests. This is just accepting some editing choices. This same comment I think Ricky had – "Why are we talking about SNOMED when we also talk about LOINC?"

So, just for clarification, "When result observation values are coded as opposed to free text, as in the bacteria identified by blood culture example above, resulting organizations should provide SNOMED CT concepts, and LOINC-based coding of tests and SNOMED CT-based coded test results should be enforced by CLIA. If this enforcement is ineffective in assuring that coded data are available to deliver consistently, use of codes for these data should be made a condition of payment by CMS." So, that's just a rewording to be clear about the role of LOINC versus SNOMED.

David McCallie – Individual – Member
Are we carving out recommendations separately from observations, or are we lumping them together? I've lost track of our organization.

Kensaku Kawamoto – University of Utah Health – Co-Chair
We sort of have, yeah. We put observations separately from recommendations. We did.

David McCallie – Individual – Member
Yeah. Oh, I see. These are in the recommendation category. Okay. We're lumping policy recommendations from other ones.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, and we had asked Arien to also see if he could provide recommendations around policy levers. That is one area where we're kind of weak with a lot of variables.

Arien Malec – Change Healthcare – Member
Yeah, he failed you.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Maybe in an upcoming week…

Arien Malec – Change Healthcare – Member
Yeah, hopefully, I can clear my calendar and get a good chunk of time attached to this. Apologies for this.

Kensaku Kawamoto – University of Utah Health – Co-Chair
No, it was a last-minute request. And then, the next one was "Assure that there's a…" Okay, so, this one was Ricky's comment saying we need to make sure there's a process that's managed and an appropriate resource for making sure LOINC codes can be added. You said, "Isn't there already one, and do you mean more support for these submissions?" So, I just took his comment and added text. "This could take the form of more formal support for the current process to submit, review, and, if

appropriate, approve new LOINC codes," if that works. I'm just clarifying that there is a process; we just want to make sure that it's actually supported sufficiently.

David McCallie – Individual – Member
That sounds good to me.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay, that's resolved. Next one: Ricky had a comment. "This should come…" Okay, so, it says, "Required enforced use of information models in determining standards for all tests, orders, and results," and we said priority should be on the test identification, numeric, and free text results. So, I just wanted to point out that test identification for sure, numeric and free for sure, but we spent a lot of time talking about the SNOMED CT, and by saying we should focus on the non-coded, which may be appropriate, we're basically saying what we just talked about as a priority is not really a priority. It's contradictory. My suggestion is to get rid of this term saying priority – clearly, test identification rate, but what we're saying here is don't worry about coding the coded value sets, just focus on the numeric and free text. I do think the numeric and free text happens to be done pretty well already.

David McCallie – Individual – Member
I found that phrase confusing, so I'm happy to drop it.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Unless there are any objections, I will delete it.

David McCallie – Individual – Member
The next point – the next bullet there, "Work with clinical groups to define standards for structured documentation of key aspects of common clinic conditions" – that was my homework that I was very tardy in submitting, so that's what I was trying to get at around the notion of what an information model needs to have in it – ways to get agreement on common structures or critical things so that people document congestive heart failure essence the same way, et cetera. I'm happy to drop it as being too detailed to worry about, but that's what I was getting at on our previous call.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Could you give that example again? What would be the example here?

David McCallie – Individual – Member
So, let's assume that in the continual struggle between structured and unstructured clinical documentation, where if you structure everything, it's too constraining, and you lose the narrative story of the patient, but if you don't structure anything, downstream clinicians don't have a quick, essential summary of the patient, you come up with some notion that you should define a central, core, structured element that ought to be captured in structured form, and the rest of it can be narrative.

So, what that translates to is that clinical groups – cardiologists, for example, would have to say, "If I'm intaking a congestive heart failure patient and there's only three things I can know, here's the three

things I really want to know – rejection fraction, blah blah blah." So, that was the essence there, and to me, that's part of the information model because you're using coded terms – SNOMED, LOINC, et cetera – but you've got to build them into higher-level structures, and clinicians need to know what they should document in structured form. Again, maybe this is opinionated. I'm basically channeling Stan Huff here.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I just moved it to the section below, where we talk about how we need to identify the priorities of things we want to do – order type. I think it fits better here. We don't really talk about notes elsewhere, but this would be the right place to put it, or in manually entered observations. I think it's less where we'd say you need to encode it and more where we talk here about how we need to define what's most important and come up with some standards around that with expectations that it's actually going to be captured and exchanged.

David McCallie – Individual – Member
I'm happy. The only concern I have is the naïve assumption that many seem to make, that if you have a LOINC code or a SNOMED code, you're done, and that's just not the case.

Kensaku Kawamoto – University of Utah Health – Co-Chair
We do talk about information models elsewhere, and we should move some things around. I'm just going to move this. And then –

David McCallie – Individual – Member
It belongs wherever we address information models. That's the place where it belongs.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I'm looking to add that here.

David McCallie – Individual – Member
It may be too detailed for this level, but I think it is the next phase of getting codified documentation that can drive machine algorithms downstream. You can do only so much with free text extraction in a safe way. You need some essence of structured input. I would also make it around what quality measures are needed downstream as well, so that you don't have to do manual abstraction for quality measures.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I agree. Ricky, I had suggested that this be higher up – big-picture – so I'm just going to put it at the top here. "Required enforcement of information model and terminology standards for all test orders and results. Terminology standards are now put on their own to meet semantic property needs. Information models are also needed."

David McCallie – Individual – Member
I like that.

Kensaku Kawamoto – University of Utah Health – Co-Chair
So, that's there. And then, when we talked about mapping, I think this one – we first should say prioritize – just moving – prioritize the source system doing as much as possible, and then, I just added, "Enable some downstream mapping in cases where coding is not done at the source." So, we're just making clear that that's the case. Okay, perfect. I think that addresses things here. I'm just going to keep this moving. Please speak up if there are issues here. I think someone else added this; I don't think this was me, but I can't see who it was. Under recommendations/policy levers, we have, "As necessary, support the workflow in development and specify the appropriate use of additional LOINC codes to accommodate involving test methodologies and address clinical needs." I think that makes sense. I think it's just – oh, the text was out of the screen. Perfect, okay. Select here – it might just be the fact that its color changed.

David McCallie – Individual – Member
You can clean that up later.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah. I was just getting confused and saying, "Why doesn't it allow me to…?" Okay. The next one – "Continue promoting use of LOINC in diagnostic device approval and oversight," and then, Clement added, "and then, the delivery of clinical trial test results." If there are no objections, I think it's reasonable. Or, I hate to add "clinical trial results."

David McCallie – Individual – Member
Well, is the subtle point there something to do with CDISC?

Kensaku Kawamoto – University of Utah Health – Co-Chair
I don't know. I don't think Clem is on, unless he is.

David McCallie – Individual – Member
I think there are certain coded results for the FDA that are required to be in CDISC. Arien, maybe you can correct me if I'm wrong, if you're still listening.

Arien Malec – Change Healthcare – Member
It has been so long since I've been in the CDISC world.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I'm just going to make a note here –

David McCallie – Individual – Member
There are a few, and there's some controversy about that. Why do we need yet another superminority standard in this space? It's not a minority in Europe, but it is in the U.S.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Let's just skip this one. We'll keep it flagged and ask Clem to clarify. We still have some meetings, so we can move on. This one – "Should the BUPS test be insufficient to promote consistent standards-

based interoperability, require certification as a condition of participation." There's a bunch of comments Ram put. Most of them plainly made sense; I just resolved and edited it. It does seem – he says, "It says 'certification' twice. Why don't we just get rid of it?" Is there any reason not to say if they're not, certification should be a requirement of participation and/or payment? Or, is there such a thing as a condition of certification or a certification beyond condition of participation and payment? Okay, I'm going to take it out.

And then, for the next one, I just had a comment. Should we delete this one? I didn't really understand it. We said, "Standard code sets are not unique or sufficiently granular to determine the clinical equivalency of tests." And, it says, "Observation: Existing standard code sets utilized for order and result metadata are frequently not unique or sufficiently granular to accurately determine the clinical equivalency compatibility tests ordered or performed at different organizations. Recommendations: Create a means of interpreting the different codes and information available for procedures and result components so that when received, they can be uniquely identified. This new way of transmitting codes would then be adopted by all EHRs and other systems exchanging results data. This means stakeholders approve standard code sets to optimize granularity and provide better mappings to improve the experience of clinicians and patients attempting to interpret the perceived results." So, this is getting at –

David McCallie – Individual – Member
Was this where we were trying to capture that there's more than one way to encode, for example, a wound culture for a different SNOMED combination?

Sasha TerMaat – Epic – Member
I thought we had a case where we talked about both cases where LOINC is overly granular and you want equivalency groupers for different clinical purposes, but then, also the opposite in cases where a particular code is not useful enough and needs to be more granular, either just in usage less than in existence. There probably is a more granular code, but the usage isn't granular enough in a particular case for that purpose. I think that was the discussion that drove this recommendation.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I got caught by the thing that's saying it's not sufficiently granular because when you **[inaudible] [00:32:30]** the first thing you think of is not – it doesn't provide enough detail, for the most part. It probably provides too much.

Sasha TerMaat – Epic – Member
We had examples of both, so maybe we should make the language a little bit clearer that we were thinking of examples of each case.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Maybe we say, "Level of granularity in standard codes may be mismatched with…required level of granularity."

David McCallie – Individual – Member

In some sense, this is part – go ahead.

Sasha TerMaat – Epic – Member
I was just going to say it's not even that they're mismatched, it's just that what is appropriate granularity in the lab is not necessarily the appropriate granularity in the primary care clinic.

Kensaku Kawamoto – University of Utah Health – Co-Chair
So, "The level of granularity in standard codes differs according to use case – according to use, causing issues." That's the underlying issue. Observations… So, "There are several issues with regard to the granularity of standard codes. In some cases, they may be too specific for certain uses, e.g. a clinical user generally would not care about the specific laboratory test mechanism used to obtain a patient's LDL cholesterol level. In other cases, the available LOINC codes or the ones selected assigned to a test result may be insufficiently granular." Is there an example of that? I'm trying to…

Sasha TerMaat – Epic – Member
I've run into it with quality reporting, but I'd have to do follow-up to get a specific code example.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Okay. So, "…e.g. for quality reporting purposes. Moreover, the level of granularity that is appropriate may differ according to use case, e.g. a desire or need to be as specific as possible for a lab versus the general and common desire to have the same lab trended together for a clinical user." So, then, we could say, "Recommendations: Where standard codes do not exist at the required level of granularity, either create such a code or a code grouper at the desired level of granularity. Where standard codes do exist, but their usage is suboptimal in terms of the level or consistency in terms of the level of granularity…suboptimal or inconsistent or problematically…" Because sometimes, even if it's inconsistent, it doesn't really matter for a use case, and sometimes it does, right? "…in terms of the level of granularity, address with…consider seeking industry consensus on the appropriate approach." And then –

David McCallie – Individual – Member
Ken, I think this is part and parcel of that broader information model discussion, and maybe it can be grouped with the other one. It might make sense to group it with the point we were making earlier. It is that industry consensus that's missing.

Kensaku Kawamoto – University of Utah Health – Co-Chair
It's actually a little bit lower.

David McCallie – Individual – Member
But, let's – an information model has layers, and this is a lower layer of it, but the real issue is consensus, right?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, "lower" as in it fits the next one. Maybe we can look at this one, and then, I'll just make a comment.

David McCallie – Individual – Member
I agree. It might get rolled up together, just to be more consistent. In a sense, we said, "Use LOINC, use SNOMED," and then we said, "Oh, by the way, that's not a sufficient solution. Here are a couple of issues that also have to be addressed: The granularity mismatch problem has to be solved, and the combination problem – when you are combining codes together to something more complex – that problem has to be solved as a part of an information model."

Kensaku Kawamoto – University of Utah Health – Co-Chair
We could certainly do things like merging at a later point. So, I just added these, and then, this one's still a little bit unclear to me. "Create a means of interpreting the different codes and information available for procedures **[inaudible] [00:39:02]** components so that when received, they can be uniquely identified." That's that information model, right? And, "The new way of transmitting codes would then be adopted by all OHRs."

I'm just going to take this… If it's okay, let's talk about information models in the next one, where I think it's talking about that. And, like David said, this is saying make sure you use the same information model, which is a little bit different from this notion that the level of granularity of codes is inappropriate. So, I suggest we just delete this and make sure that the notion of information models is captured. I'm just going to delete this one – sorry, I'm going to delete this one, and let's move on here.

Policy levers, responsibilities, "Convene stakeholders to approve standard code sets to optimize granularity for better mappings." I think this is "Convene stakeholders to address – add codes with sufficient granularity are needed…" It's really – no, I think it's just to facilitate addition of codes with sufficient granularity, and I think this is related to what we said above, of saying make sure LOINC is sufficiently resourced. And, "According to recommendations above, consider seeking and facilitate creation of code groupers at the desired level of granularity." We talk about this a little bit later – another reason why we may want to match them.

I think that's it – oh, "Facilitate gaining industry consensus on an appropriate level of granularity where needed." I don't know. These are kind of weak, fuzzy recommendations, but I'd say these can be reviewed later. I think there are more important topics, so my suggestion is to flag this for the next round of reviews, and if it doesn't make sense, we should just update them. Oh, Clem says, "I can't talk, but some of this discussion is misdirected. The labs have to pick and stand by the codes they use for CLIA labs. As for codes they further, LOINC is one of the classes that allow roll-ups." Yeah, that's exactly it. LOINC roll-ups. And, we'll talk about it later.

Oh, and Sasha suggests, "Groups of just solar and clinical information modeling working to organize concepts and classification in order to **[inaudible] [00:42:21]** in translation." Yup, that's true. I think this might be the place where we talk about information models. I'm not sure – there's a section on metadata. Just for the sake of time, let's keep moving, and then, we still have multiple rounds of comment available. "Results need to be sent to clinicians in coded format. Not all results are sent to clinicians in **[inaudible]** format with the necessary metadata of all integration-optimal utilization EHRs."

So, we already discussed this part. And then, recommendations – I added, "Similarly" – oh, this is what we added with David, the notion of – so, make sure that there is some understanding of what needs to be standardized and exchanged. And then, I think what we…need to say is, "App standard codes…" And, this says that Ram thinks the same. "Clinically equivalent…" It says, "Mitigate different points for the same…" I'm just going to put it in quotes because they're technically not the same as if they used a different machine or something.

David McCallie – Individual – Member
You could put "equivalent" in quotes.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah. "Clean methodology" – he said "Reference range." That's fine. I'm trying to look for where we have the notion of the data model. We have a section on metadata. Let me see if it's here. So, I guess the closest we get is this one where we talk about metadata. I think, David, your main comment is that "information model" is not – we don't really address "information model" anywhere, maybe because typically, the information models for simple things are pretty simple. A simple test result doesn't really need that much more work, I don't think. It's when it gets complicated, like whether you're going to pre-coordinate or post-coordinate – that kind of thing.

David McCallie – Individual – Member
Right, and we stalled out in terms of semantic interchange at the simple test results. Anything beyond that now requires human effort on a per-system interface basis, and if we want to go further than that – if we, the industry, want "semantic" to mean more than just "I know the name of that test and I understand what that test name means," you need an information model, and as Sasha pointed out in the comment window, CIMI is one such effort to create an information model that rolls up all the low-level identifiers into more coherent and standardized wholes, but that requires clinicians to agree. It's not something done at the lab level, it has to be done in the context of understanding medicine rather than just saying, "Here's a sodium test." It's a higher level. I think that's where we've stalled out in terms of semantic interchange. We're pretty good at the low-level interchange now – not perfect, but pretty good – but if we want to automate extraction of quality measures, facilitate mega virtual clinical trials, then we need a higher information model.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah. So, I'm going to try to keep it in what we have, but at a – so, "Standardization and industry consensus around information models, terminologies – including metadata and associated terminologies," right? Metadata is just a type of an element in an information model. So, "Not all results in codified format are sent to clinicians with the use of industry-consensus information models, including necessary metadata and associated standard terminologies…to allow integration." And, we can just add, "While information – where there is general industry consensus" – I'm pretty familiar with CIMI. I agree with David that it's complicated. So, "While there is general industry consensus on information models for simple results, e.g. a simple laboratory test, there is not industry consensus on more complicated results, e.g. orthostatic blood pressure – well, e.g. blood pressure – when considering issues such as cuff size, position, orthostatic, et cetera." I think that's true, right?

David McCallie – Individual – Member
Yup.

Kensaku Kawamoto – University of Utah Health – Co-Chair
"To get beyond semantic interchange of simple results, more effort – more movement, more advancement – is needed in these more complicated areas." Okay. And then, if that looks okay, then our recommendations – "Identify the most common important results of each order type." I think that's true for standardization exchange. "Similarly, work with clinics to find standards of expectations for collection exchange or structure information, documenting key aspects of common function." And, here, we need to say, "Prioritize results by which information models and LOINC codes," I think. And then, we talk about USCDI. I think that incorporates now – maybe not in the ideal format, but we do have the notion of information models. As soon as it's no longer simple, everything falls down. Okay, that sounds good.

If we can keep moving, the next one was around orderable testing to be standardized between symptoms and mapping standard terminologies. Victor Lee said, "It seems to me the problem is greater for non-medication orders because for medications, you can use an Rx form." So, I think "orderable tests" implies it's not medication because medication is not a test, but I just added, "Standardized codes should be used for orderable tests, similar to how Rx forms can be used for medication orders." That's okay. It was just a clarification.

David McCallie – Individual – Member
Ken, are you using "test" as in "lab test," but not, for example, diet or physical therapy?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah. We go beyond it because we talk about lab orders, but we also talk about things like radiology orders as well.

David McCallie – Individual – Member
So, maybe "tests…" Maybe "non-medication orderables" or something like that. To me, "test" could be taken more narrowly than you are intendent.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah. This is a huge one, right? This is the one we always kick the can on.

David McCallie – Individual – Member
We've got a lot of cans kicked here. Hard problems remain hard.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yes. And then – so, there's one coming here. Victor recommended – when we said, "Support and ensure the harmonization of the multiple existing code sets for orderable tests, including HCPCS and CPT, PLA, and a blank common order codes value set," Victor commented, "I recommend removing CPT. I'm not sure about PLA and HCPCS since it's not really an orderable catalog. I suggest adding

SNOMED as an example. For the harmonized proprietary content, we need to ensure that the results and orderable standard does not inherit licensing fees from proprietary content, which could severely limit its adoption."

Let's see. We do say here, "Avoid usage of proprietary fee-based terminologies and standard-issue orderables in order to **[inaudible] [00:52:59]** and make the work product initiative freely available to all users." I think that makes sense. Shall we just make this, "Consider terminologies, such as SNOMED CT"? How about we do that? Just say, "You should consider it," and then we can say, "Ensure terminologies are at a sufficient level of granularity to support the level of granularity needed for actual orders," right? That's a problem – that oftentimes, it's good enough, but it doesn't have the level of granularity we actually need for an ordering system. I agree. Cynthia also put that.

Maybe we should just move this, just because – we do address it, it's just a little bit lower down. "Avoid usage of proprietary fee-based terminologies **[inaudible]** orderables and order details and make the **[inaudible]** product of this initiative freely available to all users." I think that makes it, right? "Does not require proprietary online payment, as it is cost-prohibitive." Yeah, I agree.

David McCallie – Individual – Member
Should it be reiterated under the policy levers? Well…it's not really a policy. ONC and CMS together set the required standards, some of which are extremely proprietary. They could change that policy.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I'm going to just make a call-out to general section recommendations. "Make sure standards are open and free to use."

Clement McDonald – National Library of Medicine – Member
This is Clem, and I haven't been able to talk, I think, until just now. I've been listening frustratedly to this discussion. So, CIMI's an information model – so are HL7 and FHIR – and it's described as an information model, so I think there's some complication there. And, the discussion about labs being too specific – the labs define what it is they need to use, and that's what the LOINC codes are, so I don't think we have the freedom to have them change what they use to be less specific just because clinicians don't like them. LOINC also has the equivalence class, which kind of rolls them up, and it's got other ways to search it. So, I think that discussion was misdirected about – you can't just make them more general and then have them delivered by the labs because that's not what they will use.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I don't think that's what we said. So, "…differ according to use, causing issues." And, we say, "Appropriate may differ **[inaudible]** need to be as specific as possible for a lab versus a common desire to have the same lab trended together," and we talk about –

Clement McDonald – National Library of Medicine – Member
Yeah, well, that's the trick there. And, there is an equivalence class system that helps that, and there are other things that do too, but I just don't think we can say the labs – it gets confusing. If we don't have the labs send a standard code, we're dead, and they make that choice.

Kensaku Kawamoto – University of Utah Health – Co-Chair
We specifically say we don't have a standard at the level of granularity needed, do it – it's probably less for labs and more for things like other observations.

David McCallie – Individual – Member
Right, and the classic one that was a headache when I was working on this stuff was wound cultures. There is more than one way for a lab to send exactly equivalent information.

Clement McDonald – National Library of Medicine – Member
Well, the labs declare… We're still at their mercy. Granted, there's more than one that they can specify, and if we could put them together, that would be good, but to start, you want them to at least send not just the local code, but the standard code that people understand, and then people can group them somehow.

David McCallie – Individual – Member
And, I think that's what we're calling for, is enough granularity to capture the actual analyte, and then, just grouping or information models. I think it's more than just groupers because roll-ups are not sufficient. It's necessary, but not sufficient.

Clement McDonald – National Library of Medicine – Member
Well, I'd like to hear more **[inaudible] [00:57:36]**.

David McCallie – Individual – Member
At some other point. It's too deep for our call today.

[Crosstalk]

Kensaku Kawamoto – University of Utah Health – Co-Chair
I just changed it to "…consider terminologies," and then, I added CIMI for that comment. They're not mutually exclusive. At the upcoming AMIA conference, we'll be presenting work on how we're using a CIMI-based model to map back and forth from various different FHIR versions and such. Claude Nanjo, a CIMI co-chair, is going to be presenting that.

Clement McDonald – National Library of Medicine – Member
There's one other thing I'd like to bring up because I sent a whole bunch of comments in, and they just went away.

Kensaku Kawamoto – University of Utah Health – Co-Chair
They did?

Clement McDonald – National Library of Medicine – Member
Maybe they got adopted or taken, but I got no –

Kensaku Kawamoto – University of Utah Health – Co-Chair
No, I only saw one, Clem. I don't know why. I only saw one comment.

Clement McDonald – National Library of Medicine – Member
They didn't get in?

Kensaku Kawamoto – University of Utah Health – Co-Chair
I don't think they went in.

Clement McDonald – National Library of Medicine – Member
Oh, okay. Sorry.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I only saw the one about – I only saw one comment, and I did not see any further after that.

Clement McDonald – National Library of Medicine – Member
I had assumed that they were dealt with and they were taken away.

Kensaku Kawamoto – University of Utah Health – Co-Chair
No, I basically only resolved or removed if I accepted and put it into the packet.

Clement McDonald – National Library of Medicine – Member
So, you were the only one that manipulated the comments?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Well, it's possible someone else deleted it, but…

Clement McDonald – National Library of Medicine – Member
Okay. I'll figure out what happened offline.

Kensaku Kawamoto – University of Utah Health – Co-Chair
While we have you, "Continue promoting use of LOINC in diagnostic device approval and oversight and in the delivery of clinical trial results" – could you explain this a little bit more? We're wondering what this was referring to.

Clement McDonald – National Library of Medicine – Member
Say again. I've got a bad connection.

Kensaku Kawamoto – University of Utah Health – Co-Chair
There's a section where we say, "Continue promoting use of LOINC in diagnostic device approval and oversight," and you added, "…and in the delivery of clinical trial results." We wanted to know – were you referring to CDISC? What were you referring to there? Use of LOINC for FDA and delivery –

Clement McDonald – National Library of Medicine – Member

Well, FDA has specified LOINC, so I think that's what I was talking about for next March.

David McCallie – Individual – Member
What about CDISC?

Clement McDonald – National Library of Medicine – Member
Well, CDISC…

David McCallie – Individual – Member
Don't they require that also? Yeah, it's complicated.

Clement McDonald – National Library of Medicine – Member
Well, the FDA requires a lot of stuff that we aren't addressing, like WHO drug codes. But, FDA – when we're talking about what's been declared as standard code systems in healthcare, LOINC is now required for clinical trial results for lab tests, and I'm just trying to assert that – remind people of that, as of March of 2020.

Kensaku Kawamoto – University of Utah Health – Co-Chair
That sounds good. If it's okay, I'm going to keep moving us forward.

Clement McDonald – National Library of Medicine – Member
Sure. I'll have to go back to those comments.

Kensaku Kawamoto – University of Utah Health – Co-Chair
There was a comment here for the policy lever responsibilities on orderables. Victor said it's probably premature to recommend following the 2015 LOINC order codes as in a FHIR framework initiative, especially because that's only just for LOINC, right? So, maybe we say –

Clement McDonald – National Library of Medicine – Member
Well, let me say some comments. That way is way too small. There are thousands of order codes now, not counting the singletons. Mayo is putting their whole 10,000 set into LOINC, and I think how it's been expressed in the various message standards is "When available, use the LOINC code."

Kensaku Kawamoto – University of Utah Health – Co-Chair
I'm going to put your – how about "facilitate" or "spearhead"? I think there needs to be someone who does it, so I'm going to say, "Spearhead creation and adoption of industry standards around non-medication orderables. Consider leveraging prior work."

Clement McDonald – National Library of Medicine – Member
There's a – go ahead.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I just said, "Leverage prior work, such as this one."

Clement McDonald – National Library of Medicine – Member
What is "this one"?

Kensaku Kawamoto – University of Utah Health – Co-Chair
It's the ONC ABE LOINC order code and SNI framework initiative report.

Clement McDonald – National Library of Medicine – Member
Okay, well, that actually is only 300 codes, so I don't think it's enough. Maybe I'm not familiar with it. Every radiology code is orderable on a resultable, and there are 6,000 of those in the LOINC consortium, and all the individual test codes – most of them are orderable. And then, there are a ton of panels that are orderable. Now, there are probably more than 2,000, and there a couple of big lab companies that are putting them all in over time, but they have a lot of them, and it's going to take a while.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I think it's good. The key thing is saying, "ONC, we recommend you actually help address this issue and take leadership in it." As far as I'm aware, this comes up in so many different projects, including some of the Da Vinci Care ones, and it's always like, "Well, it's not really in scope for us to deal with. Somebody just needs to deal with this at some point." That's where it dies.

David McCallie – Individual – Member
It's equivalent in complexity to the lab test problems, where you have thousands of lab tests, of which only hundreds are actually in use in a particular setting. The same is going to be true of orders, which means things like interoperable order stats and clinical guidelines are really hard to do. They don't match it.

Clement McDonald – National Library of Medicine – Member
The worst is probably – the most difficult and least articulate is probably nursing orders.

David McCallie – Individual – Member
Yeah. They've fought wars over there.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I just added, "Consider prioritizing influencing source," just because there are so many. Okay, if it's okay –

Cynthia Fisher – WaterRev, LLC – Member
Hi, this is Cynthia. I'm sorry, I can't raise my hand because I'm having a connectivity problem with my iPad. I just wanted to add that on the lab standards – and, I don't recall seeing it – that it would be really helpful for patients and providers – their physicians – if the lab results were immediately available to the patients in real time.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I think it's in there.

David McCallie – Individual – Member
We haven't gotten to it.

Cynthia Fisher – WaterRev, LLC – Member
It needs to be real-time into the patient availability of access because oftentimes, patients – we just had a case exactly where the patient comes home from the hospital, is discharged, and even though the lab is available within the hospital system, it didn't go to the patient until two days later. So, the very question – say, low RBC, low hematocrit, low hemoglobin – all those questions can't be asked. The patients can't advocate for themselves without the information. That availability, even within the hospital setting, so that the patient has access to these labs in real time…

Kensaku Kawamoto – University of Utah Health – Co-Chair
The big picture – the question is for the one I have highlighted, whether we go stronger than to say "Reasonable result." Basically, I think it's based on – there are regulations now, right? It has to be a certain amount of time. It is tricky – so, for example, do you have a preliminary result for pathology? Do you provide that automatically? There are issues about preliminary versus final because you probably don't want to see something that says "cancer" when the final read says "not cancer," right? There are issues like that. It gets tricky for some things. I think the trend in the industry is to essentially go toward near real-time, as in coming out by the next morning, but the question is –

Cynthia Fisher – WaterRev, LLC – Member
I think when it's readily available, is the patient information – decisions are made – you've got teaching hospitals with residents. Everybody has that information except for the patient, and the patient is objectified if they aren't able to participate in real time. I'm just putting that out there that it should be readily available.

Clement McDonald – National Library of Medicine – Member
I think it's a good idea in general. The challenge in the hospital is that they may not have their computer systems – there are a lot of complexities. "Real time" is vague, and I wouldn't call it that. I would say, "Final results should be delivered to the clinical people when they are available," if you want to take a rule.

Cynthia Fisher – WaterRev, LLC – Member
When results are provided to clinical people – I'm pushing to say it should go to the patient.

Clement McDonald – National Library of Medicine – Member
"Final results." There are caveats in some categories. There are some special cases that can be problematic because they may be available to others than just the patient, and things like that. Some tests are special, so there ought to be carve-outs here and there.

David McCallie – Individual – Member
There was some really good Twitter discussion last week about this problem. Arien was in the middle of some of it around which results – is there justification for delay of release of results to patients and

consumers? There was a really thoughtful post from someone from Vanderbilt on the rules they use to decide the timing of release of results, but I agree – it's complicated, and state regulations actually play a role as well.

Kensaku Kawamoto – University of Utah Health – Co-Chair
So, my suggestion is to make this a HITAC discussion topic. It is a very legitimate issue of whether one business day is too long, for example. But, this is a pretty major issue, so we can discuss it –

Cynthia Fisher – WaterRev, LLC – Member
I think it's a major issue. I think there were comments for the public comment in the CURES Act to have data be available in real time. It is in every other facet of our lives, and it is in care outside of a controlled setting.

Clement McDonald – National Library of Medicine – Member
The thing that we're missing is a destination for the patients. I think that's a big gap. Where does it get sent that they'll see it in real time?

Kensaku Kawamoto – University of Utah Health – Co-Chair
I can tell you what happens with our health system because we recently shortened this, and went through some growing pains on it. You just get a notification that your results are available, and if you use your smartphone, you can just see it. Essentially, we are getting results before the providers have reviewed it and commented on it. It primarily becomes an issue for things like pathology results.

David McCallie – Individual – Member
HIV, cancer – there are a number of classes that are sensitive around timing.

Cynthia Fisher – WaterRev, LLC – Member
And yet, so many cases – we live in New England – so many cases of Lyme disease don't get reported back to the patient. There are so many times when the ball has been dropped, and the best person to control and manage their health – when they're going to get that information anyway, it's more problematic not to give the patient access to their information when there's a swarm of not sharing or not communicating.

Kensaku Kawamoto – University of Utah Health – Co-Chair
If I can, I agree this is a really important topic. We could potentially spend the next 20 minutes discussing it. Let's put it on the HITAC agenda for one of the issues we want to get the full group's input on. It is a really important one, and could be potentially a large impact if we influence it, so let's move it there. In general, I think the experience has been good to make it available basically in real time, but there are some caveats for times when it may not be the best for the patient.

Clement McDonald – National Library of Medicine – Member
So, one other caveat – not a caveat, but a think we hadn't considered – some of the primary care doctors are drowning in phone calls they never used to get asking if this hemoglobin of 13.7 means much. We may need to be able to charge for phone calls to counter that.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Well, it depends, right? It depends on how you message it. We always message it saying, "You're likely getting this before your doctor has seen it, so if you want his comments on it, please hold off for a day or so," that sort of thing.

Cynthia Fisher – WaterRev, LLC – Member
I just think we hear so often – and, I'm glad you put it on there – that patients and their advocates – it's a challenging time, and to navigate the healthcare system, which is so siloed, patients need their advocates to help them manage their health. We do need to put it on the agenda, and we move to say let's look at the next generation that's living in real time on their phones on every other facet on their lives. It's more normalized to have information and search information. We live in a different time, and the feedback is to not be so paternalistic in dissemination of information. Patients really need access. So, that would be one thing. The second point I want to raise is the opportunity for the future for us to look at standards that are not proprietary so that they don't necessarily hold **[inaudible] [01:12:06]**.

Clement McDonald – National Library of Medicine – Member
Hear, hear.

Cynthia Fisher – WaterRev, LLC – Member
So, maybe we create a parallel system that's not dependent on historical…proprietary C-based structure that one entity financially benefits from.

Clement McDonald – National Library of Medicine – Member
Actually, Cynthia, there are very few –

[Crosstalk]

Arien Malec – Change Healthcare – Member
Amen, and it exists, right? That's the issue here – the alternative to the proprietary coding system absolutely exists, and all CMS has to do is decide to change their back-end adjudication systems, and the reason it hasn't gotten done is because they have…

Cynthia Fisher – WaterRev, LLC – Member
I think it behooves us to make it –

Arien Malec – Change Healthcare – Member
Totally. Absolutely.

Cynthia Fisher – WaterRev, LLC – Member
Is that Arien?

Arien Malec – Change Healthcare – Member
Yeah.

Cynthia Fisher – WaterRev, LLC – Member
I think it really behooves us as a committee to be really responsible to save our government and save our healthcare delivery system economically from accepting status quo that's C-based and proprietary.

Clement McDonald – National Library of Medicine – Member
Just to clarify, though, Cynthia, a lot of the status quo is not proprietary. It's open.

Arien Malec – Change Healthcare – Member
We're talking about CPT.

Kensaku Kawamoto – University of Utah Health – Co-Chair
It's particularly jarring because a lot of the groups that are making it available for free are suffering financially for it, too.

Clement McDonald – National Library of Medicine – Member
That's true.

Arien Malec – Change Healthcare – Member
On the subject of patient access – because it's something I'm living with, with my leukemia diagnosis and all the follow-up care, and I feel very strongly about it – maybe it's appropriate right now to – we've had a lot of good experience with making lab data available. Maybe it would be appropriate for ONC – even on this call, I've heard a lot of stories that I don't think are actually true – to re-look at this issue and re-promulgate some guidance and best practices in this area. The reality right now is we lock things down so much that it's not helpful, and the organizations that have opened more have seen reasonable success with it, but I just don't think those success patterns are getting shared and promulgated. This might be an area where the appropriate tool for ONC is to do a state-of-the-art, and then publish general guidance.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, that's a good one. So, that's –

Cynthia Fisher – WaterRev, LLC – Member
I think that's a great idea, Arien, and I'd be happy to work with you on that in advocating for patients and their caregivers.

Arien Malec – Change Healthcare – Member
Absolutely.

Kensaku Kawamoto – University of Utah Health – Co-Chair
That's true. Usually, from a health systems perspective, it's like, "Oh, it wasn't so bad when we basically made it real-time. We're not getting inundated with phone calls." Okay.

Arien Malec – Change Healthcare – Member

OpenNotes is also a part of that space.

Cynthia Fisher – WaterRev, LLC – Member
Yes, I think you raise a great point with the two-way communication and OpenNotes. To Arien's point, patients – obviously, when they have diabetes, leukemia, or another disease, they become very informed, and they need the monitoring system to stay fine-tuned and in better health, so I just put that out there as well.

Kensaku Kawamoto – University of Utah Health – Co-Chair
We'll go to public comment in a moment. Let me just address this particular one, and then I'll switch over to whatever high-level comments came and our thoughts on them before we go in next week. So, one is very specific. We say, "CCDA standards don't prescribe how to group result components," and we require them to be put in an orderable grouper so that you know, for example, that a result component was part of a particular panel. I'm not sure about it, especially in calling it out for CCDA. The same thing could be said for FHIR, for example, where you can't tell that a white blood cell came from a CBC, at least in what's required, because it's just not provided. So, we really –

Clement McDonald – National Library of Medicine – Member
We should have another discussion. There are linkages to the order, which does connect it, and in many cases, the components –

Kensaku Kawamoto – University of Utah Health – Co-Chair
It's not required, though.

Clement McDonald – National Library of Medicine – Member
There are components that reach that in many cases, which make it clear, too. It's a longer discussion.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, a longer discussion, but I doubt the full HITAC would be super interested, so we can do this for later. We'll go to public comment in a few minutes. For this particular one, we say, "Make sure the status of an order is available." I think we should just incorporate this into metadata and just note that order status is part of metadata.

Clement McDonald – National Library of Medicine – Member
It's an attribute of the observation – oh, the order status isn't, though. Never mind.

Kensaku Kawamoto – University of Utah Health – Co-Chair
This is just a basic information model. I don't think we should just call it out. It's one attribute. If that's okay, we'll merge. And then, Cynthia recommended, "In the final OPPS **[inaudible] [01:17:38]** a requirement the hospital incorporate into their EHR by a certain date price information into the referral workflow." So, this is probably more under… I think we do that… Hmm. This is not really… If we do this, this would be under "referrals." Maybe we should discuss that more later. This would need to go into the "referrals" section.

Cynthia Fisher – WaterRev, LLC – Member
Should we add it to the comments?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Yeah, it's still here. I don't think we can resolve it yet. We need to discuss it further. We can just do it after the meeting next time. I just think it needs to be in a different section. "The new version of script…" Let's see.

Cynthia Fisher – WaterRev, LLC – Member
Can I just give another example? Two days after a surgery, where no pricing was available – and, it was an important surgery, but it was non-emergent – two days after the surgery came a cost estimate that said, "Your in-network, out-of-pocket cost will be $500.00, and we're not sure yet, but if it's out-of-network, your out-of-network fee will be $85,000.00 as a cost." We just had a patient who sent that one in to us, and that was two days after the surgery. We don't want to procrastinate on this pricing issue because there's a big difference between $500.00 and $85,000.00.

Kensaku Kawamoto – University of Utah Health – Co-Chair
Let's go to public comment, and then we'll come back. Can we switch to public comment, please?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Sure. Operator, can you open the line for public comment?

Operator
If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 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 *.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Do we have any comments in the queue?

Operator
Not at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay, we'll circle back. Ken?

Kensaku Kawamoto – University of Utah Health – Co-Chair
Great, perfect. So, the big picture, if you recall – one of the topics we didn't get to was price transparency as its own topic. It feels like we did it because that was such a big part of the medication topic. That really comes down to the meta-question of for things that we didn't get the chance to fully

go through as a part of – because we could tack price transparency onto the orders and results, or maybe we just put it in a comment in the general, cross-arching thing, like, "Hey, price transparency is really important," but we probably want to delve into this further. I think I heard this on NPR or something – the notion that there is absolutely zero legal or contractual obligation of estimates being anywhere close to correct, which makes sense from a health system perspective, but from a consumer perspective, that's horrible.

David McCallie – Individual – Member
Hey, Ken? I'm totally sympathetic to the issue here and the need for more price transparency, but we need to cast this as an interoperability problem and a standards problem somehow. The policy debate is not the purview of this group.

Kensaku Kawamoto – University of Utah Health – Co-Chair
That's a really good point.

Arien Malec – Change Healthcare – Member
We don't have the standards, so I think the hook here on the standards piece is making sure that we have the enabling standards for requesting and publishing pricing estimates.

Kensaku Kawamoto – University of Utah Health – Co-Chair
My recommendation is –

Cynthia Fisher – WaterRev, LLC – Member
I'd also like to say it's not just estimates of the real prices. We just solved the outpatient payment system and services proposed rule to ask for the real, negotiated rate and the question for real cash prices as well, so I think these are financial standards, and to Arien's point – because I do believe it is in our purview as part of interoperability to lay down the road for the establishment of financial standards, much like any other industry transacts, and I do believe it's in HL7 already for payment. Are we not correct that there already exists a standard between providers and insurers between transacting and payments?

Arien Malec – Change Healthcare – Member
That's in X12, but that's just for the back end rather than the front end. So, it's the front-end piece of this where there aren't sufficient standards.

Cynthia Fisher – WaterRev, LLC – Member
And, it's a matter of timing. The standards to transact financially do exist in many other industries and the facets already within the healthcare industry, so I say let's do it, let's get it done, and then the road will have been paved.

Kensaku Kawamoto – University of Utah Health – Co-Chair
The way I would suggest we discuss this one is in the HITAC as well, we'll probably put in the conclusions that, for example, "Hey, we really tried to tackle this for medications. It's obviously important for other parts. There were priorities we identified that we couldn't get to." I would suggest

this as another HITAC item. What did we do about the other priorities that we said were priorities, but we just didn't have the time within our scope to do? Should we do it in continuation? Would ONC start up an initiative? Basically, it seems a little bit wrong to say these other things we identified priorities, but just didn't get time to go to, should become non-priorities because we concluded. I think that's a discussion point, and it's probably something we put in the report to say that we recommend these things should not be forgotten just because we finished our timeframe for this task force.

Cynthia Fisher – WaterRev, LLC – Member
Is it possible for a subset of this task force to volunteer to try to get it done in the coming weeks so that we can submit, knowing that there is a presidential executive order, there are several administrative actions, starting with the CURES Act as well as OPPS? We have MPRN coming out, so we are in the moment of time where we could get it done, and I'd be happy to volunteer with the likes of anyone from the technology sector, and I would suggest we bring in outside app developers as well as the hospital-based system providers for input into the system. But, I'd volunteer to get it done and work hard in the coming weeks to lay this groundwork in the price transparency segment.

Kensaku Kawamoto – University of Utah Health – Co-Chair
If we do that, my suggestion would be – so, if the idea is let's not say we couldn't get to it. Let's figure out if we can introduce it. I would keep it pretty high-level, just because we definitely do not have the cycles to do the equivalent of what we did for each of these because that would probably take on the order of two or three months of work. Maybe we could do an abbreviated version. The one place it could fit would be where we have this notion of cross-use-case, sort of meta-level issues, where we need to take some of the things we came up with and put it there. That would be one potential approach.

So, Cynthia, how about this? One of the things that Steven and I need to do is create in the recommendations – before we get to orders and results, et cetera, we probably need cross-use-case observations and recommendations. That would potentially be the place we could put things in. We would certainly need review and feedback from the task force and whatnot, but I think this is a potential place where you could put it. Do you want to start drafting out something here, and then we can review it as a task force?

Cynthia Fisher – WaterRev, LLC – Member
Sure. If you want to ping me on how you want it presented, just send me an email with when you want it presented. I'll put together a team and seek any volunteers that want to take a first cut on the committee.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I think that's fair. "Beyond medications…" I think one of the easiest things there is we need to take a few things to put in here, and then, that'll hopefully have a common pattern. It'll probably look like the pattern we have for other things, but I think it's fair to say, "Hey, we recommend whatever we can come up with that we can get consensus on, acknowledging that we still need to get consensus on the rest of the document as well." I think we're almost out of time. I think those are the main things I saw. I'm trying to look to see… So, maybe – my suggestion is we'll probably go with the version of the

document we have for what we discussed next week, with this being a draft, and then, let's continue some of these discussions. In the meantime, if you haven't had a chance to go through the document, please feel free to do so, and add comments and suggestions. I think we're pretty close to having a version to go with.

Ram Sriram – National Institute of Standards and Technology – Member
This is Ram here. Can I make a quick comment on the NCPDP? I'm sorry – actually, I just got an email today about this ONC. It says, "Beginning January 2020, the CMS will require that Part B e-prescribing be conducted using solely the NCPDP script standard version 2017071," and that actually addresses some of the concerns which you have there.

Kensaku Kawamoto – University of Utah Health – Co-Chair
I see. Oh, perfect.

Ram Sriram – National Institute of Standards and Technology – Member
I have some comments there.

Kensaku Kawamoto – University of Utah Health – Co-Chair
So, does it no longer become something –

Ram Sriram – National Institute of Standards and Technology – Member
Actually, what happened – you have to reword it if you want to do that because one of the questions there is you have this free text – how do you convert that to the six? But, NCPDP actually has done a comprehensive study on that. Maybe one needs to look into it and see whether that is okay or not – sufficient or not for this particular purpose. Do we have to still do this? We are recommending some things which probably could have been done, at least – I just got the email from –

Kensaku Kawamoto – University of Utah Health – Co-Chair
So, because we're out of time, if you wouldn't mind, if you could maybe add more comments in the document and/or suggest specific wording changes with the suggestion –

Ram Sriram – National Institute of Standards and Technology – Member
I wrote a detailed note there, but I will look into it again.

Kensaku Kawamoto – University of Utah Health – Co-Chair
All right. Since we're out of time, we'll stop here. Thanks, everyone. I think we made a lot of progress. A lot of us will be in person next week. I look forward to seeing you there. In particular, if you have ideas for other topics you want to highlight for discussion at the HITAC, please let Steven and me know, and we'll see if we can add it to the agenda beyond giving the update and the topics we've already got. Thanks, everyone. Have a good week. Bye.

Cynthia Fisher – WaterRev, LLC – Member
Thank you. Bye.

David McCallie – Individual – Member

Bye.