

Interoperability Standards Priorities (ISP) Task Force

Transcript August 28, 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

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Okay. Good morning, everyone. Happy Wednesday. Welcome to the ISP task force. Quick roll call and we'll get started. Ken Kawamoto?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Steven Lane?

<u>Steven Lane – Sutter Health – Co-Chair</u>

Good morning.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Anil Jain?

<u>Anil Jain – IBM Watson Health – Member</u>

Good morning.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Arien Malec? Andy Truscott? Clem McDonald? Cynthia Fisher? David [audio cuts out] [00:00:27]. Sorry.

<u>David McCallie – Individual – Member</u>

[Inaudible] [00:00:30].

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

[Inaudible] believe Cynthia's on. Dave McCallie?

<u>David McCallie – Individual – Member</u>

Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Edward Juhn? Terry O'Malley?

<u>Terrence O'Malley – Massachusetts General Hospital – Member</u>

Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Leslie Lenert?

Leslie Lenert - Medical University of South Carolina - Member

Here. Yep.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Jack Po? Raj Ratwani? Ram Siram?

Ram Sriram – National Institute of Standards and Technology – Member

Yes. Present.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Thank you. Ricky Bloomfield? Sasha TerMaat?

Sasha TerMaat – Epic – Member

Good morning.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> <u>Federal Officer</u>

Scott Weingarten? Sheryl Turney? Tamer Fakhouri? Tina Esposito? Valerie Grey? Victor Lee. Okay. With that, I will hand it over to our co-chairs to get us started.

Steven Lane - Sutter Health - Co-Chair

Excellent. Thank you so much and welcome, everyone. Thank you for joining us for our meeting. Can you hear me all right? I'm on a speakerphone.

Leslie Lenert – Medical University of South Carolina – Member

Yep.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Yes, we can hear you.

Steven Lane - Sutter Health - Co-Chair

Excellent. Great. So, our plan today is to go ahead and just go over our task force schedule a bit. And then we're going to dive right into a review of the first third of our draft report. The ONC team has been hard at work translating all of our efforts that had been documented in spreadsheet format into a report format. You'll see, or hopefully, many of you have seen that there's a nice introduction. So, the idea here is that we can — and we can go ahead and go to the schedule perhaps, is we've got a few meetings lined up that will allow us to go through the report and to assure that it represents our best thinking and recommendations. I did want to give everyone a chance to review the work that we've done to think about whether, you know, this is our chance to make any adjustments, additions, subtractions, and to assure that we have things worded just the way we want them to be.

So, I think the way we're going to do it is spend this meeting talking about the orders and results. You guys will still have some time to go through that again afterwards and submit comments or suggestions if you'd like, but also between now and the next meeting, we're going to hopefully start to collect comments on the second section on referrals and care coordination. And then we'll spend the subsequent meetings looking back at our medication and pharmacy data recommendations. And then I think we're going to

have one more meeting to wrap things up before we bring the draft recommendations to the HITAC, and then a bit of time to incorporate any suggestions or revisions that they have provided and then be ready to present the final recommendations. So, that's kind of the overview of where we're going from here. Any questions about that? Great.

Again, a number of people did have a chance to go into the document and start submitting suggested edits and some comments. And we'll go through those, but obviously, there are almost certainly some who have not done that, and this'll be your chance. And again, you can follow up with additional comments after this and we'll try to sort of go back and catch up with ourselves at the beginning of the next meeting. I think I went a little out of order, so let's just sort of scroll back up and let's see what I missed in the slides that you guys skipped over. So, just again, to remind everyone, especially the ones who are visiting from the public who perhaps having been with us before, our interoperability standards priorities task force has a charge to make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses.

We are going to be making recommendations about those priority uses, standards, implementation specifications, subsequent steps for industry and government action, and then, publishing a report. So, we're at number two right now, and that's working on that report that we will be publishing. And I'm pretty sure we went through next slide, the membership as we took our roll. So, just again as a reminder to the public, this is who is on our task force. And then I think from there, Ken, do you want to add to that?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. I think what we'd like to do is just go through the draft report and start on seeing what we want to present to the HITAC and before we make any recommendations based on the larger group's feedback. It should be fairly straightforward in the sense that we basically took the data from our spreadsheet work that we've done and transposed it to a narrative format. But I say we just jump right in there, if that's okay. Let's see. Could we get the Google spreadsheet, Google Doc to show up?

Steven Lane - Sutter Health - Co-Chair

And while that's coming up, I'll just add a particular welcome to the members of the public who are joining us. Looking at the participant list, I see there are quite a few people who've joined, some with names I don't recognize from prior meetings. So, welcome and feel free to use the chat and public comment window to provide your input as we go along. All of that input is recorded and published with the minutes of our meetings. And then at the end, there will be an opportunity for you to get on the line and give us public comments verbally.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Thanks. Let's open up the spreadsheet.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Or the – it's the document.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Right. The document.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. They've got it up.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. All right. So, why don't we start from the top? The top parts are pretty much just front matter. So, it should be fairly non-controversial.

Steven Lane - Sutter Health - Co-Chair

Well, one question that I had, Ken -

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

Steven Lane – Sutter Health – Co-Chair

is I don't think we've done a lot of work on the title -

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

Steven Lane - Sutter Health - Co-Chair

or the subtitle or any of that.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

Steven Lane - Sutter Health - Co-Chair

And I don't know. If you can scroll back up to that very first page here, if you will. And this report, this title, I think was suggested by the ONC team. I don't think we've said anything —

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

No.

<u>Steven Lane – Sutter Health – Co-Chair</u>

- about it. So, any thoughts that people have about the title, feel free to let us know. I don't think this is set in stone at this point.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay.

<u>Steven Lane – Sutter Health – Co-Chair</u>

So.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Any comments on the title "Setting Priorities for Standards Adoption Report?"

Steven Lane – Sutter Health – Co-Chair

I think we're going to need a subtitle to say, you know, "Report of the [inaudible] [00:07:58] standards priorities task force" or something like that. But we'll work with the ONC team to make sure that that's appropriate and meets their needs.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. And I guess big picture – this kind of front matter, too, if folks just kind of want to comment on it offline as well, you're welcome to. And then, for the task force members, we sent out a Google Doc link. Anyone with the link should be able to suggest comments. So, please feel free to do that. So, if you have a copy open on your end, you can just directly basically type in – it'll enable draft changes [inaudible].

Steven Lane - Sutter Health - Co-Chair

Actually, Sasha, do you want to display the -

Sasha TerMaat – Epic – Member

This?

<u>Steven Lane – Sutter Health – Co-Chair</u>

- web meeting? Yeah. Display that there -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u> [Inaudible].

<u>Steven Lane – Sutter Health – Co-Chair</u>

And I can have the -

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

- document up, too. Okay. Good.

<u>Sasha TerMaat – Epic – Member</u>

Okay.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

So, why don't we just got through the initial front matter part? And again, the title, et cetera, I think we can just sort of do offline and please feel free if you think something's better, just rip and replace, and it'll just come in as draft changes. So, nothing too exciting about the top-level front matter. We talk about in the executive summary, 21st century cure staff requires the HIT Advisory Committee in collaboration with the NIST [inaudible] and through the use of public input, reviewing published priorities for the use of the health IT and the standards and implementation specifications. To support those priorities, this report meets that directive by summarizing the activities of the ISP task force between fall 2018 and fall 2019 describing the parties' recommendation suggestions, suggested policy options for ONC consideration. Again, if you see anything that doesn't seem right, please feel free to comment or just directly edit.

Overview. The HITAC standards adoption parties will identify the section 3003 of the 21st Century Cures Act. And we'll just read through it in the sense that we do need to review it and it's probably the easiest way for folks to review it at this point. At the implementation of the incentive programs for the meaningful use of certified DHR technology, the MIPS alternate payment models belongs to hospital value-based purchasing program and any another value-based payment program determined appropriate by the Secretary of Health and Human Services. [Inaudible] [00:10:20] there. More specifically, the priorities are related to quality of patient care, public health, clinical research, practice and security of electronic health

information, innovation in the field of HIT, patient safety, usability, access to electronic health information and other priorities determined appropriate by the secretary.

So, these are all sort of boiler plate because this is their charge. In identifying such standards and implementation specifications as stated above, the HITAC was charged to prioritize the selective standards and implementation specifications developed by consensus-based standards development organizations.

As stated in the Cures Act, beginning five years after data enactment of the act and every three years thereafter, the national coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect of whether to maintain or create [inaudible] the uses of such standards and implementation specs. The HITAC in collaboration with the NIST shall review and publish priorities annually through the use of public input, HIT standards, and implementation specs. So, just [inaudible] the ONC staff who prepare the sections. This is just regulatory kind of background, but one question I had when I was reading this too, it says the priorities need to be published annually. That's not necessarily something that the ISP task force is charged with, I'm assuming, because we're gonna be wrapping this task force with potential consideration of continuing [inaudible].

If the language says annually the HITAC must do that, and because it shows up in the TSP task force, I just don't want to make it seem that it's the purview of the ISP task force to do that on an annual basis. We will be wrapping up this year. Just want to clarify that's not part of our scope, right, for HITAC and the ISP task force? Okay. Maybe the request there is — maybe Lauren, if you could just verify that obviously everything stated we've already what we're required to do, et cetera, is in fact —

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> <u>Federal Officer</u>

Are we still connected?

Steven Lane – Sutter Health – Co-Chair

That's what I'm wondering.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Hello?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Anybody?

Steven Lane - Sutter Health - Co-Chair

Hello?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Oh.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> <u>Federal Officer</u>

Yes, Ken. This is Lauren. I can [audio cuts out] [00:12:41].

Steven Lane – Sutter Health – Co-Chair

Oh, good.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Pretty good day so far. Sorry. I think that maybe –

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

- someone else is trying to chime in. Okay. Sorry about that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. All right. So, let's keep moving. Let's maybe go further down the overview because we don't have that much front matter, but let's get through it and get into the content. Can we scroll down? Yeah. Overarching task force. Keep going down. Keep going down.

<u>Steven Lane – Sutter Health – Co-Chair</u>

I think we need -

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay.

Steven Lane - Sutter Health - Co-Chair

- to go through the overarching charge, don't we?

Kensaku Kawamoto – University of Utah Health – Co-Chair

I thought we went through that, no?

<u>Steven Lane – Sutter Health – Co-Chair</u>

Oh, I thought you just did the overview.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Oh, no. Sorry. Can you go up to where we – sorry. Can you go back up a little bit on the Google Doc?

Steven Lane - Sutter Health - Co-Chair

Want to do section three?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Section three. Yep.

Steven Lane - Sutter Health - Co-Chair

Okay.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay. Okay. So, this part again talks about what we did. As indicated in section 3003 of the Public Health

Services Act, ISP task force was established by the HITAC and charged to identify priority uses of HIT consistent with the Cures Act-identified priority standard specifications that best support or may need to be developed for each identified priority and subsequent specs for industry and government action. And the identification of priority standards implementation specs, the Cures Act specifies that the standards that were developed by the consensus-based methods used by standards development organizations should be highest priority during the initial meetings. And if you can scroll down a little bit so we can read further. Maybe there's a delay. Yeah. The task force discussed the mission charge and the members then identified high priority uses of health IT and rank ordered them through a voting process.

Following this ranking group discussion, the result the task force decided by consensus to focus on the three uses below. If given more time, the task force could explore and make recommendations regarding the additional uses in future deliberation. The task force was charged to publish a report on its findings and make recommendations to the larger HITAC. So, if you disagree with any of what was stated, please bring it up now. But as you recall, we asked each member to bring up what they felt were priorities, and then we discussed them. And then we voted on them, discussed them some more, and I think through consensus came up with the top three that we wanted to tackle first, which ended up being what we were able to get through during the scope of life of the task force this year.

So, [inaudible] [00:15:29]. This is health IT addressed in this report are orders and results, closed-loop referrals and care coordination, and medication pharmacy data. And additional priority uses recommended for future [inaudible] include evidence-based care for common chronic conditions, social determinants of health, and cost transparency with a note that this topic was a central focus for the medication pharmacy use above. Does that sound about right?

<u>Steven Lane – Sutter Health – Co-Chair</u>

And I'll just acknowledge that a number of you went through and made some suggested edits, and we've gone through and just accepted those as they've come in.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u> Okay.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Any edits just by the way that we've made that are even potentially substantive, we've highlighted in alternate colors for discussion with the group. For the most part, your co-chairs felt that this was largely non-controversial.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay. And –

Cynthia Fisher - WaterRev, LLC - Member

Can you please read the last two -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u> Yeah.

Cynthia Fisher – WaterRev, LLC – Member

- three sentences regarding transparency? I couldn't hear -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

– from the speakerphone. Thank you. Please.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. Yeah. The last one we said cost transparency, and we said parentheses note, "This topic was a central focus for the medication/pharmacy use above."

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

So, you're talking about cost transparency. Is that correct?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. If you recall, that was one of the ones that bubbled as one of the priorities identified in this task force as a stand-alone topic and one that we were planning to go through if we had the time and effort. The ISP task force is currently cycled to have at least this iteration cycle to end in the next several months. So, we're recommending that these topics be further discussed and deliberated on by the task force if its life is extended beyond this year. But we're also noting that cost transparency really was a big part of the medication one.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Yes. I would just like to add that -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

– being that it is the most impactful to families and to compliance of understanding the price, I mean, we can use the example of insulin costs going up by a magnitude of five times. Four, five times for people and knowledge of new medications rather than old, depleting their monthly outflow and not necessarily being covered. I think insulin's the one most impactful examples. The issue that I would like to see changed from the task force standpoint is that what's listed on the slide is total out-of-pocket costs as it relays to the patient. But, you know, I think it's really imperative that we look at the entire price of these pharmaceuticals and the drug outlay choices.

Steven Lane – Sutter Health – Co-Chair

Yeah. Cynthia? Cynthia?

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Yes.

<u>Steven Lane – Sutter Health – Co-Chair</u>

At this point, we're really just going through the text of the introduction of our report. We have incorporated those comments in the detail –

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Right.

Steven Lane - Sutter Health - Co-Chair

- that we're going to actually get to in two weeks' time. So, hold that thought, and we'll make sure that we capture because we've discussed that, obviously, and I think we've captured that in our recommendations, and we'll get to that when we get to that section.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Well, Steven, I think it was just the header only had out-of-pocket costs on it, and I didn't see it delineated to see total prices because the total prices affect the coverage cost and the—

<u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. Yeah, yeah.

Cynthia Fisher – WaterRev, LLC – Member

patient can share 30% of that.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Well, I appreciate that.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

So, I just know –

Steven Lane - Sutter Health - Co-Chair

Yeah. All we've got here is just cost transparency as a section that we're commenting on.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Okay.

Kensaku Kawamoto – University of Utah Health – Co-Chair

[Inaudible] [00:19:37].

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

I'm adding it to what is in bold on the slide that we add. I'm asking for the taskforce to add total price transparency, not just out-of-pocket as our coverage because –

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Right.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

-- of the impact to health plans and health coverage. And if the patient sees the total price, then they can help drive down their coverage costs, and their employees can also incentivize toward reducing coverage costs. Thank you.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yep. Yeah. [Inaudible].

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

I'm asking that we change it to be inclusive of total price as well as out-of-pocket.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. We don't specifically talk out-of-pocket here. Maybe we're [inaudible] on what you're looking up versus what we're looking up, but I think the appropriate place that that would be under are meds comments. We definitely talked about out-of-pocket there. We did not include an explicit discussion to say and of course, total cost matters because, you know, when total cost increases, obviously, eventually it catches up to that. Maybe if you can go — I think they already have those recommendations in there, or we will shortly. If you wouldn't mind going and directly adding those in as suggested edits to that section, which we will cover in two weeks. And also, I mean, I'm sure we won't forget when we get there, so if you didn't put it in, we can cover it when we get to that.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Yeah. I think it's just that out of courtesy, I brought it up at several meetings and it doesn't appear to ever get changed. And I'm not able to enter it into a computer right now, but I would just like to say that we also need to use nomenclature of price because there's an argument that costs, people don't want to disclose their own costs, but it is really about price transparency. And I think the nomenclature is important and not confusing. So, you know, what is the out-of-pocket price to the consumer, and what is the total price so we can reduce the total coverage by both employer and patient, employee alike? Thank you. But I think —

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

we really need to – if I could ask someone on the ONC team to please edit that or add it to it. I would ask that –

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

on behalf of the patient.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. We can get to it. Just as a note, Cynthia, we have very explicitly addressed and incorporated your comments in the past, and in the past here, I think your primary comment was what's really important to the patient is how much they pay out-of-pocket, and that's where the emphasis there had come. I think this is the first time I recall that the notion of that equally informed is the total price. So, just a note, this is the first time I've heard [inaudible] [00:22:22] —

<u>Cynthia Fisher – WaterRev, LLC – Me</u>mber

Yeah. I disagree with you, and maybe that's been a misunderstanding. But the total price is really needed because it affects the entire outflow of coverage, which has gone up north of eight, almost double digits for small businesses and north of 8 percent for large businesses. So, we're talking eight to 12, 13% increases annually. So, the only way the patient can deploy that, and the employer can shop is to see total prices. So, let's make sure we're responsibly looking at addressing the entire transparency issue —

Steven Lane - Sutter Health - Co-Chair

Yeah. That's -

Cynthia Fisher – WaterRev, LLC – Member

not [inaudible].

Steven Lane – Sutter Health – Co-Chair

– great, Cynthia. We absolutely will have a chance to do that two weeks from now. So, let's proceed with our review of the document that we've got posted and that we're displaying here so that we can be sure to get everybody's input on this.

Kensaku Kawamoto - University of Utah Health - Co-Chair

And Clement's I think putting some comments, and so, we'll maybe try to monitor those. But let's move on to section –

Steven Lane - Sutter Health - Co-Chair

Four.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. The next section. Okay. So, this is just membership. I think it should be non-controversial. If you can just move through this. And if you don't like the way you're characterized or whatnot, just feel free to directly edit. And then, okay. So, section five, task force recommendations development. So, this is basically the approach we're saying we're taking. So, the following recommendations were proposed by the ISP task force and endorsed by the full HITAC following review discussion modifications. Of course, we're assuming that that'll happen.

But we're just putting the wording, which hopefully will be true once they do review, discuss, and modify. And then, for each area this report provides, and this is sort of the way we were thinking about it. We started with a story that illustrates how the recommendations, if adopted, can improve health and healthcare. I think this was a comment from one of the task force members. I can't remember who it was. Maybe it was David. But the notion that hey, this is a bunch of **[inaudible]**. Let's out it into context with a story. And then, tier one issues along with recommendations, observations, and recommendations, and potential policy levers. These are the top issues that HITAC recommends addressing. And again, we're speaking in terms of the HITAC assuming that'll come through because the way this works, the task force provides proposed recommendations, and the HITAC is actually the one that makes the recommendations.

And then, tier two issues. We say these are also important issues in the view of the HITAC, but with less urgency compared to the tier one issues. And then we've put in here for reference source spreadsheets, which will be removed later, but just for to reference. Okay. And so, let's go into the section six HITAC recommendations, orders, and results. So, as just noted, we're starting with a story, and then, after that, it potentially the content we've developed as a task force literally just transposed into document format. So, let's start with this one. So, illustrate the story of what recommendations will enable. And the idea here was for the public, for policymakers, et cetera just, you know, make it less dry and more impactful in terms of the description. So, and this is subject to any editing folks want.

So, after getting your annual laboratory test completed, you receive an email notification the next day that your results are available in your personal health record. You open the results on your smartphone PHR application and can see all the results, including I think normal – something changed there. Including

normal something.

Steven Lane - Sutter Health - Co-Chair

Normal ranges.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Normal ranges with the note that the data were provided –

<u>Steven Lane – Sutter Health – Co-Chair</u>

Right.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

– to you as soon as it was available and that your doctor may not yet have reviewed the results. Because all laboratory tests are now encoded using a standard known as LOINC, there are standard patient family test names and information resource that have been linked to them. For example, for your slightly low calcium level, there's a link to the MEDLINE Plus resource that explains the significance of this minor abnormality. By the afternoon, your doctor has added a note, of which you're notified to not worry about the slightly low calcium as it is likely due to your kidney disease, is unchanged from your previous results, and will be checked again later. Your doctor is easily able to trend your lab result data on a graph, including data obtained from your other care providers because each laboratory result is LOINC-encoded, enabling similar lab tests obtained from across the healthcare system to be displayed and trended together, something that was not possible until recently through a public private partnership. So, this is what we had. We had a few comments come in. For the folks who are on, I don't know if Ming, MD, if you're on, and any others, maybe you can directly discuss the comments you put in.

Steven Lane – Sutter Health – Co-Chair

I think Jack's is the first comment. I don't know if he's on the line, but I just -

Ming Jack Po – Google – Member

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

- added including -

Kensaku Kawamoto – University of Utah Health – Co-Chair

He's on.

Steven Lane - Sutter Health - Co-Chair

that we personalized normal ranges as a way of capturing what he was after. If people are comfortable
 with –

Ming Jack Po – Google – Member

Yeah. I'm on the line and I saw that you made that edit right before my comments. I was like, I guess this **[inaudible] [00:27:38]**.

<u>Sasha TerMaat – Epic – Member</u>

Just to clarify, would that supersede the normal ranges provided by the lab?

Steven Lane – Sutter Health – Co-Chair

Well, labs often do personalize normal ranges.

<u>Sasha TerMaat – Epic – Member</u>

Okay. By –

Steven Lane - Sutter Health - Co-Chair

By age and – yeah.

Sasha TerMaat – Epic – Member

Okay.

Steven Lane – Sutter Health – Co-Chair

I mean, Jack pointed out ethnicity, which is probably not what most labs do today, but I think increasingly we do see labs certainly for age and gender there are personalization that occur.

Ming Jack Po - Google - Member

Yes. There's a bigger section later that talks about including normal ranges. The reason why I pointed out ethnicity is because most labs don't do that today and lots of times, physicians will just reinterpret themselves. But I felt like if a use case is going to go directly to the patient, which this use case talks about, if we don't do it by ethnicity, we're going to freak out lots of patients.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. I think at this point in our deliberations we probably don't have time to incorporate something that significant.

Kensaku Kawamoto - University of Utah Health - Co-Chair

That would be a pretty significant ask.

Steven Lane – Sutter Health – Co-Chair

Yeah. It would be a pretty significant ask. I definitely would think it would be a level two, tier two sort of an ask. Are you comfortable with this insertion of the appropriately personalized as a way to kind of incorporate these ideas?

Ming Jack Po – Google – Member

Yeah.

Clement McDonald – National Library of Medicine - Member

This is Clem. So, just be careful because some labs only have an accession member for the test sample and cannot personalize.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Right.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. And I think ideally, what we want the story to be is something that would happen if the recommendations we put in were to come through —

Steven Lane - Sutter Health - Co-Chair

Right.

Kensaku Kawamoto - University of Utah Health - Co-Chair

and we should make sure those are in good shape, and then, we should maybe put in a parking lot some
of these additional ideas that we could add if we had more time.

Steven Lane – Sutter Health – Co-Chair

And I think that I have a similar response to Andy's comment. He raised the issue of machine learning produced CDS note, which again, sounds really exciting and isn't something that we spend a lot of time talking about. You know, I like the idea of us being able to make some tweaks at this point in the process. I don't know that we have time to really dig into and fully discuss these substantial new ideas, you know, like ethnicity normal ranges and machine learning CDS. So, my tendency personally is to sort of accept these as great ideas, but not think that we have time to incorporate them now.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. Okay.

Steven Lane – Sutter Health – Co-Chair

Andy, are you on? Is that okay with you?

Clement McDonald - National Library of Medicine - Member

Well, this is Clem. I think it's the only plausible pathway given the timeframes.

Steven Lane - Sutter Health - Co-Chair

Thanks, Clem.

<u>David McCallie – Individual – Member</u>

Hey, it's David. Are we doing the hand raising, or do you just want us to speak up?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. We should check for hand raising.

Steven Lane – Sutter Health – Co-Chair

Yeah. I'm sorry, David. Go ahead.

David McCallie - Individual - Member

So -

Steven Lane - Sutter Health - Co-Chair

We don't have enough monitors is the problem.

David McCallie - Individual - Member

Yeah. No problem. We can do it either way. It's just I need to be consistent.

Steven Lane - Sutter Health - Co-Chair

[Inaudible] [00:30:54]. Okay. Good.

David McCallie - Individual - Member

But my comment one is that we should maybe review our observation points and recommendations and then come back and look at the story and make sure that the story encompasses the things that we recommended and doesn't introduce cool ideas that we didn't include in our discussion. So, I think the story's a good idea, but let's make sure we look back at the story after we review the individual points. That's kind of just process —

Steven Lane – Sutter Health – Co-Chair

It's a great suggestion.

<u>David McCallie – Individual – Member</u>

observation number one.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

David McCallie - Individual - Member

And then, suggestion number two is — and I'm gonna violate my own recommendation there and just point out that I think one of the issues in with LOINC is more is necessary than just mapping to LOINC because there are many different LOINC codes available for a given test. So, one of the goals here, if the main goal is comparability, then there may be work beyond just mapping to LOINC. And maybe that's a detail that we should not dive into, but that's the pain point in the LOINC discussions that I've been part of, particularly —

Steven Lane - Sutter Health - Co-Chair

Yeah. So, David -

David McCallie – Individual – Member

– in FIHR, for example. Yeah.

Steven Lane - Sutter Health - Co-Chair

David, we do acknowledge that further down, and you're exactly right. We got to the point of agreeing that LOINC was critical. Was necessary but probably not sufficient. And we do acknowledge that further down. So, you can look at how we worded that and see if you're comfortable with it.

David McCallie – Individual – Member

Okay.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

And I think the point of the story isn't that every single recommendation is incorporated because that would become a very unwieldy story. The point of the story is to take some of the main gist of what we were after and to put in the story because I think it would be —

<u>David McCallie – Individual – Member</u>

Yeah. So, I was –

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Go ahead.

David McCallie - Individual - Member

So, that's the point I wanted to just say. Comparability is the single word that would capture that notion that mapping is not sufficient. You need to be able to compare your results. So, linking and comparing or something like that. That's where –

Kensaku Kawamoto – University of Utah Health – Co-Chair

I think -

David McCallie - Individual - Member

I was headed with that long-winded detour. Sorry.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. I think it's sort of illustrated by the notion of you're going to be able to trend some results because that implies things like if the values for different LOINCs are not really the use separate units, et cetera, that you're using intelligence to put it into the right scale. That kind of thing, right? Like you could have a LOINC code that says, you know, mLs per liter and another that milligrams per deciliter. And obviously, you would need to convert between them and make them comparable if to really make that work. But —

David McCallie – Individual – Member

I like the change that just was added there. That's good. I'm happy.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay. All right. Let's maybe move on, if it's okay, to the task one issues and recommendations. And there it's – or sorry. Tier one issues and recommendations. What we did was basically take the content that was in the spreadsheets we came up with. The ones we labeled tier one just come under tier one. The tier two is tier two. And the only thing we pretty much added was the boldfaced need for consistent and coding of test results equivalent of – we did have like a summary text for a given row.

So, these should all look extremely familiar because they're in fact exactly what this task force had worked on in the past. This is really I guess another review opportunity before we submit it to the HITAC for consideration. So, here you can see that Andy provided comments suggesting some reference to semantic versus syntactic interoperability. I took about half of that and added it to the observation in this green text. Is there anyone who's uncomfortable with that? Great. Okay. Thank you, Andy. So, I guess the question here is what would folks prefer. Should we just read through them? Should we skim through them? Should we not review it on our own? I ask this simply because we have already reviewed these fairly extensively in the past.

<u>Clement McDonald – National Library of Medicine - Member</u>

Ken, I think we should skim through them because my initial questions were answered when we got deeper. And then we can –

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay.

Clement McDonald – National Library of Medicine - Member

- kind of - I think it would be more efficient to see the whole picture before we fuss too much.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Okay. So, let's kind of briefly go through them. So, how about we'll do — I know Cynthia, maybe perhaps some others are on phone only, so I'll just very quickly skim through it and sort of give a verbal update.

So, the first one, need for consistent encoding of test results, observations is that a lot of labs and other test results are not consistently encoded with appropriate standard codes, which is obviously a problem. Recommendation is that resulting organizations should provide LOINC codes as identifiers. So, that's a T1. Also, that when result observations are coded, the values should try to use some SET. Third point was in the case of labs that there should be something that CLIA considers to be something that's enforced under their regulations and that if it's ineffective, then we should consider making this a condition of payment.

So, this was a very strong one that we've deliberated pretty extensively on it. The other recommendations include assure that there's a well-managed appropriate resource process to develop and deliver additional LOINC codes when needed, requirement to enforce the use of information models and terminology standards for all test orders and results. And then, EHRs, other systems should be required to provide standardized mechanisms that allow basically an interim solution when this is not all done at the source to map internally [inaudible] [00:37:23] results. And then, if you could scroll down. And codes and standard vocabularies. Second from the bottom. Recommendation prioritize complete and accurate coding at the data source rather than trying to code or correct externally sourced data downstream and implement mechanisms to support and ensure proper LOINC [inaudible] [00:37:45] coding by resulting agencies. So,

there's -

Steven Lane - Sutter Health - Co-Chair

Hopefully, all this is familiar to the task force members because we went through this in detail.

Kensaku Kawamoto – University of Utah Health – Co-Chair

And Sasha, the addition of standardized implies there's a standard for mapping tools described.

<u>Sasha TerMaat – Epic – Member</u>

I was just commenting on Andy's comment. I think adding -

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah.

<u>Sasha TerMaat – Epic – Member</u>

standardized to the mapping internally generated results.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

Sasha TerMaat – Epic – Member

Certainly, you would map to a standard such as LOINC or SNOMED, but I'm not aware of a standard -

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sasha TerMaat – Epic – Member

– for a mapping mechanism. So, that word didn't make sense to me in that context.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Andy, can you explain? I do think we probably need to strike that because I don't understand either.

<u>Steven Lane – Sutter Health – Co-Chair</u>

I don't think Andy's here -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Oh.

Steven Lane - Sutter Health - Co-Chair

– to speak for himself. So, we'll take it out.

Kensaku Kawamoto – University of Utah Health – Co-Chair

I think it has to be struck. Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. But he also had the comment above, "Operated by whom?" And I think this was in reference to this notion of a well-managed and appropriately resourced process to develop and deliver additional LOINC codes. I think we certainly have worked with Regenstrief and the LOINC group. I have presumed in my mind that they would be the ones who would be responsible for deliberating and developing additional LOINC codes as needed. Does it make sense to —

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I mean, it's Regenstrief that does [inaudible] [00:39:24] LOINC codes.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Right. That's a good point. Right.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

And because, yeah, if we're funded to do something, we can put more resources to it, right?

Steven Lane - Sutter Health - Co-Chair

So, maybe that belongs under the responsibility section. If we scroll down, well, we have the policy levers/responsibility section. We call out ONC, FDA, and CMS. So, I guess would we say that ONC would work with Regenstrief Institute to assure that there's a process for —

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I mean, there is a process. It just takes six to 12 months right now, right? I mean, to get a new LOINC code in. But I don't know if money's going to make it much faster than six months.

Steven Lane - Sutter Health - Co-Chair

It's a deliberative process.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

They have to make sure it's right.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I mean, money always helps, right, but...

Steven Lane - Sutter Health - Co-Chair

So, are we comfortable – again, Andy not being here to speak for himself. I mean, his question's really just is it worth stating who would be responsible for that.

Sasha TerMaat – Epic – Member

It does seem that the recommendations we've made that identify the actors are stronger to read than the assure and require enforce ones that are right next to each other that don't identify who would be taking those actions. And so, I think I kind of sympathize with Andy's comment. I think if we could identify who we would be recommending this to, whether it's ONC or Regenstrief or formation of a new group or something, those would probably be stronger recommendations with a specified actor.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. And I see David has his hand up I think, and I think there's a comment that Clem had it earlier up as well. Maybe David then Clem.

<u>David McCallie – Individual – Member</u>

Yeah. So, I guess if we're just wordsmithing, I'm okay with what we've got. My concern is that the barrier to achieving the goal that we outlined in the story of comparability is not necessarily handled by just saying mapping. And here's my example is as most of you know, the AMA spent the better part of a year and lots of money to simply get agreement on which LOINC codes should be used to describe blood pressure in an ambulatory capture setting with personal devices. That's one lab result, and that's how much work it took to get an agreement. It wasn't the problem of no LOINC codes existed. The problem was which LOINC codes are relevant to which clinical scenarios. And so, the concept there of the information model begins to get at that, but I don't think we should underestimate the pain required to do that right. The cost required to do that right.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I see. Okay. And if I remember correctly, I was looking at this recently. LOINC is actually missing some codes I think still for things like not in office blood pressure readings that you want to make sure we record. Yeah. You're right. Even just blood pressure gets really, really – I mean, it becomes a major project. I guess though I don't know how you would express that differently in recommendations. I guess okay. So, we have necessary support for LOINC to develop and deliver additional LOINC codes to accommodate – I guess it's additional LOINC codes and industry best practices for using them. Is that what you're getting at, David? The notion that you could have like eight codes that could be relevant and what's important is everybody agrees this is when you use this one and this is when you use this one. That kind of thing?

David McCallie – Individual – Member

Yeah. Maybe the notion there is that on the line about information requiring enforced use of information models, maybe it should be more along the lines of "work with appropriate clinical expertise to define

and require the use of information models."

Clement McDonald – National Library of Medicine - Member

Could I [inaudible] [00:43:30] -

David McCallie – Individual – Member

Because I think that's where the gap is today is every lab, every hospital can find a LOINC code to match the way they chose to describe the result, but that doesn't solve a comparability problem. It's the Stan Huff problem. You know, it's what Stan spent his whole career working on. He would be upset that we don't have that covered here, I think.

<u>Clement McDonald – National Library of Medicine - Member</u>

Could I -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Clem then Sasha.

Clement McDonald – National Library of Medicine - Member

Could I comment on this?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yes, please.

Clement McDonald - National Library of Medicine - Member

Because I think Dave's wrong to start with. The problem is what's the same is in the eye of the beholder. So, an average clinician doesn't care very much about whether the blood count is done by auto or manual methods, but the lab does. So, what we really need is sort of a way to map them together in equivalence classes so people can roll them up when they don't care, and they can get to the details when they do. And then, the other issue is that different groups, and this is a tough problem and it might be what Dave's talking about, different groups will model things differently. You know, how they organize things as a set of answers or one answer. And that really means aggregation of the interest parties to come up with a single way, which is a different problem. It may be what the AMA did. But I think that —

<u>David McCallie – Individual – Member</u>

Well, yeah. Clem, I'm not suggesting that the lab's necessarily responsible for this, but to do the mapping that you refer to requires an information model which requires clinical agreement on how to in fact map these things together. Whether –

Clement McDonald – National Library of Medicine - Member

Well –

David McCallie - Individual - Member

that's done at a lab or downstream, it is the gap today that makes the story –

<u>Clement McDonald – National Library of Medicine - Member</u>

I think at the lab –

David McCallie - Individual - Member

- that we describe not achievable.

Clement McDonald – National Library of Medicine - Member

I think at the lab level it's not as much of a problem as in a general clinical level. There are issues because some people insist that a given method is very different from another method, where it's maybe 5% different and that counts in clinical care. So, I think the lab will work out all right. They've got livid and their industry is kind of getting together on how they decide things. The instrument vendors, which is upstream, which is the right place. But it's complicated because labs have laboratory developed tests, too. But you have to negotiate with the labs because they're the ones that know what they're doing. But the labs are easy because they have an FDA approval process. They have some strictness. It's the general clinical areas that are hard.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sasha, did you have a comment?

<u>Sasha TerMaat – Epic – Member</u>

Well, I was just going to say I think from the quality reporting perspective, we've encountered both of the challenges Clem and David were identifying. Sometimes, the codes are too specific to be comparable in the way that you want. Sometimes, they're too generalized to actually promote meaningful comparability. [Inaudible] [00:46:22] is technically the same code category, and it seems like we kind of need best practices on some sort of how specific to be with the original coding for the intended comparability among different audiences. And then, also, some sort of informatic hierarchy about when you could effectively compare things across different codes for particular audiences.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I'm just thinking how did we -

<u>Steven Lane – Sutter Health – Co-Chair</u>

David, is there another recommendation that needs to be added? Because we came to the same –

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

Steven Lane – Sutter Health – Co-Chair

- observation earlier, but we haven't really specifically addressed it.

David McCallie – Individual – Member

Well, I think that the gist of it is that simple mapping to LOINC is not sufficient. You need that information model. And, you know, that's substituting a vague word for a complex space, but to me, that's the call out here is it's not sufficient just to map to a LOINC code. To make this information comparable and useful, particularly to consumers, you need additional layers of knowledge not included in LOINC, which is where I think that information model is kind of a placeholder for.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. If you scroll down, we have one. And if you go to the bottom of page 11, maybe we can scroll down there. I think we have a recommendation around this. The bottom of page 11. Standard code sets are not unique. Page 11. Bottom of page 11. Oh, it's further down. Huh. On mine, actually, it says 11 on the document. It could be a different page number on the slides. Page 12 according to this. If you go further

down. Because we haven't had a page -

David McCallie – Individual – Member

Boy, you had a lot of...

Kensaku Kawamoto – University of Utah Health – Co-Chair

Here it is. Yeah. It's at the bottom of the screen. Do you see that? It says, "Standard code sets are not unique or sufficiently granular to determine the clinical equivalency of tests." I think, David, this is — I presume this might have actually come from you, too, in our deliberations. Maybe you can scroll down a little bit.

<u>David McCallie – Individual – Member</u>

Oh. If it did, I didn't word it very well.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. We could reword it for sure.

David McCallie - Individual - Member

Yeah. I mean, I think that — and maybe this is a rathole that we don't need to go down, but LOINC is a highly granular nomenclature as is necessary because what labs do is highly granular. What's missing is the layer above that, add the semantic meaning for comparability. So, to me, the granularity problem is essentially being solved by LOINC. It's what happens above that —

Sasha TerMaat – Epic – Member

I added -

David McCallie - Individual - Member

is more of a challenge.

Clement McDonald – National Library of Medicine - Member

Oh. So, David [inaudible] [00:49:18] -

Sasha TerMaat – Epic – Member

I think I added this one based on the experiences of my colleagues because the use of insufficiently granular codes was so risky as a safety issue that we were focused on it in particular even though I think from a usability perspective, the use of overly granular codes and an inability to map those together might be more significant, David. I would I guess like to see us address both if possible.

David McCallie – Individual – Member

Yeah. You've got to have the granularity. Absolutely. I'm just saying the gap that I'm describing is not solved by increasing granularity. That won't make the problem go away of comparability.

<u>Clement McDonald – National Library of Medicine - Member</u>

I agree. You need a roll-up.

David McCallie – Individual – Member

Right. That's what I'm calling an information model. Because -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

David McCallie - Individual - Member

– it does things like, you know, an information model says if you're describing a wound culture, for example, do you describe a generic test called wound culture and then a subcategory called source of the specimen, or do you in fact have, you know, knee aspirate as a test? You know, LOINC has both choices. Which is the right way to do it if you want to query a system to say were there any positive cultures? The models don't work very well when you have nothing but granularity. You can't do those higher-level functions. But –

<u>Steven Lane – Sutter Health – Co-Chair</u>

So, David? David, I think we get it, but -

<u>David McCallie – Individual – Member</u>

Okay.

Steven Lane - Sutter Health - Co-Chair

- we're trying to get the language right. And again, if you look at the section that's displaying on the screen, I think we would welcome additional suggestions to the wording so that we're capturing what you're trying to say. I think this is a really good start, but it may not have everything that you're after.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

And for me to comment, so, I think clearly the low hanging fruit is 50% of labs are LOINC-encoded, right? That was the big picture issue –

<u>Steven Lane – Sutter Health – Co-Chair</u>

Right.

Kensaku Kawamoto - University of Utah Health - Co-Chair

– of the hemoglobin A1C or whatever. I think the point David brings up is particularly important, and he brought up the example specimen source. That's a really common example. Another one might be urine tests where the hours of collection may be, you know, you could either order a 24 – the LOINC codes could be 24-hour urine volume or it could be urine volume combined in an information model with the hours of collection, right? So, I mean, I guess big picture, I would describe that as the decision to whether precoordinate or post-coordinate observations and the associated code is one where there's no clear right answer. And for more complex observations, it's an issue because it could be done in multiple different ways and none of them are actually wrong. It's just different approaches to doing it.

I think the question is, and I don't think we've addressed it here, is it a primary or secondary additional recommendation, or do we feel that it's something that...I mean, because the way to address that is, for example, to create industry consensus on the detailed clinical models that should be done and then to try to propagate that through the system at least, you know, to say when we communicate it across systems and we talk about, you know, an example we're looking at now is LDH from pleural fluid. Do we try to create a LOINC code for LDH pleural fluid and make sure that a lab which receives a specimen from a fluid source and reports it uses this new LOINC code instead of saying, "Here's the LDH from body fluids," and the fluid source we're going to call pleural fluid, or is it going to be this downstream groups map to it?

But there are a lot of implications of changing from current practice. So, I don't know. I mean, we see it and we struggle with it, but it's certainly not in the 80 or 90% issue, I think. I think that particular issue tends to be more of a 10% issue because most observations can be sort of precoordinated with a single code, and it typically is done that way.

David McCallie - Individual - Member

I —

Steven Lane - Sutter Health - Co-Chair

And I'm going to move this tub section up so it's where – it came up in our conversation –

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

underneath the need for coding in the first place, just so it flows more logically. But David, please do dig
 into this. You know, sleep on it –

David McCallie - Individual - Member

Yeah.

Steven Lane - Sutter Health - Co-Chair

- and see if you can refine the language to make it clearer.

<u>David McCallie – Individual – Member</u>

Okay. I'll take a look.

Steven Lane - Sutter Health - Co-Chair

Thank you. Shall we go –

<u>David McCallie – Individual – Member</u>

And Ken's description was good. That was a good example, Ken. I thank you for that.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

So, it's really hard because there really is –

David McCallie - Individual - Member

Yeah.

Kensaku Kawamoto - University of Utah Health - Co-Chair

– no right answer.

David McCallie - Individual - Member

I spent the better part of the last third of my career at Turner trying to solve the problem. It's really hard. So.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay. I wonder if one thing we could do is start marking things that we've reviewed as a group, like say

and highlight green or something. And then try to – one approach is maybe go for ones that we think are relatively non-controversial and get those all greened. That way, like it would be nice if say 80, 90% of our recommendations are ready to go to HITAC. And then there's a 10, 20% we can delve in, if that makes sense. So, perhaps we should almost purposely choose I guess the ones that probably are simplest or least controversial at least within the task force.

Steven Lane - Sutter Health - Co-Chair

Also, I think it's worth pointing out that we don't have all the time in the world.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

We have three more meetings after this before we go to HITAC, so we need to be selective in how we invest our time and invite people to provide comments offline that we can then review together.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

At the very least, we should get through all the comments –

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

Steven Lane – Sutter Health – Co-Chair

– on this section that people have submitted so that we can hear them out.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah. Do we have many other comments, Steven? Do you remember?

<u>Steven Lane – Sutter Health – Co-Chair</u>

Well, I think we want to be at the results need to be sent to clinicians in codified format. Jack had a comment there.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay. What page would that be on?

Steven Lane - Sutter Health - Co-Chair

Looks like we're on page eight of 32.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

All right. Yeah.

Ming Jack Po - Google - Member

Sorry. That was more of a comment about how annoying that problem is. I think what you guys wrote is perfectly fine.

Steven Lane – Sutter Health – Co-Chair

This was your comment about DICOM, Jack.

Ming Jack Po – Google – Member

Oh, sorry. You guys **[inaudible] [00:56:24]**. The comment about DICOM was more that the I think example section or just slightly earlier you guys mentioned imaging.

Steven Lane – Sutter Health – Co-Chair

Right.

Ming Jack Po - Google - Member

You mentioned imaging that we would have to mention DICOM given the other standards that you guys listed.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I think there was a public comment on that as well. Yeah. That's a good question. So, I guess because LOINC is often used for things like even for imaging results types, I guess, you know, obviously, labs have been sort of our main focus. But —

<u>Steven Lane – Sutter Health – Co-Chair</u>

We do care about other categories. I'm wondering, though -

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

– where you put it, Jack. So, the recommendation is to utilize USCDI to assure that prioritized results are interoperable via the two CCDA and FIHR. I mean, DICOM isn't part of that family of methods for transport.

Clement McDonald - National Library of Medicine - Member

Could I just clarify? DICOM is a standard for the image and the things related to making the image and a few other things. It really isn't big into identifying its studies.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It's [inaudible] [00:57:35].

Clement McDonald - National Library of Medicine - Member

So, there's actually [inaudible] -

Steven Lane - Sutter Health - Co-Chair

Yes.

Clement McDonald – National Library of Medicine - Member

- ACR-NEMA -

Ming Jack Po - Google - Member

That was a [inaudible]. Sorry, Clem.

<u>Clement McDonald – National Library of Medicine – Member</u>

ACR-NEMA and Regenstrief collaborate to make test names for radiology studies. And for the text report, that's what you need.

Ming Jack Po - Google - Member

Yeah. So, there's a section actually later that talks about that. For example, I think exactly as Clem you just mentioned, there needs to be for example a standardization process, even just on test names on imaging files. And right now, that –

<u>Clement McDonald – National Library of Medicine – Member</u>

But -

Ming Jack Po – Google – Member

isn't addressed by USCDI, right? Just figuring out what the canonical name for chest X-rays right now is essentially a [inaudible]. So, things like –

Clement McDonald – National Library of Medicine – Member

No, it's not.

[Crosstalk]

Clement McDonald – National Library of Medicine – Member

It's not. ACR-NEMA and Regenstrief have defined 6,000 terms for the test names for the radiology studies. And HL7, FIHR recommends those LOINC codes for that purpose to cover the text report, the narrative report.

Ming Jack Po - Google - Member

So, yeah. I think I agree, but the actual usage right now out in the field is not comprised of those things. So, maybe what I'm saying it would be helpful –

<u>Clement McDonald – National Library of Medicine – Member</u>

Oh, I agree. I agree. Yeah. I agree.

Steven Lane - Sutter Health - Co-Chair

Yeah. So -

Ming Jack Po - Google - Member

So -

Steven Lane - Sutter Health - Co-Chair

– if we scroll down to the context comment on page 10. Let's look at that one. I think that this is probably the place where this belongs, this discussion. So, scroll down just a bit. Jack has another comment on page 10. There we go. Now we're there. So, I think this is where we are.

Ming Jack Po – Google – Member

Yeah. This is exactly I think just what Clem and I were talking about.

<u>Steven Lane – Sutter Health – Co-Chair</u>

Right.

Kensaku Kawamoto – University of Utah Health – Co-Chair

So, I guess it's kind of -

Ming Jack Po – Google – Member

And given that we have this section about radiology orders. That is hard to not talk about DICOM, et cetera. But it would also be weird to leave all the imaging out.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. So, I think the point you're making is for labs for saying, hey, you know, CLIA-based labs, right? Like basically any lab provider, we're recommending that there be assurances and policies and procedures, incentives put in place so that labs actually send things in LOINC. Whereas we're [inaudible] [00:59:58] on for example an imaging producer should do. So, for example, are we saying that a radiology unit that produces imaging reports but doesn't tag its own images as what the LOINC code would say this is a chest X-ray or, you know, this is a hep CT contrast, that basically, we're silent there, right? And silent means we're not recommending anything. Does that sound about right, that your recommendation is there could be standards, but it doesn't really mean much if no one's using them?

Ming Jack Po – Google – Member

Exactly. Yeah.

<u>Clement McDonald – National Library of Medicine - Member</u>

Well, it's a vicious cycle. You know, if you don't say you have to use them, no one uses them. But there are some places using them currently, and they are specified in the FIHR spec, which is specified as in the regulations. They are specified in the diagnostic report. So —

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah.

<u>Clement McDonald – National Library of Medicine - Member</u>

And they're also specified in CDA. So, I think there's some specification already in regulation.

Kensaku Kawamoto – University of Utah Health – Co-Chair

I think the focus on -

Clement McDonald - National Library of Medicine - Member

The regulation -

Kensaku Kawamoto - University of Utah Health - Co-Chair

But realistically, imaging reports are typically done as notes, not as, you know, typical observations, right? Like in fire speak, you're not going to get a chest X-ray port when you do an observation query. The idea there is you would get that as a document reference search, looking for a note. So, I guess this gets into didn't we just have a discussion in USCDI in proposed rules of the types of notes and what the LOINC codes should be? The idea, and we defined like 10 or 12 things you should classify it as, if we reach into there, we're saying instead of having 12 codes you should use, you should 12 plus like 4,000. And you should classify down to that LOINC level. That would be the recommendation we'd be making if that is – it would

be contraventional to what the other task force has recommended there. So, they're - anyway -

Clement McDonald – National Library of Medicine - Member

And see, I didn't get that. I got that they had to recode specifically notes under their – even the physician's notes. And there's a gazillion codes for them as well or more.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

[Inaudible] [01:02:22] that level?

Terrence O'Malley – Massachusetts General Hospital – Member

Ken, this is Terry. I don't think we called out any codes. We just called out note types.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Terrence O'Malley – Massachusetts General Hospital – Member</u>

Very high levels.

Clement McDonald – National Library of Medicine - Member

But the regulations I think do, through their dependence on FIHR.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It depends on FIHR's finding level, right? If it's extensible, which means if there is an appropriate LOINC code you must, or if it's more like a –

Terrence O'Malley – Massachusetts General Hospital – Member

Yeah.

Kensaku Kawamoto – University of Utah Health – Co-Chair

– you know, recommended, which is like we recommend you use LOINCS, but realistically, you can use whatever you want.

Clement McDonald – National Library of Medicine - Member

I think in the diagnostic report it's higher strength than you use whatever you want. No. I think it's at least extensible, though.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Well...

<u>Clement McDonald – National Library of Medicine - Member</u>

If you don't have that specificity, you can't find [inaudible] [01:03:17].

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah. And just maybe as a pause and just thinking of how we're going to go through these, going over individual comments I think is important. What it also is indicating is it's going to take a lot of time. I wonder if we should for the upcoming calls go with a plan that members need to review the documents beforehand, put in comments and suggested changes for anything they want changed, and we will assume since we have reviewed these over and over again, that if you don't put in a comment, you are agreeing

to them. Because I think we just have to do it given the time individual comments are taking to adjudicate. So, maybe let's plan on that kind of an approach. And of course, if we have extra time, we'll just, you know, review that as a group.

But I think we have to do that. That being said, this notion of how do we recommend that imaging studies always are encoded with LOINC indicating what type, that's a pretty big one. Do we feel that that really should be something that at this point we should say should be mandated, or should it be something we say we should recommend it?

Steven Lane - Sutter Health - Co-Chair

You know, I just realized that we hadn't –

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah.

Steven Lane - Sutter Health - Co-Chair

– indented these sub-bullets here. So, this recommendation to support the harmonization, advancement, consensus, development is standards-based catalogs of orderable tests.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

Steven Lane – Sutter Health – Co-Chair

That's just what you're getting at, Jack, with mappings to associate code systems and codes with special emphasis on the following. And we say labs use LOINC and a LOINC, and then we talk about lab ordered details, radiology ordered details. Should we say lab and imaging orders using LOINC? Does LOINC provide that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

But would we expect imaging to be ordered? The order, would it be LOINC, or would it be SNOMED?

Clement McDonald - National Library of Medicine - Member

Well, it's generally the – no. It's not SNOMED. Not in the U.S.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

For lab ordering. I'm sorry. For imaging ordering. Isn't it usually [inaudible] [01:05:39]?

<u>Steven Lane – Sutter Health – Co-Chair</u>

[Inaudible].

<u>Terrence O'Malley – Massachusetts General Hospital – Member</u>

I think with CPT – yeah. CPT generally. You could do it via LOINC.

David McCallie – Individual – Member

Which is awful.

Kensaku Kawamoto - University of Utah Health - Co-Chair

But, yeah.

David McCallie - Individual - Member

What could be better?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

CPT doesn't provide the granularity that people need to be able – which is why people create custom order codes.

Terrence O'Malley – Massachusetts General Hospital – Member

Yeah. CPT provides plenty of granularity for most imaging orders, but it doesn't provide -

David McCallie – Individual – Member

But it is tied -

<u>Terrence O'Malley – Massachusetts General Hospital – Member</u>

all of the detail that's needed for actually conducting the images, which is why you need the notes.

David McCallie - Individual - Member

And it is biased towards payment [audio cuts out] [01:06:11], which is used by the ordering physicians because they want payment to happen.

Ming Jack Po - Google - Member

Yeah.

Terrence O'Malley – Massachusetts General Hospital – Member

Well –

Ming Jack Po – Google – Member

Well, Clem would probably know this better, but RadLex is also frequently used by a lot of commercial [inaudible] [01:06:25].

Clement McDonald - National Library of Medicine - Member

That's the point of time, hey, RadLex has jointed with LOINC and they have a combined proposed set of terms. RadLex and [inaudible] or RSNA. It's been –

Steven Lane - Sutter Health - Co-Chair

Okay. So, I think then we do capture this in our text. When you're asking ONC to support the harmonization, advancement, and consensus, and then we specify radiology orders and order details. So, I think we've got this.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Steven Lane – Sutter Health – Co-Chair</u>

We're not saying with whom they are going to harmonize that, but they need to work on that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. And I'd say just watching a lot of ONC-supported initiatives and other initiatives, that this particular part about orderables, it comes up in almost every project that's come up and a number of Da Vinci ones. For example, for prior auth where the current [inaudible] says, "What are you trying to order?" And it says pretty much use any code. And you put in a comment saying, "We should probably really standardize," and the answer is no. That's too big of a challenge. We'll wait for the next project to work on. So, yeah. I think it just needs to be prioritized, right? People have known for a long time the orderable catalog needs to be standardized, et cetera. It just — unless there's concerted efforts, the can's going to be kicked on this forever. But yeah. I don't think we're at a stage especially with the discussion we had now to say we should mandate a certain approach. I think it's probably too early. I think it should be with recommend an effort be put in so that we can get towards standardization. Because where [inaudible] [01:08:02] —

Ming Jack Po - Google - Member

I think that makes sense.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Okay.

Ming Jack Po - Google - Member

Clearly, there's a lot of discussion. Yep.

Steven Lane - Sutter Health - Co-Chair

Okay. So, next comment. Again, Jack, thanks so much for adding comments as you did. Is on the section regarding – and I'm on page – what am I on here? Eleven. Results need to be available for patients and their proxies effectively view, receive, and utilize. You started a comment, but it looks like it's not – oh. There it is. I can't see that. Oh. Go to show more. Authenticate patients. Authenticate on behalf of – oh. You're getting into a whole other world here.

Ming Jack Po – Google – Member

Yeah. It's just the things that you guys talk about basically all assume this. It's not at all discussed, but this is also exactly what you mean by a whole other world. But it seems like we're just assuming all of that will get done.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

This authentication, that's covered by the patient facing API requirements, right? I think. So, authenticate on behalf of patients. Are you thinking their family members, retrieving family members' results or otherwise duly authorized?

Ming Jack Po – Google – Member

I'm thinking about apps who are going to sit in the middle.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

So, basic to my understanding of how this would work for a patient facing practice lead is using the USCDI APIs that are consumer facing. A patient would say, "I want this app to have access." The PHR, you would be able to log in with your PHR log in and password, which would generate an O off token, which you would use to pull data in and out or mostly pull data in. But I mean, that's the mechanism. So, isn't that already defined? I think. I mean, there's [inaudible].

Ming Jack Po – Google – Member

Is that the requirement?

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

What was that?

Ming Jack Po - Google - Member

Is that the requirement?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I thought it was. Isn't it? No?

Sasha TerMaat – Epic – Member

So, in the current ONC 2015 edition, there's not a specified approach for authentication, though I think many folks are using the approach that Ken described. The proposed updates that ONC 2015 edition that we saw in the proposed rule earlier this year specified the use of O off with the type of flow that Ken describes. It's not mandated that a patient portal credential would be the approach used for O off. You could use a different credential if there was an approach that made sense. But because of the challenges of using a different credential and then establishing that match to the patient record, I would imagine that many folks would use a portal credential because at least the patient's identity has already been established prior.

So, that's maybe a long-winded answer of I think that the standard use for authentication has been proposed by ONC and I didn't hear a lot of controversy in the comments about use of that standard. I do think there's some initiatives, but Karen is working on and others to say are there even more advanced or cooler authentication methods. It's certainly worth exploring, but I don't think that's within the scope of what the task force considered as we discussed this. It would be a separate area to look at.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Cynthia has a comment.

Ming Jack Po – Google – Member

Okay. That's helpful. Thank you.

Cynthia Fisher – WaterRev, LLC – Member

Yes. Hi. Thank you. As I'm looking at the opportunity here, especially with labs and images and patients having access to these results, [audio cuts out] [01:11:55] been the ideal world that we can get to is the ability for us to allow a standardization pathway so that the actual image potentially could be in the cloud, that the patient can have access to through their portable phone, be it a digital X-ray, a digital MRI. You know, I think we look at today, so often, patients have to go back to the center. They get the report physically. They get a CD-ROM. Nothing that's usable to the patient on that CD-ROM.

And oftentimes, the orthopedic appointments or those images for instance are totally wasted because they can't get it to load onto their systems. So, you know, if we just used the cloud and have our standard be able to have access to the actual image itself and shared readily by the patient, I just wanted to pose that to the technologists in the room as how readily we could potentially catapult to be able to deliver this to the patients near-term.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Thanks, Cynthia.

Ming Jack Po – Google – Member

I think that is the scenario that I was kind of thinking about. I think we're quite far away from doing that today. I actually just experienced exactly what you described. I guess the DVD that has a bunch of .exe programs I can't load on my computer, I was thinking about some middle layer app, whoever happened to be. It could be Apple. It could even be Epic. It could be whoever. And then, how do you potentially access joint resources, or how do you even make sure that across multiple institutions these resource either stored in the same place or you can link everything together? I sort of probably overloaded the word "authentication," but a lot of this is sort of implied in the patient story and a lot of this stuff that is in that section. But unclear whether it's in the scope of this particular recommendation.

Kensaku Kawamoto – University of Utah Health – Co-Chair

And I -

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

I guess my point is that it's doable in any other venue. I mean, look at YouTube, for instance. I mean, it's very – in film. We do it in our everyday lives and a lot of other industries. So, you know, I would just want to push to the committee to say, "We can deliver this now because the technology is there." And how do we get out of our own entanglements to be able to do that because that is a huge – I don't know who has just responded that they just experienced it themselves. But, I mean, this is an everyday occurrence which is a waste inordinate amount of time and resources for physicians and patients and families alike.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Anil has a comment and we'll be going to public comment in about three, four minutes.

<u>Anil Jain – IBM Watson Health – Member</u>

I'll just make a quick comment. I mean, [inaudible] [01:14:57] is here today. I think what the broader point that Cynthia and others might be making is that as the technology evolves where information may not be stored in a [inaudible] by a single provider, but it's out there in the cloud, that the consumer has the ability for that information to be standardized so that they can access it from wherever they like, and that the authentication mechanisms be developed with standards so that if a rural hospital chooses to use a cloud patch, so that patient could be anywhere. And the doctor could be anywhere and access it. But the technology, as you guys have said, it exists today. It's just the standards that are lacking and maybe that's our recommendation.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

So, I've got a –

<u>Cynthia Fisher – WaterRev, LLC – Me</u>mber

Yes. So, I don't know who said that. This is Cynthia. I can't thank you enough -

<u>Anil Jain – IBM Watson Health – Member</u>

This is Anil.

Cynthia Fisher – WaterRev, LLC – Member

– for – Neil. For saying it so clearly. And I mean, how exciting would that be if we delivered this change to the marketplace to consumers and patients? I mean, patients and physicians. It would be huge and hugely appreciated. And in fact, I do believe it would be a great priority for us to really catapult us it into, because the technology is there, to catapult us to have the discipline to get this standard in place.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

So, Jack and Anil and Cynthia, can you look at the text that I've added here under recommendations and see if that begins to capture what you're saying? I added "advanced technical standards to support secure authentication of patients and their designated proxies to support access including bio-level technology.

Anil Jain - IBM Watson Health - Member

That's -

Ming Jack Po – Google – Member

Can you just include -

[Crosstalk]

Ming Jack Po – Google – Member

Yeah. Exactly.

Anil Jain - IBM Watson Health - Member

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Yeah. Likewise.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

I didn't hear it.

<u>Anil Jain – IBM Watson Health – Member</u>

Via mobile or [inaudible] [01:16:46].

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay. Okay.

David McCallie – Individual – Member

Cloud doesn't mean anything specific. So, I don't know that that — I think the thing that might be the barrier here is business model. The technology exists to do it today. You know, in Kansas City area all providers have cloud-based access to all radiology results from the major imaging centers. But the patients don't, and it's a business model problem. Who pays?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. [Inaudible].

David McCallie - Individual - Member

It's not a technology problem.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u> [Inaudible].

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

But doesn't the patient pay? I mean, this is what's so frustrating. Doesn't the patient pay? The patient already paid for the image. Now, the role of the provider of that service is to enable the image to be delivered to the patient. And we know that the cloud is the most cost-efficient mechanism to deliver that. So, I don't think we need to add anything here on who pays to get access to that. The issue is is that we owe it to the American public to efficiently get a standard in place that —

David McCallie - Individual - Member

It's not a standard problem.

Cynthia Fisher – WaterRev, LLC – Member

-- we can share the patient's [inaudible].

David McCallie – Individual – Member

My point is it's not a standard problem.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay. And on that, we're going to go to public comments because we want to be sure to give everyone a chance to participate. I think those are really good points. Let's make the announcement here and go ahead with that.

Operator

If you would like to make –

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Sure.

Operator

– a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the questioning 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 the handset before pressing the star keys.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated</u> Federal Officer

Thanks, operator. Any comments in the queue?

Operator

There are no comments at this time.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer</u>

Okay. We'll circle back just to be sure.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. And one comment I just have with this discussion of imaging results being available. I think the place to really address that is in USCDI to say, you know, if we feel that imaging results should be easily accessible, the actual images, then that's a USCDI issue to say, well, you know, this is why the actual images [inaudible] [01:19:04] be able to access, et cetera. Once you have that then, for example, if someone who creates a patient-facing app wants to pull it and serve it up into the cloud, right, you could do that. There's nothing that would prevent you from doing that. So, I think the core issue there is a USCDI where there needs to be a proposal assuming that that — and it makes sense, right? Having the actual image rather than the interpretation being available, though some images certainly take a fair amount of space and bandwidth and to make it that a USCDI issue.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

And could we also do it so that we use belts and suspenders as a committee to say, you know, this is a remarkable change that we could deliver. And so, is there another place other than USCDI that we could make it a standard, you know, that the patient gets not only the report but gets the image as part of completion of their service. Somebody even had said conditions utilizing before for the laboratory standards using conditions of payment. But I don't know why when it's so important for the actual orthos – or I'm using an ortho example because of frequency. But if the specialist physician is looking not only at the report, they want to see the image as well. And this is how it works, and it's broken. And we can fix it.

So, I would really seek our committee to figure out how we can get this done and done timely because images are up, and it could be so doable and transformative and cost-efficient and get rid of so much waste. Look at Neill's situation. But I can tell you, you know, especially for advanced pediatric orthopedic issues like a digit transplant, for instance, families fly to these special hospitals, spend couple of days in a hotel, and then the images don't work, and they have to come back. They've spent thousands of dollars and incredible stress and there's lack of compatibility when in fact they could just have it available on their smartphone and access to any specialist they want to see anywhere. So, I really would beg us to put belts and suspenders and get this one done. It would be a home run for all of us and we could all be pretty proud.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

And David has a comment.

David McCallie - Individual - Member

Yeah. I think that I totally agree with the importance and the power of having remote access to imaging studies be available to providers regardless of where the provider is with respect to the source of the imaging study. That's highly desirable. And if you want to use the consumer as a digital mule to carry the images on a phone, you know, that's okay as well.

But I'm going to say again, I don't think the fundamental problem is standards problem. The fundamental problem is lack of pressure on the imaging centers to incur the costs to deliver this capability. Some imaging centers in some communities have figured out how to do it. Kansas City is one city where this happens routinely all the time. Other cities haven't figured that out. But it's not a standards issue. It's a regulatory and/or business model issue. I totally agree that it's incredibly important, and it ought to be available everywhere. We worked hard in Commonwealth trying to pull this off, and we ran into business model problems that made it very difficult to get any traction.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think we have -

Cynthia Fisher - WaterRev, LLC - Member

That -

Steven Lane - Sutter Health - Co-Chair

I think we've reconciled all of the comments that task force members submitted on this first orders and results section. We've added a bit of text and made some clarifications. And again, we invite task force members to go back through this section and consider whether you want to make any other comments or suggested edits. But we really appreciated all of the input. We really want all task force members to be comfortable when we advance this to the HITAC. The next section that we're going to be tackling at our next meeting, and I'm not sure I'm going to be there, is going to be the closed-loop referrals and care coordination, which again, the ONC team and the co-chairs will have a chance to go through in detail.

I see Jack again, Terry, a couple of you have gone through and entered some comments. And what we'll do is we'll go through them and consider them and potentially make, you know, just accept simple edits and make suggestions for more substantive changes. And then we'll spend our next meeting both following up again on any [inaudible] [01:24:13] and results and then digging through the referrals piece.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

And I think it would be helpful if – comments are certainly very helpful and members should have the access to also suggest actual text, whether it's in modifying an existing equivalent of a row or adding a new row. My suggestion would be to, if you can, to try to do that as well, to say this is the actual text that would address my comment because then there's something very concrete for us to review and to deliberate on. I just think because these are the most tricky issues we're attempting to add, right, we've already gone through the things that we're already pretty much agreed on. So, each topic may easily take 20 or 30 minutes to talk about, which means anything that folks are commenting can do to provide like if the wording was changed this way or if we added this recommendation, whatnot, that would be helpful. Otherwise, likely, we may run out of time.

<u>Steven Lane – Sutter Health – Co-Chair</u>

So, Terry, yours in particular, I think you've entered some suggested just edits. You know, grammar and spelling and things in comments, and it's harder to find where they are. Oh, I - now, I'm seeing them better. I'm sorry. So, yeah, again, those kind of things are great because we can just accept them as they go.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Okay. Well, I think we're almost -

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

This is Cynthia. Just -

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Yeah.

<u>Cynthia Fisher – WaterRev, LLC – Member</u>

Just some closure on the images discussions that we result before you launched into how to comment. And, you know, I'm happy to comment when I can sit at a keyboard to do that and will do so. I was just

wondering of the people on the call if there is support to make a recommendation to ONC that ONC consider the images themselves as so making the recommendation that ONC to require that not only the image reports but the images themselves be digitally open standard APIs and open access to both patients and patients' designees as well as providers. So, I guess my recommendation would be to see if any of the committee members would agree with making such a recommendation to ONC.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah, this is Ken. I think in principal, yes. One question I have is I'm not quite familiar how big these image sizes are. So, I would appreciate maybe David, Sasha, folks who deal with these, if we can get some more information on what that means. So, specifically, right, if, for example, an image is going to cost 10,000 times the bandwidth and sort of the [audio cuts out] [01:27:21], from a health system perspective, for example, right, if we want to support these APIs and have people have access, and for example, because the imaging results may not be properly LOINC-encoded, which means the default is every single image you have, please let me search and retrieve, which is a reasonable kind of patient-level request that if a patient who had, say, MRI [audio cuts out] [01:27:42] whatnot and pulled it, what does that actually mean, and is it going to be, say, 100,000 times the bandwidth that every other request for things like allergies, problems, medication costs?

I just would want to know that it's actually feasible to manage. If it is, I think it would be great. If not, I think we need to think about things like, well, you know, do we need first to make sure that the images are actually LOINC-encoded so that you pull the ones that you're actually interested in, not just get me everything because it's not properly tagged and you don't know which ones are which. And I know some of these images have really many slices at really high resolution, and that could be a ton of data, which I would be afraid that, for example, that would be pretty substantial. Potentially. I don't know.

Cynthia Fisher – WaterRev, LLC – Member

Well, I think the issue, you know, perhaps what we could do is do some technology review with those centers that do do it. And Kansas City is a good example because it is being done, right? And is being done efficiently. And so, why don't we ask those that are successfully sending images to patients today to share with us the feasibility? Because they're doing it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah, and I think –

Cynthia Fisher – WaterRev, LLC – Member

And I think the question is, you know, are we in a moment of time where ONC through this patient access of Secures Act can actually deliver this system-wide to the American public?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yeah, and I think we're pretty much out of time. But yeah, let's continue that discussion, and certainly, I would strongly support trying to move towards that. I just want to make sure that it's not going to have unintended consequences like close every other access to data because the pipes are all full now with people retrieving 10 years' worth of their imaging data, which could be, you know, gigabytes and gigabytes of data.

Cynthia Fisher – WaterRev, LLC – Member

Well, we all watch movies on Netflix and our kids' YouTubes and you know, video constantly. So, I do think we can look at the how to rather than how not. And that would be my encouragement for our committee.

<u>Kensaku Kawamoto – University of Utah Health – Co-Chair</u>

Okay. Thanks, everyone. Great discussions. Again, please comment, and if possible, suggest actual wording for how you want the recommendations updated. Thank you so –

<u>Steven Lane – Sutter Health – Co-Chair</u>

And you can do that as track changes in the document and we can just accept them as needed, as some of you have figured out.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Great. Thank you so much.