



Interoperability Standards Priorities (ISP) Task Force

Transcript
September 25, 2018
Virtual Meeting

Operator

All lines are now bridged.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Good morning, everyone, and welcome to the Interoperability Standards Task Force. Today is September 25th. We have a full agenda today, so we will go ahead and call the meeting to order, starting with role call. Ken Kawamoto?

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Steven Lane?

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Anil Jain?

Anil Jain – IBM Watson Health – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Arien Malec? Andy Truscott? Okay. Clem McDonald?

Clement McDonald – National Library of Medicine – ISP Task Force Member

Here, but I have to apologize – I have to get back to a board of regents meeting at 10:30, so I won't be on the whole time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Okay, thank you, Clem. Cynthia Fisher?

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

David McCallie?

David McCallie – Cerner – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Edward Juhn?

Edward Juhn – Blue Shield of California – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Leslie Lenert? Not yet? Jack Po? Raj Ratwani? Ram Sriram?

Ram Sriram – NIST – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Ricky Bloomfield?

Ricky Bloomfield – Apple – ISP Task Force Member

Good morning. I'm here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Thank you. Sasha TerMaat?

Sasha TerMaat – EPIC – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

And, Scott Weingarten? Okay. Cheryl Turney? Tamer Fakhouri?

Tamer Fakhouri – One Medical – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Just joined. Tina Esposito? I believe she said she was gonna be absent today. Valerie Grey? And, Victor Lee?

Victor Lee – Clinical Architecture – ISP Task Force Member

Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Thank you, everyone. I am going to now turn it over to our co-chairs, Ken Kawamoto and Steven Lane.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Great, thank you. So, last time we met, we discussed what the task force members thought were issues in the area of orders and results, with a particular focus around labs. In the interim since then, we created a Google spreadsheet that's available only to the task force members, and Steven, Arien, and I started editing it a little. We had a meeting last week with a number of subject matter experts, many of whom gave us information at the last meeting. What we basically did was organize the issues into problems, examples, associated standards and issues, and importantly, proposed remedies. One of the issues we discussed in particular was once we have a recommendation of what needs to be done, how will we potentially get that to happen and what are the different levers that are available?

So, that's where we're at now. I'd say at this point, we'd like the task force to review what we have come up with, to prioritize and probably prune to come up with a prioritized list of recommendations and approaches, at least in this area, with an acknowledgment that if we decide to hold off on some areas – let's say for non-lab resultables or observations – that we can always come back to it later as well. I don't know if Steven or anyone else engaged in this would like to comment.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

I'll just add that we're really trying to winnow down the larger set of ideas and recommendations that have come out of our discussions to really have something that will be able to turn into our report out on this domain of orders and results, and again, we're trying to develop a bit of a methodology here that we'll be able to apply as we go on and look at other priority domains such as referrals and others that we have discussed.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Okay, and – go ahead.

David McCallie – Cerner – ISP Task Force Member

Hi, Ken. It's David McCallie. I had to miss the last meeting due to travel. I'm just curious what the goal of the report is. Is it to identify new standards or actions? If we identify a problem, are we proposing solutions?

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Yes. So, I think that might be the thing that's the trickiest. So, we identify a problem. At this point, there's no clear major lever that ONC controls in some of these areas, such as new meaningful use or EHR certification requirements, so the issue is how do we solve our identified problem? I think that'll be a key focus and an area that Arien, in particular, spent a lot of expertise and effort contributing to that we'd like to discuss today.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Specifically, David, our charge as a task force is to make recommendations regarding "subsequent steps for industry and government action." That's our charge.

David McCallie – Cerner – ISP Task Force Member

Okay, recommendations for action. That makes sense. And, that could include anything from new standards needed to something else. "Argonaut should take up such-and-such," or whatever.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Exactly. Another thing that is – again, referencing the text in our task force charge – we are meant to identify the standards and implementation specifications that best support or may need to be developed for each identified priority.

David McCallie – Cerner – ISP Task Force Member

Thanks.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Sounds good. Okay. Well, we'll get to that in a second. We would like to start with a presentation on LOINC from experts at Regenstrief, obviously because LOINC is quite important in this field. If there's no other discussion at this point, I'd like to move us forward to that, and then come back to this discussion. Okay. Dan, would you like to move forward with the presentation? Are you on the audio?

Clement McDonald – National Library of Medicine – ISP Task Force Member

Maybe he's on mute.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Dan, you're muted if you're on.

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Am I on now?

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Oh, we can hear you now.

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Awesome. The multiple mute buttons always get me. So, this is Dan from Regenstrief. I'm the director of LOINC here, and I'm going to try to address some of the questions that came up. It's broad territory,

but I'll try to stay at a level that I think will be helpful to the task force, and I'll just ask to advance the slides as we go through. So, the first one is just a disclosure there to let you know that I'm part of a company that wrote a book about LOINC, and I'm a TI on some commercial sources of LOINC. On the next slide, I put the full list of funding sources for LOINC, so you get a sense of how a standard like LOINC gets produced, and it's from the support of a lot of different organizations. Next slide.

So, the first thing I wanted to do is remind you that I'm coming at this from the perspective of viewing LOINC as one piece of a broader set of solutions, but ultimately, it comes down to people who actually want their health IT systems to work together. So, there's a technical component, but for sure, there's an ecosystem component that's enabling data sharing. But, it doesn't take too long to realize what we're trying to accomplish. Please go to the next slide.

LOINC is focused on solving a particular part of this interoperability puzzle here. And so, technical standards that move data around, like HL7 Version 2 or FHIR, are wonderful and we need them, but if you start moving data around without a focus on coding stuff, you get to a thorny place. Here's a picture of the codes that represent a test here in the Indianapolis region, and you see the wild variation that exists, and this is the problem that LOINC is trying to address: To come up with a coding standard that matches the level of granularity that reflects these kinds of observations in real systems. Next slide.

LOINC's purpose is basically to be that universal standard for identifying health measurements, observations, and documents. That's the main focus of LOINC's content, and it's designed to have a level of specificity that distinguishes between clinically important differences, and of course, that's use-case-specific and purpose-dependent, but it distinguishes from, say, a billing purpose. What we're trying to do is create codes that reflect that level of precision that's needed for exchange and action from a clinical perspective. Next slide.

So, the scope of LOINC is that realm of observations, measurements, and documents, but it covers a broad territory, and if you zoom out and take a view from a precision medicine perspective where, on the one hand, you've got detailed clinic-level data, and on the other hand, you've got environmental context or behavioral information, LOINC fits across that whole spectrum, which might be somewhat of a surprise to some folks – certainly, there are areas where we're more robust – but it's essentially across that whole continuum wherever you're trying to record information in that observation/observation value paradigm.

LOINC is trying to create codes that identify those different variables for observation, so it certainly takes into account laboratory and traditional clinical measurements, but also some lifestyle, behavioral, or even environmental variables where the analysis might not even be an individual patient. Just to give you a spectrum, that's the overall place that LOINC covers. Today, there's about 87,000 variables in it. Next slide.

It's being used not only in the U.S., but around the world, which just gives you some context about how content gets into LOINC, as well as the impact of what we're doing and how that translates to an

international audience, but the vast majority of those users are from the U.S., probably about two thirds. Next slide.

So, just to make it clear, LOINC is designed for the specific role of identifying observations. It works equally well whether you're talking about a transport mechanism like HL7 Version 2, a document paradigm like CDA, an API-based access like FHIR, or even something like a common data model that's used in research networks like PCORI, OHDSI, and so forth. Any time you have this pattern where you want to store a variable and its result, you need a consistent way to identify variables across producers of data, and that's the job that LOINC is trying to fulfill. Next slide.

So, not only does it have codes – we create codes for the individual observation, which is the bread and butter of LOINC – there are also codes for collections of those things. On the laboratory side, you might – is there a question?

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Sorry, Dan. Can I interrupt? David, I see you have your hand up. Did you have a question for Dan?

David McCallie – Cerner – ISP Task Force Member

No. That's probably left over from before. Sorry.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Apologies. Please continue.

Daniel Vreeman – Regenstrief Institute – Director of LOINC

No worries. So, on the laboratory side, we might think of collections like order panels and batteries, but in other clinical spaces, you might call those things forms, datasets, structured enumerations, or variables, and LOINC creates codes that represent those collections as well as more loosely structured collections of information, such as clinical documents. That could be a discharge summary, or you might think of a radiology report as a loosely structured collection. LOINC creates codes that identify those kinds of things too. Next slide.

And then, the last elements of what LOINC is covering are connections to structured answer lists. These are particularly important in some subdomains of clinical content – for example, patient-reported outcomes measures such as the PROMIS measures, other standardized assessment instruments, and survey instruments. LOINC has a mechanism for defining these allowable answers, packaging them into a list, and then connecting them to the question variable that they pertain to. And so, in some areas, this is particularly important, and it's a little bit more of a recent evolution in LOINC history. Next slide.

These are the nuts and bolts. LOINC is packaged into distributions twice per year. It has a whole set of release artifacts that people can pick and choose depending on what their needs are for that content, and also, along with the file structure, you can search the content online or view it in a desktop browser, and recently, we've also made the content available through a FHIR terminology services API. Next slide.

So, just to give a quick overview into some areas that might be less familiar, I thought I'd give a small taste of some of this content so you can have a picture of what is inside LOINC, even beyond lab stuff. Next slide. Certainly, many of you in this task force have a focus on lab, which I think is great, but even within that space, you might not know about the full spectrum of variables that LOINC has – for example, in newborn screening, which is actually a subsection in the HL7 lab results implementation guide covering that use case.

Similarly, there's a whole spectrum of variables in clinical genetic reporting which includes tests that are reported just as single-test measurements or presence/absence kinds of things, but also, whole collections of variables that have organized structured reporting of different styles of genomic reports for simple variants or structural copy-number variants from genomic studies and so forth. And, this too is included in – these sets of terms are organized in the laboratory results implementation guide from HL7, which is also being worked on and actively developed from the FHIR implementation guide perspective as well.

Now, LOINC lab content – for sure, single tasks can use the same LOINC code, both on the order side and on the results side – so, the test you order and the thing that you get back – but there are also these collections of order sets or panels in LOINC, and a couple years ago, stimulated by an SNI framework initiative, we built out a set of additional order panels and got consensus to vet down a list of common order codes that covered a good portion of the volume, and while it is not as widely implemented, that subset is available at LOINC and had significant community input. Lastly, I'll just mention that LOINC does work actively with CDC and others in the public health domain for any tests that are relevant for emerging diseases and reportable conditions as well. Next slide.

On the clinical domain, LOINC has two big sets of content that I think are important for your priorities. One is a set of terms that identify clinical notes and documents. We refer to this as the LOINC document ontology, and it's because there's a special set of attributes that can be used to organize those terms, but it's been an active area of development in LOINC for quite some time. In addition, there's a really robust set of terms for radiology procedures to be used for ordering and resulting diagnostic imaging reports, and that was the product of a great collaboration with the RSNA, and today, there's a whole set of just under 6,000 radiology procedure terms that have a really detailed modeling connected to them, which can be powerful for aggregating or displaying or doing decision support against those procedure terms. Next slide.

Lastly, I'll just mention that there is a broad collection of other clinical variables spanning things that you might be familiar with, like vital signs and other kinds of traditional clinical measurements, but other kinds of datasets as well, such as all of the items on the patient assessment instruments that are required by CMS in post-acute care. So, the structured assessment forms such as the MDS, OASIS, IRF-PAI, and so forth – we've been working very closely with CMS to represent all of those instruments, the question and answer structure, and so forth in LOINC, and there's a huge collection of those other kinds of assessments and patient-reported outcome terms in LOINC as well. Next slide.

So, how does LOINC fit into this current landscape of implementation standards and so forth? I'll just give a quick highlight here of how it fits together. So, on the next slide, I just highlight the famous HL7 lab standards quartet, which with some members of the band might be more familiar than others, but I refer to this quartet as the lab results implementation guide, lab orders interface guide, the public health electronic lab reporting guide, and the eDOS standard, which is for definition and communication of a directory of service, a master test list, a catalogue, or whatever. And, across these four implementation guide standards, LOINC is the coding system identified for all the places where you want to identify the test or the order set, so that appears as OBX-3 or OBR-4, but in the eDOS standard, there's a couple of other places where it's linked to what test it is. There might be a producer code, like a local lab code, but also a LOINC code to identify what this is.

And, in each of these places, I will mention that the wording on the binding of what you put in here always has this little caveat, which is basically saying LOINC is the thing you should use, but if there isn't an appropriate LOINC code, you can use a local code, and that escape valve is a necessary one because the world keeps changing and it's unrealistic to think that the instant a new test is created and performed, a standard code would exist for it, though we might be trying to work closer and closer to that goal. There might always be a period of time when a result needs to be sent out, but there might not be a standard code available for it.

On the next slide, you can see where this pattern has carried forward into the work that Argonaut took up with the FHIR implementation guide and the U.S. CORE implementation guide, which is the SU-3 version of that, in the places where the defining data element queries based on the ONC common clinical dataset. It follows that same pattern. Observations are tagged with LOINC codes, but other codes can be used if there isn't a suitable LOINC code. In addition, you'll find LOINC is the referenced vocabulary for documents and other kinds of clinical observations that are currently listed in the common clinical dataset, such as smoking status, the observation code part of that, and vital signs as well. Next slide.

I'll take you back to consolidated CDA 2.1 and list there the places where LOINC is specified in the result observation section, define that same language as you saw it in the Version 2 guides for identifying LOINC codes for results, and then, other places across that set of document templates, including for document codes, section codes, and other kinds of observations like vital signs, scanner measurements, and so forth. Next slide.

So, there are two other things that I just wanted to highlight for the task force from a broader ecosystem outside the LNC domain, just to make you aware of it. So, the FDA has been moving toward a broad vision of using real-world evidence and post-market surveillance, and under that umbrella, there are two important things. One is they have made a requirement for sending lab test data in regulated studies to them using LOINC codes to identify that data starting in 2020, and so, from the clinical research side, this is something people are moving toward. In addition, the FDA has been pretty supportive of the direction of having IVD test vendors identify standard coding for their tests and making that information readily available to the consumers of that data, i.e., laboratories themselves and folks that are purchasing instruments, kits, and so forth.

That conversation that FDA was helping to encourage inspired the development of a standard called LIVD, which stands for “LOINC for IVD tests,” and it’s a specification that’s designed for vendors to publish the connection between instruments and the local codes that those instruments might produce, the measurements that they might produce, linked to the specific LOINC codes that are appropriate for that test, with the idea being that if there was a standard format that IVD vendors could use to make this information available, it would dramatically simplify the process of setting up these new tests in LIS within the laboratory, and we believe that will be a huge benefit, and that particular standard – the LIVD one – was also recommended by the CLAC, the Clinical Laboratory Advisory Committee to HHS, and is being transitioned and is currently under ballots at HL7 and the FHIR implementation guide. Next slide.

And then, two other agencies to bring into perspective here – so, certainly, from a public health standpoint, CDC has been a longtime user of LOINC in all of its lab reporting, case report definitions, and so forth, as well as some of the other national reporting initiatives – for example, around EMS data and trauma registries as well. And, of course, CMS has been using LOINC inside eCQM definitions based on recommendations from the standards committee, but as I mentioned earlier, on the side of post-acute care assessment instruments, they are working closely with us to find LOINC codes that represent those instruments and have providers use them as well.

On the next slide, I’ll just give you a sense of – having heard a little bit about the federal standards ecosystem, what does it look like today? As an SEO, we don’t have perfect information about this because we don’t have RFIDs on LOINC codes as they go out and there’s no central stream that we can dip into to get a sampling of what the real-world usage is like, but we do know, for example, that all of the big reference labs have mapped their observation codes to LOINC codes – Mayo, Arup, LabCorp, et cetera – and many of them are working on the order side, so that is a work in progress more than a work completed.

We know that the big research networks use LOINC in their common data models – so, OHDSI, PCORnet, and so forth – and, after running some statistics on what they have PCORnet has told us that about 94% of the results of the lab tests in their network had LOINC codes hooked up to them. But, on the wire-coded results, we know that it’s happening for sure, but it is less frequent. For example, we heard from Diameter Health, which organizes an HIE of about 200 organizations, that they are seeing more than half of the lab results coded with LOINC, and I bring this up because the simple existence of mappings does not necessarily mean that those mappings make their way into all emitted data streams from a source.

And then, lastly, I would just mention that there is an emerging ecosystem of knowledge products that are leveraging LOINC, and this is important just to recognize because it helps understand what the value propositions are for the different stakeholders and the data producer and receiver stream for tackling the standardization problem, and having additional value adds for doing that standardization work can certainly help. So, for example, smart FHIR apps that help in calculations of various things that are powered by having LOINC-coded data and info button-powered decision support tools that leverage the standardized coding available as well.

So, just to wrap up, then, I'll make a couple of comments by way of recommendations, or what I see as some low-hanging fruit. So, the first thing I want to mention is there's sometimes the idea that if a code doesn't exist for the particular thing that I want, that all standards are broken and we need a new one, we should give up, or we should create a new terminology. I would just point out that all the vocabulary standards that I was talking about grow because the users make requests from them, and it's an ongoing process as people expand to cover new areas, new territories where they didn't have structured data before. That stimulates requests for codes, but also, certainly, as I was saying, the tests keeps evolving. You guys know the places where there is missing content. We would love to work with you to add codes that address those gaps.

In the next slide, though, I would say that what I see as low-hanging fruit are certainly the areas where people are already capturing structured data or haven't organized it in a way that adding the layer of semantic coding on top of it would have a huge value. And so, some of those areas are diagnostic imaging reports, and so, the structures are all there. Whether you want to use consolidated CDA, FHIR, DICOM, et cetera, those all exist, but there hasn't necessarily been a broad push to get the standard coding tagged to the report level, and yet, it seems like most people would want imaging reports in their exchanges and so forth, so that seems to me to be low-hanging fruit.

In addition, general clinical measurements and observations don't necessarily need new structures, but they do need the extra work of tying standard codes to the local variables that exist, but that, too, could have a nice input. Clinical notes as well – surely, everyone has document repositories and so forth, but the extent to which they've been identified using a consistent and common framework is probably low, though we know there are many places that are working on that, and I know this is part of Argonaut's focus, but I would say that is one of the areas of low-hanging fruit.

A little bit lower down the chain would be areas where people are recording structured data, such as patient-reported outcomes measurements or other standardized assessments, and they just aren't using standard codes for that stuff, but yet, they're capturing it in a structured way. I'm not saying we should necessarily push capturing more of it, but if they are doing it, they should apply standard coding to it. And then, as I mentioned this lab order side – there's been a lot of work to develop the specifications, including some pilot tests and so forth, but it's a little bit of a harder domain because order sets are not as standardized across all laboratories, but there are techniques to address some of those variations. So, while I think the standards exist, there really haven't been any direct new requirements or incentives to use them, and I think it's something we should keep our eye on. Next slide.

But, in this, I would say overall, the idea of standardizing as far upstream as possible is the right approach, so, to that end, this effort to help engage the IVD vendors to identify standard codes has tremendous benefit downstream, and I think sometimes, we get in trouble where by policy decision or whatever, we say that all the data has to be standardized, but it might be too far down the pipeline to make it really efficient. For example, the point at which you're converting your data into a common data model for research purposes is probably too far downstream to be doing standardized mapping. You want to try to get that closest to the source because it'll be more consistent, more accurate, and so forth.

Lastly, the committee chair has been talking a little bit about how LOINC and SNOMED work in this, and I'll try to be as crisp as possible. Basically, think of LOINC as what you want to recommend for observations. Anywhere you have that question/answer paradigm, you want to use LOINC codes to identify the question or the variable. And then, in a lot of spaces where the observation value is an organism, a condition, or whatever, you want to use SNOMED for that, and for other places where the data doesn't take that observation value format, where it's an assertion, a problem list, and so forth, these are the places where SNOMED shines. This approach – the question and answer of LOINC and SNOMED model – using them both together, but for distinct purposes, is something that's part of the Regenstrief and SNOMED agreement, endorsed by both organizations.

I will mention one caveat here, which is that particularly in these areas of standardized assessments for nursing questionnaires, nursing assessment instruments, patient-reported outcomes, and so forth, the answer sets really require very specialized strings, and they're not very easy to represent as concepts in SNOMED, and so, for many purposes, when you're communicating an exact questionnaire – and, this is the recommendation from the nursing groups, for example – using LOINC answers for those highly specialized strings helps you retain the fidelity of the original instrument. I'll also just point out that in some other areas, such as genetics, you'll also need other kinds of standards for observation values, whether it's HGVS, ClinVar IDs, and so forth. But, this pattern of using both LOINC and SNOMED together works, has been done, and I think is the right way to go.

The last thing I would mention is this ecosystem from producers to receivers or actors applying data – there are two new tools that I wanted to bring to the task force's attention that we've been working on in response to some of the priorities of the LOINC user community. The first is a way to roll up sets of LOINC codes that could be treated as equivalent for a particular purpose. So, these purposes, of course, are quite varied. One might be for flow sheet display, another might be for retrieval in a quality measure or research study – show me all the LOINC tests that have to do with X condition, X bug, or whatever – but, this technique of having a structured way of saying, "For this purpose, we're going to aggregate all the tests that measure the same substance that vary only by whether they are arterial blood, venous blood, or whatever, and put them into a group." That's the design of what these things that we call LOINC groups are. So, for data receivers, we think this is a useful tool for doing equivalences.

The second is based on a lot of input from the community, we've been working hard to create some better display names. This might not be an eternal problem, but it is a challenge when there are lots of different kinds of stakeholders in this game. Our goal in developing this set of better display names was to keep them unique, but improve them and make them more user-friendly, and those came out for the first time in our June release, and you'll see and hear more about them, but the community put a lot of input into coming up with rules that will help us think about how to make better display names that retain that fidelity that LOINC is trying to shoot for. With that, I'll wrap up and say thank you for the opportunity to share. I hope I hit the main targets of the questions you have. In whatever time is remaining, Sullivan and I would be happy to answer questions that the group might have.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Great. Thanks, Dan. Questions from task force members – David?

David McCallie – Cerner – ISP Task Force Member

Dan, thanks for a very clear presentation, but I have one question that you may have commented on, but I might have missed it or maybe you only answered part of it. If you had to assess the overall flow of lab results back and forth between clinicians and the performing labs – be they the national reference labs, local hospital labs, or whatever – would you hazard a guess as to what percentage of those are coded in LOINC? How close are we to everything being coded in LOINC? Any guess?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

The closest I know to the truth is the sample we got from the Diameter Health HIE. So, they're receiving it from the system. I don't know the side that's between the lab and ordering provider sides as much. What I would say is we know that the codes exist, and I believe that many of the mappings are done, but that doesn't mean that they're literally in the exchange message, meaning they could be looked up on either side, but that doesn't necessarily mean they're in the transaction. There might be a lot of reasons for that, but I would say that with some caveats, I don't know the actual frequency, but that's about as close as I can get. I know there's a ways to go.

David McCallie – Cerner – ISP Task Force Member

Just for reference, when was that analysis done?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Within a year.

David McCallie – Cerner – ISP Task Force Member

Fascinating. Just for another data point, when we had significant lab volume flowing through us – actually, we could probably rerun this analysis – it was about the same: Heavily skewed toward the reference and the large hospital labs and less adoption for your everyday hospital lab that serves as community lab support. So, it may be that what we're seeing is a lack of progress over the last five years, since that's the time when we did that poll. So, what was the percentage? I missed the number.

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Fifty, five-zero.

David McCallie – Cerner – ISP Task Force Member

Thanks. That's roughly what I would have guessed from our experience, but we haven't looked at it in quite a while.

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Dan, this is Steven Lane. I also wanted to say thank you for that very clear and concise presentation. I think there is just a tremendous alignment between what you just shared with us and the discussions that we've been having over the past few meetings of our task force where we really see this as an opportunity to help close the same gap that you've identified, and we've been thinking about ways to

do that. Some of them sound pretty dramatic, but I think we have Cynthia Fisher to thank for being here and representing the individual patient perspective.

And, one of the ideas we've thrown around is that LOINC coding – from the resulting laboratory or any resulting agency – should be a requirement for payment before getting paid to do a test, that the coding should be maintained with the result as it flows from the resulting agency to the ordering provider in the receiving systems and whenever that result is shared between systems, whether you're talking about EHRs, PHRs, et cetera. What do you think about those ideas, do you think that they are reasonable for a group like ours to be recommending, and what do you see as the challenges as we move those ideas forward?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Thank you. In general, I think that is the right direction to go. I do know that there are examples of that model in play already, where certain insurance companies have required for participation in their plans that laboratories do provide LOINC-coded data. Of course, they are interested in population health management and other kinds of services around their beneficiaries. They want that same power of semantic aggregation as well. I think a broader approach to that as an incentive to help move forward is a good one.

I do believe that, as you articulated, the benefit of standardization happens when it is applied at the source and is maintained throughout the set of transactions that happen later. It is more error-prone to try to do standardization anywhere else because you lack the specificity of what was performed, how it was done, and so forth. And so, the upstream part is important, and maintaining that connection between what was done and wherever that result flows throughout the other ecosystem participants is a good strategy.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

I see hands up. Let's go to Terry, and then David.

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member

Great. Dan, thank you. That was a great presentation. Something that got raised in the USCDI was the issue around local codes and the lack of mapping them to a standard like LOINC. Do you have any other examples of where you think interoperability is being held up, citing that one as probably the principal, or is that the principal one? Any others where you think there's a breakdown in getting the results into a standard?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

I think that is by far the biggest one. That's the largest inertia that we have – the proliferation of local codes that exist. So, the challenge of moving from that paradigm to one in which those codes are linked to standards is a matter of getting the incentives right to make it happen, and then, as we discussed earlier, getting it connected to the data flow of the outlets from that. The other challenge in interoperability is that there are some kinds of information that are organized more loosely than some receivers would like.

For example, in the clinical genetic reporting sphere, a fair amount of that has been happening in laboratories and so forth, but the vast majority of the reports that I've seen that are flowing in exchanges are still pretty much PDFs of that information, and yet, within the lab, there are some very structured things about the variants to look for, what was found, et cetera, but on the outside, it's formatted in a way where you lose that. That's one area where I think it's very useful to have additional structure network within HL7 to define a generalizable structure that at least pulls out the key items that you want in a discrete fashion, letting the text be there in places where it's helpful and useful, but having key variables as structured data. But, I think your first problem – the proliferation and existence of local codes everywhere – is the prevailing problem.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

I see David, Arien, and then Ricky who have their hands up.

David McCallie – Cerner – ISP Task Force Member

It's David. I have just a couple of comments. We could talk about this for the rest of the meeting, and I'm sure that's not the agenda, but I want to reinforce Dan's value of the work on equivalence classes, as Clem called them in our previous call, and you called them groups – the LOINC grouping. LOINC has the same problem as any bottom-up nomenclature, which is the excessive granularity from the point of view of many use cases. The granularity is necessary from the labs' point of view – obviously, every distinction matters – but to the clinician, if you want to look up glucose and there are over 300-400 LOINC codes where glucose is the analyte, it's overwhelming and doesn't make for easy use of the LOINC codes. So, there's a huge value in making those equivalence classes – or, an ontology, if you would – available. So, that's just a comment to reinforce how valuable that work is.

Secondly, this mapping thing is really complicated and potentially fraught with error because the mapping from randomly assigned local codes – and, obviously, they're not random, but they're random in the sense that they weren't necessarily starting with LOINC in mind – to a LOINC code requires a lot of judgment calls, and since there aren't high-level grouper codes that are equivalence class – “This is a kind of blood pressure, but it's so granular in this institution that we can't map it to an existing LOINC code” – you end up getting mappings that may not be perfectly accurate.

I just think that that's an issue in the long run that we'll have to figure out. If it's a lab test, getting the lab originator to assign the right LOINC code is the best solution, as you point out. They can get it at the source because they're the only ones who know exactly what they're doing. But then, don't forget that there are hundreds or thousands of observations generated locally that are coded to LOINC that aren't lab tests. They're data from forms or other structured assessments where institutions are doing the assigning, and it's a challenge to get those mappings right. We should just be aware of that.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Thanks, David. In terms of the logistics of this meeting, this particular topic of how we get more upstream LOINC coding of labs was going to be an important topic, as well as what the policy levers are and who is responsible, so my suggestion is we continue this discussion. Arien, I see your hand is up. You have a lot of recommendations around here. I wonder – if it wasn't what you were going to

comment on, could you add in a comment on your proposal of how we actually get that to happen? Maybe we can discuss it as a group. If you're talking, you're muted.

Arien Malec – Change Healthcare – ISP Task Force Member

That would be the mute button. So, first of all, thank you. I'm super pleased that some of the recommendations – and, it will be no surprise to anybody that some of these are recommendations I've been making for many years – are actually in flight, and in particular, FDA embracing LOINC for IVDs to make sure that we have true upstream generation of LOINC codes at the source. Do you know how many IVDs are being issued with LOINC codes? Is there anything being done right now to retrofit to provide standardized LOINC mapping for the output of IVDs?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

What I do know is that nearly all of the big IVD companies have mapped their internal codes to LOINC codes. Many of them have made those mappings available to their customers in a variety of ways from their internal portals, the PDF technical documentation that goes along with it, and so forth. But, some have been more reserved or cautious about making such mappings available, in part because they were waiting for the assurance that they couldn't get into trouble with the FDA if they made them available.

And so, the August guidance from the FDA on this topic was a long time in gestation, as I guess all guidance from the FDA is, but it was kind of to address that point, and they were worried that, say, if I mapped to a generic LOINC code or a ser/plas LOINC code, but my test is only approved for use on serum, am I going to get in trouble for off-market labeling by publishing these mappings? Rightfully so, there was some caution about how they should approach this. In addition, because of that caution, they are more sensitive to wanting to get the mappings right for the most part, which is a good thing, but the fact that some have mapped it does not necessarily mean that they're widely available yet, partially because of that ecosystem thing.

Arien Malec – Change Healthcare – ISP Task Force Member

Thank you. And then, just a little editorial because I'd remind the committee that the full ecosystem in the line of fire, if you will, for physicians getting beautifully trended results that are LOINC-native includes the IVDs, the labs, the lab system vendors, the intermediaries who route and manage lab data, and the EHR vendor and actual EHR implementation. So, to some extent, you ideally have everything perfect at the source, which is the actual analyte machine, and then you flow through, but this is a somewhat sticky ecosystem because the IVD vendor could publish the LOINC mapping, but the lab is up and running with proprietary codes and doesn't want to make the effort of remapping. Out-of-the-box mappings at least lower the perceived effort there.

I want to ask a question about CLIA and the CLIA Committee – CLIAC. Has the CLIA office formally recommended the LRI and the associated LOINC mapping as a target for CLIA-regulated laboratories, and from your perspective and knowledge, what else could CLIA be doing to encourage CLIA-regulated labs to standards, and LOINC in particular? This is one of those terrible questions that has an editorial baked into it.

One of the things that I've been pushing for a while back when I was at ONC and working with CMS and the CLIA office was to establish whether it'd be safe harbors or equivalence for safe harbors for new EHR onboarding. As I think some people know, when labs onboard results delivery, the lab has an obligation to verify that the lab results are received in the EHR in ways that are clinically valid and satisfy the quality conditions that CLIA has established. I've been proposing for a while that if you use standards to a certified EHR technology, if not a safe harbor, that should at least allow you to document the test more effectively, but there may be other things that CLIA can do, and I just wonder if you've got knowledge and recommendations for what the CLIA office could do in its oversight for labs.

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Thanks, those are great comments. I did speak to the CLIA Committee in April at their meeting with some others around this interoperability topic. They certainly have discussed it and made a series of recommendations, which I could send to the committee, but previously, they've been less specific, I would say. In general, for example, CLIA will recommend to HHS that the laboratories have a better understanding of the nuances of LOINC codes and others, use cases of them, and so forth, but they won't specifically say they should use LRI and there should be, for example, a certification around the mapping of local tests to LOINC codes or anything around that space.

Most recently, they did make specific recommendations to the FDA and CMS to – I think the wording is something around “create guidelines for IVD and MYS manufacturers around interoperability specifications, and they actually had in there a requirement to use emerging standards, such as the lab analytic workflow profile from IHE and the LVD things that I mentioned earlier. So, the LAW profile is the internal lab workflow profile, which does have support for LOINC in it, but I don't believe that they've come into any other more specific recommendations around this, but it has been a relatively frequent topic of their deliberations.

Arien Malec – Change Healthcare – ISP Task Force Member

Thank you.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Thanks, Dan. Just for the sake of time, let's do Ricky, Steven, and then circle back for any further comments. We need to have time for potential future topics as well. Ricky, Steven?

Ricky Bloomfield – Apple – ISP Task Force Member

Sure. I'll keep this super brief. This was related back to a comment that Steven made around tying use of LOINC to reimbursement or other incentives or requirements, and my question was what appetite there is for specifying LOINC as a required standard? Obviously, it's a sticky subject in regulation that often comes up. Even FHIR wasn't required for use of APIs, and because of the various consequences, I understand the hesitation to do that because new standards can come along at any point, and we don't want to limit ourselves. But, I was wondering if you had some thoughts on what the right path is there from a regulatory standpoint. Should it be required or not, and how can this group best help?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Thanks. I think the key is what Steven talked about – required for whom and how? I think we get into trouble when the requirement is on the person who's too far away to make the accurate thing and we didn't give any incentives or leverage to the laboratory or the data producer, who have to do the work of not only mapping, but paying for changing their interface, which we know can be a nontrivial matter.

So, in general, I think it is a reasonable participation requirement, which is why the payment route is a good one, because especially as we consider changing payment models and so forth, that can be a start, but it can also be in the realm of value-based payment. The participation in a network is another place in which those regulations or requirements can be helpful. So, I think the direction of payment-based is a good one, but there's been a little bit of hesitation thus far. The other thing is people don't necessarily realize the extent to which the existing regulations have named or adopted an implementation specification like HL7, IG, or consolidated CDA, and then inside there were these terminology requirements. It took the community a little while to figure that out. "Oh man, now I've got to map these things." That wasn't front and center in their mind at first, so it might have come downstream as they were working on it, not during the first pass.

Ricky Bloomfield – Apple – ISP Task Force Member

Great, thank you.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Thank you. Steven?

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Thank you. I just wanted to say if we were successful in creating this requirement – if you want to get paid for doing something, you have to produce the output with appropriate LOINC coding – would that be problematic for Regenstrief or LOINC to keep up with that? Presumably, that would create a new demand for folks to figure out what they're going to be coding to. I think it would also create a demand for LOINC coding of locally generated results. So, two questions – can you keep up, and do you see a substantial risk that people will just start coding things willy-nilly and inaccurately, and if so, how would we avoid that?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Great question. To some extent, we don't know if we can keep up or not, though we are... What I would say is the landscape has been evolving in such a way that as more and more of the IVD test manufacturers come and request codes from us early in their process, it's not that we're getting 15 independent requests from different labs for the same thing. We get it done once and for all, and so, that scope of things is manageable, particularly when the interaction is with the person at the source that knows that test and knows exactly how it's measured and performed, so our work to create a code that matches that is far easier than dealing with interpretations of that from many different stakeholders.

Is it problematic? So, what it would do – so, there are ways in which people would try to shortcut and make things easier. It's certainly the case that you could map a lot of tests – your entire reference –

you could map all the tests that you send out to a single miscellaneous test code, and technically, you'd be compliant – you'd have the LOINC code there – but it wouldn't really serve the purpose. So, I think there is probably another layer of – and, I don't exactly know where the right place would be, but certification around the accuracy or appropriateness of mappings is something that can't really be automatically tested unless we get to a point where we have codes for devices and those are all electronically connected to output codes from LOINC, but we couldn't really test a given lab's stream of data without significant subject matter expertise to review whether they were good mappings or not, and that would surely be a potential challenge.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

I have one question that's a little bit different. You mentioned about how the recommendation now is that orderables are also done by LOINC. Is that something the ETIDO folks also agree with, that orderables should be LOINC-based and not SNOMED-based?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

In our current agreement with them, we included the scope of some of our orderables, but there's one important difference between what LOINC does and what SNOMED does, which is that essentially, there's no model in SNOMED for connecting an order to the set of things that would come back from it. That's been the standard way in which LOINC has done it. Not only do we create a code that represents CDC, but we enumerate the set of child elements that are linked to it. But, that doesn't mean that...

So, within the U.S. compared to other countries, there are different paradigms for ordering. There are places that don't use LOINC codes; they use very general codes, and the provider orders one of these, and the lab does whatever it wants. In the U.S., it's a tighter connection between what's specifically ordered and what exactly can be expected as a result, which is why the model that LOINC has is a nice package, because you can enumerate exactly what those things are. I guess that's the current state and the shortest answer I can think of.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

To put it another way, if you look at the FHIR U.S. core procedure resource, they say that if you can express it in CPD or SNOMED, you must express it at SNOMED or CPD. Are you basically saying you disagree with that assessment?

Daniel Vreeman – Regenstrief Institute – Director of LOINC

Here's the problem: The idea of procedures can have a variety of meanings. In some views, procedure can be everything under the sun – every action can be thought of as a procedure – whereas in general, the more circumscribed notion of a procedure is something like an operation or an ordered thing. That's not the same as a diagnostic test or a laboratory measurement. So, on the one hand, you might – people can conceptualize a lab test as a procedure, but it doesn't fit that same paradigm, so you can get tripped up thinking about that. One doesn't have codes for an appendectomy or any other procedure, nor do we have a vision to do that. It's only the things that would be ordered as a collection, where your expectation is that when you order this thing, what you get back is a set of

results, and that's where the radiology side is different than some of the other things, which is you're expecting back the report with the detailed findings on it.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Thanks. So, I'm going to table that topic, but if we get into the notion of order catalogs, we will need to have a pretty detailed discussion on value sets for that. We have about 13 minutes until public comment. We've already been getting into what our recommendation should be for moving forward with the discussion of how LOINC codes are implemented upstream. We did want to discuss a little bit where to go next. Steven, do you have thoughts on – do you want to spend the rest of the time going over how we make sure LOINC codes are done upstream, or do you also want to spend time on the domains we want the labs to go to? Thoughts?

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

My thought – and, unfortunately, I'm going to have to start boarding a plane soon, so I apologize – is that we've done a lot of good work, and again, I think we should just give Dan our final thanks for an excellent presentation. Thank you, Dan. But, I do think that we're coming to a close on this. I think we're really narrowing in on what our recommendations are going to be. They are reflected in the recommendations document that we've prepared. I think we will continue to refine that and hopefully shrink it down a bit so it's quite understandable, but I think we're interested in getting people's feedback on that document as it exists.

Everyone on the task force should have access to that, and please send feedback to Ken and me so that we can incorporate that as we refine it. I think we'd like to bring that back for our next meeting as a detailed discussion and, hopefully, a finalization. But, as you say, Ken, I think it's also appropriate to start to prepare for what we're going to do next. We have a number of other prioritized domains that we've talked about focusing on. We've talked about splitting into multiple groups to work in parallel, and Ken, if you can take us through that and get input on what our next steps are going to look like, we should be planning for the meeting after next to start chartering those next sets of groups.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Let's spend five minutes on – I'm going to start sharing the screen here – on these recommendations, and then five minutes on the next steps, and then take public comments. If there is extra time after that, let's come back to some of these. So, I'm sharing my screen. Is it visible? I can zoom it in further, but is it generally visible?

Steven Lane (Co-Chair) – Sutter Health – Co-Chair

Yeah, it's visible. It needs a good zoom.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Okay. I'm going to zoom in, then. So, there are a number of recommendations – and, everyone had access to this, but I think we should focus right now on the top recommendation that we're all honing in on. For lab results – already scoped down a bit – and for results, a big issue is that many of the results in actual practice are not LOINC-coded, particularly for non-referenced labs, local hospital code

labs, et cetera, and that was a sobering assessment of 50%. In my experience, it hasn't been that low, so that's bad.

So, Arien was kind enough to think through all the policy hats, et cetera, to have some recommendation. I think we've covered a lot of this, but do you want to give a quick overview of this? We obviously want to shorten it a little bit, but I think this is worth having more group discussion on.

Arien Malec – Change Healthcare – ISP Task Force Member

Thank you. I basically wrote down a number of the policy recommendations. We've already discussed many of them. The first is that we've identified that we have good implementation guidance and standards for lab delivery, but we don't have the document delivery equivalent, so part of the recommendation here is to make sure that we extend the LRI to the appropriate standards for delivery of textual documents. Some of this work has already been done, but let's make sure that we harmonize all the way through.

I believe this has actually mostly been done, but we should harmonize from LRI, LOI, SMART, FHIR, and all the rest of the standards to make sure that if a test is generated upstream, it's available to patients downstream. Again, most of this work has already been done, but we need to normalize the eQMs as well. We talked about this, but we need to make sure that we address where we are and get better numbers about where we actually are so that we can identify areas of focus, and my hypothesis is that if we've got a broad base in the commercial lab space, but weaknesses in the smaller hospitals, we may take different policy levers than if commercial labs were recalcitrant and the like. We talked about the FDA coordination, and that work is already going on, but we can do a better job of making sure the standard mappings are available to labs.

And then, the lab ecosystem is really the critical linchpin. I'd say the two critical linchpins right now are the lab ecosystem, which is regulated by CLIA and has oversight by CAP, and the EHR connectivity endpoints. One of the things I want the task force to think about is that in many cases, we have trenches already dug for gas lines to the house, and those gas lines were done years ago. You need to re-dig the trench in order to lay the LRI/LOINC-compatible lines. So, if you're an EHR, if you're a hospital, if you're an ambulatory provider – sometimes it's a little easier for hospitals, but if you're an ambulatory provider and you already have an existing lab interface, is it worth – and, we're talking about conditions of payment, for example.

If the condition of payment is on the lab to get paid, it also has to be on the EHR to receive. Is it worth digging up all the existing lab interfaces and redoing them? Sorry, that was a little digression. We need to be working with CLIA and CAP to identify and remove obstacles for use of standards. We talked about FDA. So, CMS has a ton of levers, including some underutilized levers through the CLIA office. CLIA has tended to be a little standoffish with regard to adoption and use of standards in labs as well as adoption and use of policy levers in order to drive the labs toward use of standards. CMS can include lab requirements in more programs. So, short of conditions of payment, there are conditions of participation and other programmatics relative to promoting interoperability, the QPP, ACO requirements, bundled payment requirements, and the like that could and should address use of standard-based labs.

I talked about the opt-out nature of the electronic lab receipt – again, just for some of the inside baseball for people to understand, the reason why the measure was topped out is because it was defined as EHRs that can receive labs electronically. And then, the associating standard on the ONC side was use of LRI and LOINC, but there’s no tie between those two things. So, an EHR or physician that receives labs electronically – maybe from its commercial lab vendors like Quest and LabCorp that have very aggressively made electronically available – may be able to report and test the measure, and may have some subset of their electronic receipt that’s LOINC-encoded, but may not have basically addressed the need end to end. So, I think we’ve identified that we’re in a somewhat sticky state. We may want to reconsider that certification requirement and the associated meaningful use measure to address the full lab experience as opposed to the mere receipt of electronic information.

And then, I mentioned a number of other federal agencies – VHA, DOD, Indian Health Services, Prison Services, Department of Homeland Security – many federal agencies run organizations that have healthcare treatment facilities that receive electronic labs, and using those federal providers as a lever for standards adoption would be useful. My suspicion is that many of them already do this for their in-person labs; for example, VHA outsources many of its radiology labs and works with organizations, so VHA would be an interesting lever for standardization of receipt of the results.

And then, I think there are better certification criteria. In CLIA, one of the ones I’ve endorsed in the past – and, people may not be aware that under CLIA, a lab has an obligation to verify that the receipt of that lab is received in a way that is clinically valid. So, in the old days, if I sent a lab out via pieces of paper, I needed to verify that the tabulations on those pieces of paper actually mapped to the clinically valid output of my lab. When I send electronically, the way those requirements are interpreted is a requirement that when a lab sends something electronically, the EHRs actually verify that the screens in the EHR are configured in ways to view the lab.

Part of my idea here is that if the EHR is a certified EHR and certified to the LRI guide using LOINC, and if the lab is sending via LRI and LOINC, that at least some of the requirements there should be minimized. Part of the problem is that CLIA is adamant that there’s no regulatory burden caused by this additional review, and so, there’s no burden reduction that’s possible and available. In the real world, there is a burden, and there is a burden reduction, but there are other tools that CLIA could use, including the outright mandate for availability and use of LRI and LOINC, to mandate the use of mapping tools, and even to promote the use of mapping tools.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Thanks. We’ve hit the public comment period, so let’s switch to that for a moment. Could we check if anybody has public comments? Can you call in – do we have any public comments on the queue?

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Sure. They may have to open a line. Operator, would you please open a public line for comment?

Operator

Certainly. If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue, and you may press *2 if you'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing *. Again, it's *1 if you'd like to make a comment at this time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Thank you. I'm just going to go back to a quick roll call to see if any other members have joined. Do we have Andy Truscott on the line? Leslie Lenert? Jack Po? Raj Ratwani? Scott Weingarten? Cheryl Turney? I think I saw her on the Adobe. And, Valerie Grey?

Cheryl Turney – Anthem – ISP Task Force Member

Cheryl's on, and I announced in the beginning also.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Okay. Sorry I missed you.

Valerie Grey – New York eHealth Collaborative – ISP Task Force Member

Hi. Val Grey is on too. I apologize. I was a little late.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

No worries. Thank you, Valerie. Operator, do we have any comments in the queue at this time?

Operator

Not at this time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Okay. I'll turn it back to you, Arien or Ken.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

Let me go on for a second. Let's discuss a little about what's next for this work on orders and observations, and then we'll move on to what's next after that. I'll put a straw man up, which is that it seems the biggest issue in the space that we've identified is, again, the fact that blank codes are not provided from upstream by many folks, particularly local hospitals. We've discussed hospital labs. We've discussed a number of potential recommendations. My suggestion would be that we work on those recommendations a little bit more offline, streamlined, et cetera, and make that available to the task force members, and then review it perhaps at the next meeting to finalize the recommendations around that specific aspect. Any thoughts from folks on whether that's the appropriate priority or whether that's an appropriate mechanism to get at the recommendations around that issue?

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member

Ken, this is Terry. I think it's a great recommendation. I'm wondering if we couldn't make a list of the policy levers that exist. Arien went through a bunch of them. My suspicion is we're going to be pulling the same levers for everything.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

That's a really good point. A separate thought on this – Arien had nicely listed for us from just talking about it to encouraging people all the way down to condition for payment – all the potential levers that can be done. I think that even having that as a separate reference point that we can work on together and pull from would be useful, and we'll be very mindful when we're using a heavy-handed one. David, you have a comment.

David McCallie – Cerner – ISP Task Force Member

I think there's no question that we could go from good to better with some of these recommendations. My question is when we zoom out, is this the primary thing we'd really like to do? If we have a limited number of opportunities to change things, to get the political will to do something, is this at the top of our list? I'm not saying it isn't, I just think that we need to be careful not to take a situation that isn't completely broken or isn't even really broken and making it better, but giving up some opportunity to do some more important and fundamental work.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

I completely agree, and that gets at the notion of what we do with the other issues we identified. One suggestion for those is that – and, this may be a pattern that we view for these other items – whatever we view as the most important things – maybe, for a topic, it's a maximum...I don't want to do a number, but the maximum amount that it's doable or manageable, and we never get rid of recommendations or issues we've identified; it just goes into a parking lot of things we'll come back to and flesh out if there's time, or recommend that we flesh out more in subsequent periods. I think the key question is are we missing something in this discussion right now that we consider to be very important, that hasn't been done, that should not be a parking lot item or whatnot?

Maybe what the task force members can do – everyone does have access to the document, and as we define what we think is the top priority or priorities and the recommended actions, if task force members see areas that they think should be bumped toward the top, then we should do that and discuss it with the goal of coming up with a list of – I don't think there's any hard and fast number, but I think the issue is if we come up with 20 recommendations, the likelihood of any of the recommendations being followed becomes much less than if we come up with three recommendations. The recommendations can have subtasks, of course, but I think we should be mindful that we need to prioritize what we think are the highest issues, and if we disagree on them, then we need to address those as well.

So, I think as far as action items go, it will be document-driven over the next few weeks, so please keep an eye out for requests, and let's discuss that and hopefully finalize it two weeks from now. We have a few minutes left. Can we move on to the discussion on the prioritization matrix and survey results from before? This is what we ended up with at the initial cycling, and now that we've done this or have gone through this process, I think we have two questions. The first is should we do this as a group and try to spend three or four meetings on each topic, which is going to be the equivalent of a month and a half to two months, and then move on to the next, or should we split up into parallel groups? Any thoughts on that from folks? What would you like to do?

Okay, then. I'm going to go with an assumption that perhaps – I think the diversity of opinion and thought is good in that if we split up the bandwidth available from the task force members, it may be a little bit of a challenge, so my suggestion is initially, we continue this path of marching down this list and spending three to four meetings doing what we've done with the idea that the main important issue is to come up with problem identification and potential recommendations, and then to prioritize them with the notion that we may put some items in the parking lot. My suggestion is that folks are always welcome to work on those parking lot items even after we've moved on to other general topics so they can bring them up after the committee or task force.

So, the next question is whether medication pharmacy data is the right one to move on to next. That would be the default, given what the original rankings were. Does anybody feel that we should put something else when we start on a new topic, say, two meetings from now?

Arien Malec – Change Healthcare – ISP Task Force Member

This is Arien. This may just be part of the design of the committee, but we haven't addressed the unmet needs of existing forms of exchange, and maybe we down-prioritized them, but query-based access to data, directed exchange of data – we haven't addressed the usability some of the basic fundamentals, and again, that may just be the design and we didn't feel like those were actually important policy goals.

Kensaku Kawamoto (Co-Chair) – University of Utah – Co-Chair

I think part of the issue was because our charge was around clinical use cases, infrastructure didn't make it to the list. We're about to close. Because of the lack of time right now, let's plan on having a little bit more discussion on this next time we meet, but in the interim, now that we've gone through this and have a sense of what this is going to entail, please keep in mind that if you think our focus has changed, either communicate that to Steven and me offline or let's discuss it at the next meeting. Okay, I think we're right at time. Thanks, everyone. We will close now.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer

Thanks, Ken. Thanks, everyone. Bye.

[End of Audio]

Duration: 89 minutes