



Interoperability Standards Priorities (ISP) Task Force

Transcript
September 11, 2018
Virtual Meeting

SPEAKERS

Name	Organization	
Kensaku Kawamoto (Co-Chair)	University of Utah	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	Cerner	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	NIST	Member
Ricky Bloomfield	Apple	Member
Sasha TerMaat	EPIC	Member
Scott Weingarten	Cedars-Sinai and Stanson Health	Member
Tamer Fakhouri	One Medical	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Tina Esposito	Advocate Health Care	Member
Valerie Grey	New York eHealth Collaborative	Member
Victor Lee	Clinical Architecture	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

Operator

Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Good morning, everyone and welcome to the ISP task force at ONC. We will officially call the meeting to order starting with roll call. Ken Kawamoto.

Ken Kawamoto - University of Utah - Co-Chair

Here

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Steven Lane.

Steven Lane - Sutter Health - Co-Chair

Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Anil Jain.

Anil Jain – IBM Watson Health - Member

I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Arien Malec. Andy Truscott. I believe he said – oh, is Andy on?

Terrence O'Malley - Massachusetts General Hospital - Member

This is Terry, sorry.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Oh, Clem McDonald.

Clem McDonald - National Library of Medicine - Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Cynthia Fisher? Not yet. David McCallie. Not yet. Edward Juhn.

Edward Juhn – Blue Shield of California – Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Terry O'Malley.

Terrence O'Malley - Massachusetts General Hospital - Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Les Lenert. Jack Po. Raj Ratwani.

Raj Ratwani – MedStar Health – Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Hi, Raj. Ram Sriram. I thought I saw Ram on the Adobe. We'll circle back. Ricky Bloomfield. Not yet. Sasha TerMaat.

Sasha TerMaat - Epic - Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Scott Weingarten. Sheryl Turney. I guess Sheryl is on as well. Tamer Fakhouri.

Tamer Fakhouri – One Medical – Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Tina Esposito. And Valerie Grey. Not yet. And Victor Lee.

Victor Lee – Clinical Architecture – Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Great. I will turn it over to Ken and Steven, our co-chairs.

Arien Malec - Change Healthcare - Member

Arien is here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Oh, hi, Arien.

Steven Lane - Sutter Health - Co-Chair

Well, good morning, everyone. I think Ken is still getting himself set up a little bit with his technology. So, Ken, just let me know when you're all settled.

Ken Kawamoto - University of Utah - Co-Chair

I'm all settled, thanks.

Steven Lane - Sutter Health - Co-Chair

Oh, excellent. Well, welcome, everyone, to our meeting. I appreciate everyone's time as always. And we can see that there are a number of additional participants who have dialed in today. So, welcome to the public as well. We want to go through a little bit about the comments that we have received just to reorient everyone. We are looking at priority uses of health information in response to priority areas that were identified in 21st Century Cures. We are going to be focusing in on the standards associated with those uses and where there may be opportunities for improvement. And we went through a process to organize some priority uses and use cases. And we did a balloting. And we prioritized the initial focus on the domain of orders and results.

Within that, we have decided to focus initially on laboratory as well as on the resulting process with the hope though that the insights that we gain would apply to other order domains and that we can then back up our way into the ordering the process. So, what we did was we put up a chart or a spreadsheet, if you will, on the Google drive that all of you have had a chance to contribute to. And I think what we wanted to do was just go through that and look at the general domains or the general problems that have been identified. I think a lot of people put some serious thought into this. I've actually gone through and tried to combine some of the information into individual rows so that everybody can see that. So, we actually ended up, I think, with four through sixteen so about twelve different individual items that we've called out.

So, we just wanted to kind of walk our way through that. And then, we do have a number of guests with us today, specifically Brett Andriesen from the ONC as well as Ken McCaslin from Accenture and Virginia Sturmfels from Quest Diagnostics. These are all domain experts in the applicable standards. So, we're going to be educated about the standards that exist, their state of evolution, and hear from the people who really work to maintain those standards so we can start to go towards our next step, which is really identifying opportunities to advance the standards in support of these uses of health information that we've identified. So, that's kind of just to bring everybody up to speed. Ken, do you want to add to that?

Ken Kawamoto - University of Utah - Co-Chair

That sounds good. I think the idea is to use what people commented as the springboard for the discussion so maybe not to go into too much detail at this point but I think with the subject matter experts here, it would be great to get their thoughts on some of these issues that the task force members thought were issues.

Steven Lane - Sutter Health - Co-Chair

So, somebody should share the spreadsheet from the Google drive so that we can go through that kind of line by line.

Ken Kawamoto - University of Utah - Co-Chair

I can do it. Is my Google doc showing?

Steven Lane - Sutter Health - Co-Chair

It looks great. Yeah, that's coming through very nicely.

Ken Kawamoto - University of Utah - Co-Chair

So, maybe what we can do is go through these but with the intention of going through it just to get the thoughts but not necessarily to deep dive discuss them. For the folks who commented, maybe they can take their own comments for the most part but with the request to go after the expeditiously through these at this point. The first one was just from – oh, and just as an approach to doing this, all task force members had access to the Google doc and we asked for problem issue examples, associated standards and issues if any, proposed remedies, and other notes and comments. I don't know if you want to take on this first one that was just from the general and I think you had a lot of comments that you put on these as well.

Steven Lane - Sutter Health - Co-Chair

Actually, those are not my comments. I've mostly been editing here.

Ken Kawamoto - University of Utah - Co-Chair

I think the big picture here was just not all results are available for patients to see. We have proposed remedies withstanding USCDI and making them available via Fyre APIs from EHRs. And then, there were other comments. And I guess one request would be, to the extent possible, if folks can maybe spell out their first name on these comments, too. And I'm not sure what the standard issue is here, what results are commonly available, what's the blocker.

Arien Malec - Change Healthcare - Member

AM is Arien Malec, by the way. I apologize.

Ken Kawamoto - University of Utah - Co-Chair

And then, SAT said there are also policy issues affecting this. The state prohibits or has specific requirements for the electronic release of certain [inaudible] [00:07:58]. Additional

alignment of state and federal policies and space might further availability. I don't know if either Arien or SAT would like to comment on those before we move on?

Arien Malec - Change Healthcare - Member

Yeah, I just was confused – oh, sorry. Go ahead, Sasha.

Sasha TerMaat - Epic - Member

I was just going to say all of the SAT comments were me.

Arien Malec - Change Healthcare - Member

Did you score well?

Sasha TerMaat - Epic - Member

Yes.

Steven Lane - Sutter Health - Co-Chair

I think these comments are pretty clear unless people have clarifications. I think then we can probably just go through them. I think this will help everyone to orient to where our thinking has gone so far. And I think especially our subject matter experts who are going to be helping us with the standards piece of it.

Arien Malec - Change Healthcare - Member

I do think it would be useful if there's a perspective that some result types aren't available to the patient to enumerate what the result types are so that we can address whether there is an underlying standards issue.

Clem McDonald - National Library of Medicine - Member

Well, do you want a comment on that or how are you going to go forward?

Steven Lane - Sutter Health - Co-Chair

Yeah.

Clem McDonald - National Library of Medicine - Member

Well, this is Clem. I don't know if I had my hand up but I can say something. Basically, it's not just the positions. If they're not in a big hospital system, physicians also have the same problem, not just the patient. But the types that are generally not specified to be available in detail in any of the guidance are EKGs, pulmonary functions, radiology tech reports, and on and on. So, most reports, except for lab, are not specified to be provided to anyone in a well-formed fashion. There is a little bit of stuff in CCDA that might hint they are required. We're missing most clinical reports and lab reports aren't complete.

Arien Malec - Change Healthcare - Member

And Clem, just to be really clear, what you're – maybe we can dive into the labs are incomplete. But with respect to the other report types, for example, with respect to an EEG

or with respect to an MRI, you're not looking for, at this point, the raw underlying data, the EEG wave form or what have you. You're looking for the interpretive report.

Clem McDonald - National Library of Medicine - Member

Correct. Structured or unstructured. And they're mixed. Cardiac is about half are structured and half of them are narrative. But whatever they are, it gets sent out or could be sent out. That's what we should be doing.

Arien Malec - Change Healthcare - Member

Right. So, maybe as a first approximation, there's a perspective because they're different – I'm only pointing this out because they're different standards issues. To the first approximation, there's a set of textual report types for which there is no corresponding consolidated CDA and USCDI support.

Clem McDonald - National Library of Medicine - Member

That's maybe too strong. They aren't urged or clarified strongly in terms of coding.

Arien Malec - Change Healthcare - Member

Got it. Well, that's the clarification I was looking for. Thank you.

Sasha TerMaat - Epic - Member

They are actually by policy required in –

[Crosstalk]

Clem McDonald - National Library of Medicine - Member

There's another comment. Someone was clarifying.

Sasha TerMaat - Epic - Member

This is Sasha.

Cynthia Fisher - WaterRev LLC - Member

I did not hear Clem's last point. I just wanted to –

[Crosstalk]

Clem McDonald - National Library of Medicine - Member

I'll repeat it but there was maybe a clarification of my comment, which might come first.

Sasha TerMaat - Epic - Member

Sorry. This is Sasha. So, Clem's point was the radiology narratives are often missing as a result of a patient view. And I wanted to add that from a policy perspective, ONC 2015 edition certification does expect that the diagnostic imaging reports, the narrative component,

would be made available to the patient.

Clem McDonald - National Library of Medicine - Member

But it's not well specified in any delivery mechanisms. It just says it should be made available, I believe. And maybe I'm wrong so get me fixed if I'm wrong.

Cynthia Fisher - WaterRev LLC - Member

Clem, this is Cynthia Fisher. I think this is a really valid point because at least here in Massachusetts, you get a radiology image of an MRI. It's not ready that day. And the only person that can go back and get it has to drive back to the clinic and get it. They won't even transmit the radiology results, the descriptive. So, it is absolutely onerous. And I think if we are very clear about once it's digitally available that it needs to get pushed to the patient, you think about all of the nonproductive work time people are down just to try to gather this information.

Clem McDonald - National Library of Medicine - Member

I'm absolutely for pushback. I think we should distinguish between the image itself, which you can usually get on the way out with the DVD but that's separate and the report. Both are important. The report is easier and we should make that a priority for both of them.

Cynthia Fisher - WaterRev LLC - Member

Agreed. And at what point do we also leave it open for the cloud to be able to provide transfer of the actual imaging itself with capacity in the cloud? So, I just thought to rewrite it for the descriptive with as soon as possible as technologically available to transmit imaging as well because certain centers can be our link to getting those images. It just depends upon which network you're in.

Clem McDonald - National Library of Medicine - Member

No, I think that's a good goal but I think there's a whole hoard of diagnostic studies that are not routinely reported with enough coding that you can store it on a receiving system. That's what I think we should be seeking. So, the patient could put it somewhere and find it because it would be coded as being a radiology chest x-ray report or being an EEG report. Without that, you really can't do anything electronically with it in your own system.

Ken Kawamoto - University of Utah - Co-Chair

And just as a point of order, again, we will have plenty of time for deep discussion. What we really want to do is do an initial high-level discussion of the points that were raised and then, since we have some guests who have thoughts that won't be on our future calls necessarily, we wanted to go to them. So, if it's okay, let's sort of fairly quickly move through these with the notion that we'll discuss this in more detail with our SMEs. Terry, do you want to cover the ones that you had commented on?

Terrence O'Malley - Massachusetts General Hospital - Member

Sure. Just sort of a broad overview. I thought about these as are there standards to support the sender of the lab, the generator of the test. And are there standards to support the

receiver of those results? And then, are there standards that actually impact the results themselves? But I kind of broke it into three pieces, whether those are the right three pieces or not but that's what we did. So, these are just sort of issues that come up.

Clem McDonald - National Library of Medicine - Member

Can you make the slide bigger? It's just hard to see the words on the –

Ken Kawamoto - University of Utah - Co-Chair

Yes, I can. I'm sorry. I'm on a big screen. Let's make it – is that better? It will just skip the comments but I can scoot over there.

Clem McDonald - National Library of Medicine - Member

It's better.

Ken Kawamoto - University of Utah - Co-Chair

Great.

Terrence O'Malley - Massachusetts General Hospital - Member

And then, my comments are really on issues that I face daily taking care of patients. They're just the first couple that came to mind.

Ken Kawamoto - University of Utah - Co-Chair

So, the big picture was not all results available for clinicians. Not all results can be used for clinical use and support, getting too many lab results of low value, can't send or receive a series of [inaudible] [00:16:27] results. Okay. Terry, anything else to add with these before moving on to the next ones? And, again, we'll come back to these with more detail later.

Terrence O'Malley - Massachusetts General Hospital - Member

No, thanks.

Ken Kawamoto - University of Utah - Co-Chair

I'll go on next to mine. So, this is a set that I'm coming to. I think it's pretty similar to what Terry had noted. So, the first issue was a fair amount of lab results are not encoded with appropriate LOINC codes or the expected units. And they may also be missing units all together. And somehow I'm not showing someone. I'll zoom out a little bit. I'll zoom back in once it's past this part. So, the issue is this means that things that require this kind of semantics make it difficult. For example, one thing Terry mentioned was trending similar labs with each other or clinical distance board or de-duplication making it so that you only see the things that are relevant. All of these require these semantics. So, when you don't have it, you can't do this. And the result is you have incomplete decision making.

Clem McDonald - National Library of Medicine - Member

Ken, I just think it can't be overemphasized because people don't realize that just getting the report without the right semantics, you can't do much of anything with it. You can't find the

last result to compare with the previous and etc.

Ken Kawamoto - University of Utah - Co-Chair

Yeah. So, this is an issue we face on a routine basis. So, agreed. Without semantics, the data – the usefulness goes way down. Obviously, even just free text is useful but there's a lot that you want to do beyond it. So, and this is where I may have a myopic view but some of the sources of this might include the smaller labs including hospital labs don't LOINC encode their labs or are not doing it to the extent needed. And then, we also find that there's a decent amount of manual entry of labs in our EHRs. So, for example, for outside labs that aren't interfaced in or point of care labs. In that case, for example, it's fairly common for a user to not enter units, for example, or to choose the wrong one or for that concept to not be encoded. So, it's not a 10 percent issue in our experience but it can be a 5 percent issue.

And if you're willing to accept five percent error rates, it's not an issue. But if you're not then, it's a problem. I'll go into this a little bit in the sense of proposed remedies because it's, basically, repeated for all of mine and I can skip it after this one. But the main one I think minimum and some EHR vendors already do this so it's not necessarily something new, but I think EHR should provide a mechanism that allows clients to properly map internal lab codes and LOINC codes when they're missing. And then, there are a whole bunch of other potential solutions. But one big one might be to just say let's allow for this kind of – let's prioritize which ones need to be accurately semantically mapped and actually get it done as a community with the key part being prioritization because just in our institution, we have like 4,000 labs that can be resulted.

But one-third are never used or only ordered less than five times a year. And do we really want to focus on those when it's a Pareto kind of principle where there are a lot more that are ordered a lot more frequently in terms of volume? I'm just going to go on to some of the other ones so that I don't take too much time. Another one was results and observations outside of lab tests are not interoperably shared. So, this is pretty similar to the other so I won't go into too much detail. And there's a question of whether we want to include these in scope. But, obviously, there's a lot of what you would consider observations that are outside labs that are pain points for sharing like gestational age or Glasco coma score or pain assessment results or photo therapy admission times, imaging results, echo results, etc. So, I won't go in too much detail other than to say this is a big point of pain.

And I'll just note that in some EHR systems, it's required that observations are LOINC encoded elements, even if they're non-lab codes. It's just the way it's supported. And that poses the obvious challenge of what if there isn't a LOINC code for what you want to express? What do you do then? Especially as LOINC, I believe, don't allow local extensions so you basically have to go through not only seeking LOINC itself to be extended but then, for the change management process that usually takes some time, at least in our health system, of that actually getting incorporated and pushed out and being adopted into the system. Another one is it's often important to know what has been ordered and what the status is. So, this is important, especially if you're recommending something. So, if you're recommending that something be done like a user is going to be very annoyed if you say hey, you should order a pulmonary rehab referral or you should order home oxygen.

And they say, well, I ordered it 15 minutes ago. How come you don't know that I've already done it? I'm going to ignore this from now on. So, this is not really well supported right now, I think, in what's currently available and in a standard form ideally. I think where things like meds, labs, and lab results are already well encoded and things like conditions, things like orderables currently aren't very well mapped to standards or even searchable using standards. So, really to this is the lack of standard order catalogs, which is an issue. And I'll just note the biggest challenge here is that, often times in orderables, you want metadata other than just the "code" of the order. Like do you want it stat, do you want it for a future date, if so, what date and those kinds of things that you, often times, want to prepackage in an orderable. So, there are some issues there.

And then, those were mine. And then, David McCallie had a number of comments. I don't think he's on. He said he was going to be on PTO in an area with poor cell reception. David is not on yet, is he? Okay.

Steven Lane - Sutter Health - Co-Chair

I don't see him.

Ken Kawamoto - University of Utah - Co-Chair

So, Steven, do you want to go through these or do you want me to?

Steven Lane - Sutter Health - Co-Chair

Yeah. I think they're pretty self-explanatory. Again, the key issue about the integration of external clinical decision support, I think, is a key issue that a number of us have discussed. The next one, I think, may be a bit duplicative, and we may be able to combine the comments in some of the above discussions regarding results delivery both to providers and patients that we have mentioned the challenge of prior authorization and what are the standards that can be used to manage that step in the ordering process. And David also re-raised the issue that Clem has been so stalwart in bringing forward, the issue of imaging results both the textual report as well as getting access to the images themselves. And David gave us a lot of detail about some of the players in that field. So, and, again, what you can see we've done here is we're trying to kind of boil these down into the key issues.

I think we can still do some more of that. This relates very much to the other work that we've done in terms of identifying the steps in the ordering and resulting process. And then, I think we can now – I see one hand up from Ricky so maybe we can take Ricky's comment and any others before we transition over to the discussion of the standards that apply here. Ricky, do you want to go ahead?

Ricky Bloomfield - Apple - Member

Sure, yeah. This was a while back but just related to the item of uncoded lab values and I think it relates to some of the other points that came up and that's just that it would be helpful to have some hard data on which items aren't coded, if it's possible to get some reports from representative health systems and EHR vendors. That might help inform the

discussion in prioritization. And I think that relates to some of the others as well.

Ken Kawamoto - University of Utah - Co-Chair

Good point. I'll note it.

Steven Lane - Sutter Health - Co-Chair

And then, Clem, your hand is up.

Clem McDonald - National Library of Medicine - Member

Yeah. So, I think the issue and the solution isn't as much the availability or the existence of a given standard for a given area, although there are some that probably need to be embellished. But it's that there is not push or enforcement or regulation or encouragement at the level necessary. So, the commercial labs mostly all provide LOINC codes because they are incented, I think, by the insurance companies principally. But the little labs don't. And I think if we could get **[audio interference]** or CMS to do the right incentive, it would solve itself in a year.

Ken Kawamoto - University of Utah - Co-Chair

Yeah, and I think there is always the issue of what to do also when there is manual data entry. And I think it would be useful to get some quantification on it. We found that it's a non-trivial issue, at least when we're trying to reach something like a 98 percent or 99 percent accuracy.

Arien Malec - Change Healthcare - Member

Yeah. As a suggestion to the task force, it might be helpful to classify issues where standards are appropriate but aren't being sufficiently widely used. Areas where standards are there but are inadequate and areas where standards are missing. And maybe to use, to some extent, and in power team chaired by Dixie Baker put together a really nice framework for assessing standards maturity. So, you might need to reach into that. But I think as a first approximation, we're going to discover that in a lot of these issues are issues of the standard like LOINC and the LRI exist, are perfectly sufficient, but aren't widely adopted. And that's a very different kind of problem from lack of standards availability. So, I think as we go through this, being thoughtful about this and classifying this appropriately might be useful.

Ken Kawamoto - University of Utah - Co-Chair

Yeah.

Steven Lane - Sutter Health - Co-Chair

Okay. I think we've gotten through the comments. We are at the half hour, which is just about where we wanted to be. And I think what we'd like to do, we talked to Brett Andriesen yesterday about walking us through the standards that are applicable in this area. And then, as we said, we've invited some additional subject matter experts who are helping to manage the standards themselves. And I think, Brett, you had a pretty clear approach as to how you were going to do that. I'm not sure why we're looking at this agenda from July but I don't think that's the document that we need. Thanks. Brett, do you want to sort of start us off?

Brett Andriesen - Office of the National Coordinator

Sure. So, I don't know if I should be sharing my screen or I can pass links to other folks who can. I was just going to walk folks through what is on a number of the interoperability standards advisory pages that relate to lab orders and lab tests and kind of just orient folks to what's there in the ISA and then, pop over to Virginia and Ken to maybe dig a little bit deeper into the underlying standards that are listed here and then, give folks a chance to chat about each one.

Steven Lane - Sutter Health - Co-Chair

Brett, because you probably know the ISA better than anyone, if you wanted to share your screen and walk us through that and give us a little bit of a tour, if you will, of where things are. I think our goal is for the task force members and the public to be able to get comfortable with this resource. And I'll just put in a plug that it is currently open for public comment through the end of this month and for an annual update. So, I think this is a great opportunity for people to understand what's there and for us as a group and as a community to identify opportunities to improve on it.

Brett Andriesen - Office of the National Coordinator

Sure. I'm not sure how to share my screen on the Adobe Connect.

Virginia Sturfels - Quest Diagnostics

Let's just go to the first link for –

[Crosstalk]

Brett Andriesen - Office of the National Coordinator

Yeah. Or someone can go to the link and I can talk it through. That's fine, too.

Ken Kawamoto - University of Utah - Co-Chair

I think you should be able to present now.

Brett Andriesen - Office of the National Coordinator

There we go. All right. Folks should be able to see the ISA page. Can you?

Steven Lane - Sutter Health - Co-Chair

We've got it.

Brett Andriesen - Office of the National Coordinator

Perfect. All right. And hopefully, it decides to – okay. So, here, this is in Section 1 for representing laboratory tests. We have a standard for observations that is LOINC here and then, a standard for observation values that's Nomad. So, that's kind of a pairing we've seen a lot throughout Section 1. Those are in final status. They both should really be in production here but I think we recently added the observation values so wanted to get some feedback from folks on adoption level and implementation maturity. But those are federally required,

free. And we also have kind of a list of applicable value sets and starter sets here from LOINC, which includes the top 2,000 plus lab observations. And I'll link directly to that. And then, a host of information that folks have asked us to provide around LOINC and how that works within lab tests.

Steven Lane - Sutter Health - Co-Chair

Brett, I see under the standards for observations LOINC, the adoption level is flagged as three out of five. Can you say more about that?

Brett Andriesen - Office of the National Coordinator

Sure. So, in terms of adoption level, we don't really have a strong scientific data collection really for the adoption level component. It really is kind of our best guess based on what we're hearing from industry and based on public comments we receive. We sometimes have a little bit more insight into some versus others. But really, that's kind of our gut check of kind of where we think it is and, certainly, if we get comments that it should be higher or lower, we do take those and consider them. But we don't have a strong current way of measuring that and collecting that information. We provide it because we think it's helpful to provide some level of detail there but it's certainly not the most scientific.

Arien Malec - Change Healthcare - Member

This is Arien. We've done, in previous FACA incarnations, we've done slightly more quantitative work here. I agree with Ricky that, for example, going to one of the cloud EHR vendors that may be able to quickly pull percent of labs that are and are not LOINC encoded would be incredibly useful. But the general trends here are that the national commercial labs are able to LOINC encode. That the large particularly academic hospitals are able to LOINC and code. And that the issue occurs the smaller down the rank you go, whether that be a community lab or a smaller hospital system that may not be able to go through the time and complexity it requires to completely recode their lab systems. And the trends are favorable but that long tail is fairly slow.

Steven Lane - Sutter Health - Co-Chair

Another question, Brett, under SnoMed you – we just lost it. But it's listed here as implementation maturity feedback requested. What is it about the use of SnoMed for the observation values that is less mature than these of LOINC or the observations themselves?

Brett Andriesen - Office of the National Coordinator

Go ahead. My assumption is just simply that there is actually relatively little that's SnoMed encoded for observation values. So, this is not for lab results but are 3.5 mg per deciliter. You wouldn't use SnoMed CT for that. This is for things like you did this assessment and the result was, I guess, the patient entered this classification category from this assessment, which tends to show up in free text. I think that's what it's referring to, although it says it's representing lab tests.

Clem McDonald - National Library of Medicine - Member

I could comment on that. At least 90 percent, maybe even 95 percent of lab test results are

numeric. So, it doesn't apply. It's for the categorical test results like high, low, reactive, nonreactive, and for bacterial names that it's really being important for. And I think it's required for reporting to CDC for communicable disease reporting. And it is supported there but it's none as sort of hand work by the lab sending especially to those areas.

Brett Andriesen - Office of the National Coordinator

My assumption is the adoption level for this is actually like one out of five maybe. I don't know. More data needs –

Clem McDonald - National Library of Medicine - Member

I'm sorry. The other problem is the labs tend to want to be expressive. And they although say no evidence from micro bacteria, [inaudible] [00:36:38] – it goes on and on. And those are not the kinds of things SnoMed likes to have.

Brett Andriesen - Office of the National Coordinator

Yeah. It's obviously an issue but yes. I don't know.

Virginia Sturfels - Quest Diagnostics

Do we want to go to the next set of standards?

Steven Lane - Sutter Health - Co-Chair

Well, I thought, Brett, that you had mentioned that with your introduction, we were then going to turn to Ken and/or Virginia to provide some perspective from deeper down inside of these code sets. Do we have – I see Virginia on the web meeting. I don't see Ken. Yeah, now I see Ken. I see you both. So, would you guys like to comment? Hopefully, you've been listening to this full discussion for the last 40 minutes and can educate us further about the state of these standards.

Virginia Sturfels - Quest Diagnostics

Sure. This is Virginia. Can you hear me?

Steven Lane - Sutter Health - Co-Chair

Yes.

Virginia Sturfels - Quest Diagnostics

Wonderful. We have a little bit of a presentation, Ken and I. So, if you could display that would be great. And then, the next slide and then, it will start there. Yeah. Let's start from there. Ken, are you on? Do you hear me?

Ken McCaslin - Accenture

Yes, Ken is here. Can you guys hear me?

Virginia Sturfels - Quest Diagnostics

Yes, I hear you.

Ken McCaslin - Accenture

Excellent.

Virginia Sturfels - Quest Diagnostics

Okay. So, Ken and I, I work for Quest Diagnostics. I'm the manager of medical licensure and regulation for Quest. And Ken, do you want to introduce yourself?

Ken McCaslin - Accenture

Sure. Ken McCaslin, Accenture. I'm a senior manager in the health and public services. I'm also the co-chair of Orders and Observations at HL7 and I serve on the technical steering committee at HL7.

Virginia Sturfels - Quest Diagnostics

So, going back four or five years ago, both Ken and I acted as co-chair persons on some of the implementation guide work groups, specifically, I worked in the vocabulary area and LRI. So, we wanted to thank you for moving the slides forward. And I do want to say I was listening intently. I love the comments that were initially stated at the beginning of this call. I thought that it shows real experience with the use of these implementation guides and, specifically, vocabulary. It shows maturity and some further thought on how these can certainly move forward in the future. I also have some thoughts about SnoMed and why the adoption level isn't quite so high. And we can talk about that in just a moment. But I did want to discuss that we did create, at the time, three different implementation guides represented here as EDOS, LOI, and LRI. They're each different.

They're independent. And they provide a service in and amongst themselves. This defined, of course, the functionality that was to occur between an EHR and the reference laboratory. Though previously, we didn't have a lot of guidance in this area, and we had all of these guides are based on the HL7 version 251. The 251 version itself did not create a lot of instruction for the conversations and interfaces between EHRs and laboratories. However, the IGs were developed to constrain this information and the data that's in an HL7 message to the clinical interfaces. And so, as I said, these guides were developed to provide the foundation for an interoperable solution. We have the EDOS, which is test compendium provided by the laboratory, which has identified all of the components of the tests, the requirements for the testing, and the requirements for the identifiers to be used in the message.

The LOI we developed here also is the laboratory order message from the ordering provider that gathers the appropriate information that needs to get submitted to the laboratory in order to perform the testing. And this information is provided based on the requirements of EDOS. And the LRI is the laboratory result message, which is consistent with the requirements of the LOI and EDOS and can provide the results back to the EHR. What we were able to do and show in these profiles is that the profile constrained the contents of the field. So, we were identifying specific data sets to be used such as the vocabulary data sets that should be used in each of the results that were reporting back. We were talking before about the importance of the semantics that is used to create interoperability. We worked with defining what LOINC subsets should be used.

We talked about SnoMed. And, again, I think the implementation of SnoMed we see is not as great as what we had hoped or anticipated due to the individuals that need to do the mapping of the SnoMed code, I think, is we may not have as many individuals or SMEs out there who are also capable of doing the SnoMed coding. Also, as, Clem, I think you pointed out, there is a negation factor there. In the LOINC mapping, one person made a comment about that in the EHR system, maybe the LOINC mapping could be installed there. I just want to make a caveat from the laboratory perspective that LOINC codes are to be assigned by the laboratory based on their best knowledge of the testing that's being performed. So, if there was a LOINC mapping provided into an EHR system, we would expect that it would be something that was approved by the laboratory performing the test.

And, of course, we talk about also the laboratory and standards of vocabulary standards such as the inclusion of ICD-9 codes and UCOM. There was some limited discussion about including UCOM at the time that the LRI was published. I just also want to say that what was helpful was the fact that these guides, the implementation guides, were produced and created by a cross-functional group of folks. We had people from the EHR systems, from Epic who helped us. We had people from the CDC. We had the laboratories involved, the commercial laboratories. We tried to get some of the reference laboratories involved. And so, we wanted to kind of share that that knowledge was collected and decisions made by a cross-functional team. Also, these profiles can be grouped together to improve the constraints of the 251 message. We want to make sure that information is gathered together.

We can use it to define sometimes the date and time, make things more specific where needed, date and time is a field that sometimes doesn't need to be very specific and can be broader. But sometimes, we definitely need collection time, for example, down to minutes or seconds. Also, the profiles can be decided upon through conformance statements. So, this would be from between the sender and the receiver. There is agreement upon what's going to be sent and received. And that can also help to constrain the message. And then, also we know that there need to be profiles based on the patient's criteria or the type of care that's being performed and testing being ordered. And this could be an example of newborn screening where we need to have special information. So, this can be an agreement to have AOE questions asked.

These are the observations that the laboratory needs to ensure that both the testing is accurately performed and results provided that can be interpreted along with these observations. There was a comment mentioned before about gestational age. Of course, this type of information does come to the laboratory through AOE questions, which can be coded, by the way. Just, in summary, the constraints that –

Clem McDonald - National Library of Medicine - Member

Excuse me. Just one insertion. I don't know if you said AOE is ask and order entry. I don't know if people know that acronym. That's why I thought you ought to say it.

Virginia Sturmfels - Quest Diagnostics

Oh, thanks, Clem. Yes. Ask and order entry questions. Yes. They're important to the

laboratory. And then, on the right-hand side, we just really summarized the constraints because we think that these are important. They drive the message behaviors. We are able to enforce conformance between the parties by these agreements that are set up between the lab and the EHR systems. And they also define some testable outcomes, which we are going to talk about a little bit further down this presentation. So, these are the constraints that we feel are important to maintain with these guides. Ken, did you want to add something?

Arien Malec - Change Healthcare - Member

Sorry, this is Arien. Just apologies if you already have this. But can you comment on the inclusion of these implementation guides in existing certification criteria? My belief is that LRI and LOINC are required of EHRs both from an incorporate perspective, from a receipt and incorporate perspective and for the subset of labs that are attached to an EHR. There's an existing certification criterion for the send. But it's not universally required. So, maybe if you can correct my perspective there or if Sasha or somebody from the ONC can.

Virginia Sturfels - Quest Diagnostics

I'll just start off because I do want someone else to comment on current behavior. But you're right. When the IGs came out, we didn't recognize immediately the need for this testable outcome. And this is where quickly NIST was able, I think, to step in and assist in determining certification of the use of the LRI required guides from the implementation guide in those profiles. Can someone else comment on current certification?

Clem McDonald - National Library of Medicine - Member

This is Clem. Those things, the LRI are the, I think, it was V5 5.2 was included in the draft of the Orders of Proposed Rulemaking. But it was taken out of the final one in 2015 or whatever that year was. But it's also true that the LOINC is required inside of the computer system. So, there is both of the statements I heard are true. But that specific specification was not imposed because they retracted it and someone else from ONC might be able to be more clear.

Arien Malec - Change Healthcare - Member

A receipt is definitely required but, yeah, we should make sure that ONC provides the current summary of certification requirements in this area.

Sasha TerMaat - Epic - Member

This is Sasha. I stuck a link in the chat, too. But there was actually some evolution between the 2014 edition and the 2015 edition in the lab criteria that was specified because of the removal of the measure of incorporation of lab test results from the meaningful use program. So, I think some of the standards were specified in the 2014 edition and consequently, likely have widespread adoption, even though they were removed in the 2015 edition and no longer are listed.

Arien Malec - Change Healthcare - Member

That's right. They were removed because they were topped out because we actually had a

fairly universal ability to incorporate. And they were being reported out in meaningful use at very high levels.

Clem McDonald - National Library of Medicine - Member

Can I just clarify that? There was a letter from some major libraries that disputed the widespread use question. And I know from Lab Corp, a major person in Lab Corp, sent the letter that did not agree with that interpretation and the removal.

Virginia Sturfels - Quest Diagnostics

Yeah. They got topped out, exactly. It would be interesting to see if anyone is still obtaining the certification through submitting LRI using the LRI specs.

Steven Lane - Sutter Health - Co-Chair

Excuse me. This is Steven Lane. I'm sensitive to the time. I know that you have substantial additional material that you're going to present and I see that Terry O'Malley has a hand up and there may be others who have questions. But let's let you get through your presentation and then, maybe take questions at the end.

Virginia Sturfels - Quest Diagnostics

Thank you. Next slide, please.

Ken McCaslin - Accenture

So, the next slide is Slide 3. And, unfortunately, I lost my connect to you guys so I'm assuming you're seeing the approach to the flexible guide. And to a conversation that we heard earlier, results are not appearing in places. And I would suggest that part of the reason is that we're not driving the behavior based on an order message. Lots of data is collected as the EHR sends an order to the lab so that we can connect the order to the results correctly within the EHR. And we're trying to make sure that we capture the information in a way that makes sure that we have a good relationship not only to the EHR but also to that patient record within the EHR so the laboratory on the order can capture that. And that might solve some of that interoperability problem if we enforce better behavior around the laboratory receiving electronic order.

As best as people can, they type in patient identifiers. And we know that there are high incidents of errors in that. The other thing is that with the basic lab message, we are putting constraints based on profiles. And as you add additional profiles, they constrain things further. And in this particular guide, what we did was we took the data types and we actually add flavors to them. And Virginia had talked very briefly about newborn screening where there are additional criteria we need to not only capture on the front end but we also have to capture a more precise date of birth and when the collection was done because there are normal ranges that are unique to every moment in that newborn's life. And so, if you look at the top of the screen, you'll see that I put it in yellow, newborn screen requirements. You add that in as a profile constraint because now, you're saying I need more detail around date information.

And then, that can pop out because you're dealing with adults. So, there are some profiles that have constraints that are only there for a particular care episode. So, within these different profiles, there are things where if a laboratory can handle the universal identifier, which in HL7 terms is an OID, we can create a profile where that happens. But a lot of the partners were identifying that they could not do a universal identifier. And so, we gave them the option so that as people are able to get more sophisticated in their interoperability, there were profiles that would manage that kind of sophistication. So, that's the way that we've structured the guides so that the basic interface will work consistently the same. And as you develop your ability to manage a better quality of information then, you can add in the additional profiles and make sure your partners can do that.

And as Virginia had mentioned, we had an evolutionary process that happened because, initially when we were trying to put conformance statements in, we discovered that we weren't making those statements operable. And so, we ended up having to re-engineer the way we did conformance statements so that we could actually test them. So, we had NIST involved helping us put the correct terminology in place so that it could be put in a rules engine and actually drive better behavior. So, I'm going to jump over to the next slide, which says example constraints of profile construction. So, newborn screening is a clear example of that. Time zone offsets. Some people were not doing the time zone offsets. And in a lot of cases, it does not make a difference. But when you're dealing with newborn screening, you do need to know the time offset, particularly, if you go across barriers, time zone barriers.

I talked a little bit about identifiers. So, you have people who can support OIDs, the global identifier, and you have people who could not support OIDs. So, we have a profile that manages both. And I'm going to turn it back over to Virginia. I'm going to end up getting kicked out of this conference room in two minutes probably. So, I'll have to drop offline.

Virginia Sturmfels - Quest Diagnostics

Thank you, Ken. I appreciate it. So, one last slide. It's really a summary slide so we can get into more discussion. Okay. So, these just show outcomes from the development of the IGs. Again, we talked about what stage. It's very important that the EDOS is shown first or provided first with the framework for the requirements for the performing laboratory as they define it that the EDOS then creates the parameters for the LOI, which then drives the LRI reporting process. So, the inclusion and the thoughtfulness for anything going forward needs to be thought of in each of those IGs and that the IGs conform to each other. They provide guidance on the conformance between the partners, the EHRs, the EMRs, and the laboratory interfaces.

They provide a path, hopefully, these constraints so we don't have to actually re-engineer an interface but it can be configured appropriately.

Ken McCaslin - Accenture

Virginia, I think that's a great point because one of the things that I heard was the results are not appearing. So, in some interfaces, just because the lab is sending the LOINC code doesn't mean that the EHR is actually capturing the LOINC code and putting it into their patient record. So, that may be the problem with the downstream effect. And this particular group of

implementation guides actually have conformance requirements that not only do you receive the data but you actually make it available. So, that's also a conformance criterion. Sorry, Virginia.

Virginia Sturfels - Quest Diagnostics

No. Thank you. Great point. And then, the last one was just, as we talked about, we want to have testable outcomes. And so, the discussion about certification of these interfaces and moving forward to make sure they're in compliance. So, I think that's the last slide. So, Ken and I want to thank you for the opportunity to join you today. Great discussion. We'd love to try to be included going forward. I can especially speak for commercial reference laboratories. We definitely want to be here to support.

Steven Lane - Sutter Health - Co-Chair

And thank you so much. Before we lose Ken, hopefully, I just wanted to kind of lay out what I see as our biggest challenges here. And that is there has been a lot of discussion within our task force about not only the importance of moving results between laboratories and the providers, both the ordering and CC and others downstream, but also to **[audio interference]**. So, all of this references lab to EHR EMR but not so much lab to PHR or to a patient receiving this information via perhaps a direct address or unsecured email, etc. Has any work in this space been done looking specifically at making these results more available to and useful for patients?

Virginia Sturfels - Quest Diagnostics

So, I can speak for the commercial reference laboratory side. We certainly make results available. We have specific customer identified reports so that the reporting is to the customer or the patient different. It's not necessarily going through the EHR when they make their requests directly from the laboratory. We have an app called My Quest, for example, that you go on, you register, and you see results but they can be viewed in a more customer friendly way. Vocabulary standards are not – LOINC and SnoMed are not presented. There are also usually some insights, which are provided with those types of patient reports that are going directly from the laboratory. Now, I can't speak for EHR systems and what kind of reporting that they might have to the patient. If that's where you – I hope I understood the question correctly.

Arien Malec - Change Healthcare - Member

Virginia, it also might be worthwhile because there were some comments on ancillary clinicians, the support of LRI for copy to providers.

Ken McCaslin - Accenture

So, within the interface, we do provide the documentation of who the copy to's are. And we do provide that information in a structured way with the intent that we can send it if the laboratories know who these people are. But there are situations where there may be a new physician and they may not be able to identify that physician.

Steven Lane - Sutter Health - Co-Chair

I think the other big area that I think we're going to want to work with you on is really understanding what are the opportunities for us to support moving this forward. I think that what we've heard in our conversations from many sources is that while these standards exist that they are incompletely implemented or inadequately constrained. And you guys have done tremendous work putting this together but, as you said, not all of the EHRs can receive all of the key metadata elements, that they may not maintain them, and that may impact their ability to then subsequently share the data. I think that this focus has really been on the order from the provider to the lab, the result from the lab to the provider.

But what we're dealing with is both this downstream delivery to the patient or their proxy but also the ability for the initial receiving provider to then share that data with all of the associated metadata so that it can then be interoperated between systems. With regard to the work that you've done, has that been a consideration that requirements to maintain and then, subsequently share the metadata when the data moves on beyond the initial recipient?

Virginia Sturmfels - Quest Diagnostics

I think that needs to be more fully discussed and developed. I don't think that we have, other than a copy to type situation, that we've addressed that fully enough.

Cynthia Fisher - WaterRev LLC - Member

This is Cynthia.

Virginia Sturmfels - Quest Diagnostics

I was just going to say I will bring that back to our member laboratories and make sure that I am correctly stating that.

Cynthia Fisher - WaterRev LLC - Member

I want to thank both of you for your input into the task force. It's been very, very helpful. And I come into the task force from a layman representing looking at it from a patient, a family, a caregiver's point of view. And at 30,000 feet looking at what's relevant to the patient in getting these results, 1) timely and 2) that they can provide it then to a specialist or back to their care provider, an interesting case in point from a practical standpoint having just had a healthy 22-year-old get a blood test at the Brigham and Women's. And I am looking to you all to also look at connecting to the patient the delivery of the actual conformity and coding because the Brigham's did a standard blood test, which I happen to have been 25 years in the blood agency so I know the cost and the types of tests that are done and the machine capabilities.

But we had, out of a healthy 22-year-old, a blood analysis result sent to us first of a bill of \$4,300.00 of which our self-insured Blue Cross administered to pay \$2,200.00 and give us a \$700.00 bill. And the results were a thin blood test unremarkable. That said, my next pursuit was to go to Quest and to go to Lab Corp and get competitive pricing for the same blood tests, which you can imagine are substantially lower by one-tenth of the cost at list price. Now, I'm trying to get the negotiating price. But what I noted was the coding of the testing was different. So, trying to compare apples to apples and then, prevent this type of billing in future blood analysis of the healthy 22-year-old and to be able to articulate a discrepancy by

a factor of \$1,000.00.

So, as from the patient's standpoint, it would be very helpful if we looked at a1) providing a link of what a commonality of coding, 2) that we could compare apples to apples and know that patients will be getting involved in price handling because, otherwise, these types of charges are going to bankrupt our economy. So, I just kind of put that towards our task force laying the groundwork for that future. And then, finally, what would be helpful if someone has grabbed or had a look at their blood analytics over time just to make sure that everything is back to normal is that you're able to, basically, do data analytics in a machine-readable form so you can plot any discrepancies and chart over time.

Ken McCaslin - Accenture

So, Ken and Clem, this is Ken McCaslin, again. I believe that SIMI, actually, would help with that issue. Would you guys agree with that? That's a new standard around conformance regarding criteria of what should be included in a particular package. I guess, theoretically, it could be something and we could support it as equivalent to saying things like conformance profile or a Fyre profile could. I think SIMI or any other approach for constraining could work, I think. SIMI certainly could.

Steven Lane - Sutter Health - Co-Chair

Clem, do you want to comment on that?

Clem McDonald - National Library of Medicine - Member

Well, I was going to comment on an earlier statement about getting the data to the patient because two of my employees came in excitedly showing me the Apple health application that they get and the data they get from their hospitals. And they can push a button and you can see the LOINC codes, and you can see all of the structure underneath adjacent, or you can see it in text. So, I think Apple Health and I think things that will evolve along the same line are solving the patient getting the data problem already.

Arien Malec - Change Healthcare - Member

Sorry, I had my hand up. So, I just wanted to make sure that you all note that I've got my hand up.

Steven Lane - Sutter Health - Co-Chair

Yeah, go ahead, Arien.

Arien Malec - Change Healthcare - Member

Okay. So, just a little history lesson. And I think it's instructive for the task force. This is a little bit of welcome to my world. The LRI guide was kicked off based on during my time at ONC when I was coordinating with standards and interoperability framework and Ajit Nani led the work from an ONC coordination perspective. It was a joint effort between ONC with some funding and the lab community that Virginia and Ken are representing. And that was done in 2011. The LOI, the lab orders interface, was done subsequent to that, I believe, in 2012. So, these guides have been out and available. And I think you're going to find that there's a fair

amount of specification and detail behind both the LRI and the LOI and that we're in an area – so I think sometimes the perspective is that clinicians in the field, and I think the perspective of this task force, has been really wonderfully clinically weighted.

The perspective in the field is that the clinical outcome is falling short of what the goal is. And, therefore, there must be a standards problem. I think we're going to find that the majority of the issue here is there may be additional standard and standards developments necessary. I think we've noted things like creating hierarchies between LOINC codes so that similar analytes can be compared. That kind of work is incredibly useful. I think in this area, what we're going to find is that the standards are sufficient but either A) inadequately supported in practice and we should distinguish between inadequately supported in practice on the spending side versus on the receiving side. And in particular, because the oversight mechanisms and the regulatory mechanisms are very different.

CLEA regulates labs in HHS CMS perspective. CAP also has certification oversight for labs. And in many cases, EHR certification is not the appropriate policy lever. And I think in other areas, we may have the technical means to incorporate LRI but, as I think we've heard in practice, that may not be supported end to end from a user experience and a data flow perspective. So, it's important to distinguish areas where we've got an underlying standards problem and then, areas where the standards are – and I think we've noted LRI, the ability to support copy to, the ability to support FHIR based API access when the labs are incorporated and in order to provide access to the patient. And we've got the mechanisms in place from a standards and certification criteria. There may be some incremental efforts. But then, I think we're going to find we're still going to have gaps in practice.

And that really is a different set of issues. And it's what are the hooks to make sure that those standards are more appropriately supported in practice whether those hooks are regulatory or whether they're, frankly, the EHRs and the lab community getting together and doing another turn of the crank on the end to end user experience might be an appropriate mechanism. So, again, just a warning that we do not jump from – we're not getting a clinical outcome to, therefore, we have a standards problem. In many cases, the standards are actually – we've actually done a ton of work on the standards. And what we have is really an ecosystem problem. So, thanks.

Steven Lane - Sutter Health - Co-Chair

Arien, thank you for those comments. And, again, while we still have Ken and Virginia and everyone else here, I think that we want to reiterate that what we've discussed as a work group and we didn't reiterate it earlier is the concept of making the requirement to adhere to these standards a prerequisite for labs getting paid to do this work. Basically, really forcing compliance with the standards through the payment mechanism. And, obviously, there could be all sorts of unintended consequences to that.

But I'd be curious from Virginia and Ken's perspective that if we made this a condition of participation that all of this metadata was both sent to the ordering provider system and the CC'd provider systems and maintained by those systems and then, subsequently utilized for ongoing interoperability and/or if we made it a requirement that these results and their

associated metadata were made available to patients or individuals as part of the process. What do you see as the potential risks of moving in that direction or unintended consequences that we should consider?

Ken McCaslin - Accenture

Virginia, do you want to take the lead?

Virginia Sturfels - Quest Diagnostics

Well, sure. So, I don't really want to – I don't see the value necessarily. Oh, boy, these are tough questions. I'm not trying to make this metadata necessarily available or make the claim submissions of payment anymore complicated than it currently is. So, we have standards that seem to be able to identify what is performed and should be paid for. I am potentially in favor of this metadata and availability potentially to patients. As I described before, we have a patient-friendly version of our reports at this point in time, which is what we would normally give over to patients. And we did develop these reports. And I'm sure the other labs had the same experience, without really much guidance out there on what is a patient-friendly consumer-friendly report.

And what should it contain? And should there be the opportunity for the patient to also receive a report that contains additional information and data as you are suggesting? That is certainly something that needs to be explored. I don't know. Ken, do you have any thoughts, please?

Ken McCaslin - Accenture

Well, in the LOINC standard, there are so many different statements that are in there. I wonder if that's a LOINC community opportunity to provide an additional field in LOINC that says this will help the patient understand the data. Would that make sense?

Clem McDonald - National Library of Medicine - Member

It's a good idea.

Virginia Sturfels - Quest Diagnostics

Yeah.

Andrew Truscott - Accenture - Member

Could you just amplify that a bit more, Ken?

Ken McCaslin - Accenture

So, where I think we already need to identify the analyte with a LOINC code so that we have that universal relationship. And then, when you say I'm bringing that data into a PDR then, rather than bring the technical information in, let's bring in that patient centric information and make it universal so that regardless of which laboratory you're engaged with, everybody would have the same patient descriptions and make it patient friendly. That's sort of what I'm thinking. Clem, is that –

Steven Lane - Sutter Health - Co-Chair

I think it's a really interesting comment because it sounds like the labs now with developing patient portals are kind of where the provider and the EHR community were some years ago where there's a high degree of paternalism and a desire to make this information safe and palatable for the patient. But what we just heard from Clem, and I think we've heard that from others, is the patients just want it all. They don't want anyone being too worried about protecting them. When Apple shows the results, they see the results and they can get to the metadata all the way down. And I think that what we're hearing from our community and our stakeholders here on the task force is a desire to make all of this much more transparent and to keep the metadata with the results. So, again –

Arien Malec - Change Healthcare - Member

Just to be fair to the lab to Quest and Lab Corp and other major labs, I think the notion of direct to consumer has been an area that the commercial labs have been advocating for a long time. To be frank, a lot of the opposition has come from the physician community. And in many areas that opposition is enshrined in state law that expressly forbids labs from being released to patients on a direct consumer basis because of the fear that providing access to lab data without clinical interpretation would provide major harm to the patient. So, I think, in some areas, we may have some policy preferences that are going to run afoul of state regulation that actually forbid the kind of data flows that we're looking for. I just want to be fair to the lab vendors, the national labs.

I actually think the national labs have been on the forefront of trying to make data available to patients and, in many cases, the opposition has been from their critical stakeholders, which are the physicians who are doing most of the ordering.

[Crosstalk]

Steven Lane - Sutter Health - Co-Chair

We're going to cut off the comments, for now, Cynthia. Just hold tight because it is time for us to go to public comments and we want to do that in a timely manner. And then, we'll come back for additional comments. Please raise your hands so we can get back to everyone in turn. Shall we go to public comment?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Sure thing, Steven. Operator, can you please open the public line?

Operator

Yes, thank you. If you'd like to make a public comment, please press star 1 on your telephone keypad and a confirmation tone will indicate your line is in the question cue. You may press star 2 if you'd like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology -

Designated Federal Officer

Great, thanks. And I just want to circle back to roll call from earlier. I believe I've captured Andy Truscott and Les Lenert. Is there anyone else who didn't announce themselves during roll at the top of the call?

Sheryl Turney -

This is Sheryl Turney. I did respond but you didn't hear me. And I also put it in the chat.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Yes. I got you, Sheryl. Anyone else?

[Crosstalk]

Cynthia Fisher - WaterRev LLC - Member

This is Cynthia Fisher. I'm here as well.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

And that was Cynthia and Jack? Anyone else? Okay, great. Operator, do we have any comments in the cue at this time?

Operator

There are no comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay. Thank you. I'll turn it back to Steven to finish up with the comments.

Steven Lane - Sutter Health - Co-Chair

Great. Thank you. And, again, for task force members, we really want to be respectful of the role of the public in the meetings. So, I appreciate your patience. So, Cynthia, I know you don't seem to be able to raise your hand so why don't you go ahead and make your comments.

Cynthia Fisher - WaterRev LLC - Member

Yes. I just wanted to follow up on Arien's comment regarding direct to consumer and the public. For awareness, just since 1992, the umbilical cord blood banking world has actually delivered directly to the consumer the results of both the mother's infectious disease as well as the analytics on the child's cord blood. And there is now over decades of probably about 4 million cord blood results that have been provided directly to the consumer in 50 states. So, if we would want to pursue anything there, I have not known in that industry any problems and, in fact, it's been very well received by the consumers.

Steven Lane - Sutter Health - Co-Chair

Thank you. I noticed that most of the hands have comedown but, Sasha, if you're still with us, I wanted to circle back to you. You put in the public comments a number of links and some information. And I wanted to give you a chance to clarify what your thoughts were there.

Sasha TerMaat - Epic - Member

Sure. So, I am still here. And most of my links were, I think, actually explained well by some of Arien's history earlier in the call. I linked a couple of things that came up about policy questions in terms of the current policy both what is required by certification to be made accessible to patients from an electronic health record, which included both the diagnostic test reports as well as a series of information about lab test results, which is kind of pertinent to some of our questions today. And then, also the current lab standards that are included in certification though as we discussed, some of them were in previous phases of certification and no longer listed.

Steven Lane - Sutter Health - Co-Chair

I'm curious. There's this notion that standards have been dropped from the certification. While I appreciate the idea of trying to remove topped out standards as a way of at least appearing to reduce burden for providers and health systems, etc., it seems odd to me that if we've identified a standard that is helpful, that is valuable, that we really want everyone to continue to comply with that we would remove it in that way. I know many of the people on the call have been involved in this process. Do we feel that that's a good thing continuing to remove topped out standards and kind of leaving the assumption that they're going to continue to be followed? Or does it make more sense to try to keep them in the standards?

Arien Malec - Change Healthcare - Member

And, again, this is –

Sasha TerMaat - Epic - Member

That's a much larger question about the sort of value of standards and the value of certification. So, I think we should have separate conversations about each of those. The standards themselves are not removed or not used. They're still identified within the interoperability standards advisory as we saw earlier on today's call. I guess the question is is there enough value to merit third party conformance testing of each of those standards of all current systems in use or at least EHR systems. The certification process never actually covered the lab and the interoperability.

And so, I guess, there is a larger debate there to say what things are worth paying a third party to test specifically in terms of assuring that we get the outcomes that we want and where is it worth being judicious with our spending to say no, we don't need a third party verification of that particular item. But I don't think that's something we can resolve in the next four minutes. I think that's a whole discussion in and of itself.

Arien Malec - Change Healthcare - Member

And just a quick history lesson here of the way this came about is that there were originally

certification criteria that weren't tied to meaningful use criteria. And I think there was an appropriate decision that that was sort of onerous on the EHR developers. So, there was a policy decision to tightly align meaningful use criteria with the associated certification criteria. And then, as a sub consequence of that, when we started removing topped out measures that were fully achieved on the implementation side, we ended up as a consequence removing the associated certification criteria. So, just so people understand how that came about.

Clem McDonald - National Library of Medicine - Member

There was a dispute as to whether the data saying it was topped out was right. I think they had like an eight percent response in the topped out things. And I know that Lab Corp sent a formal dispute or at least disagreement with it that they shouldn't have removed it and it really hadn't topped out. And that's what we're talking about today. Everybody is not getting this stuff.

Sasha TerMaat - Epic - Member

Actually, Clem, I think there are two separate questions. One is whether the meaningful use measure had exceeded the level CMS considered topped out. And I don't have the background on sort of what that level was or how CMS responded to Lab Corp's dispute. But the other question is whether it makes sense for the certification standards to remain required for both electronic health records developers as well as purchasers of electronic health records to have given CMS's decision to remove the measure as being topped out. And each of those is interrelated but they're somewhat separate questions. I agree. Life is complicated.

Steven Lane - Sutter Health - Co-Chair

I think Andy Truscott has a question.

Andrew Truscott - Accenture - Member

Not so much a question, more of a comment. Thanks, Steve. In response to an earlier point that I think was very well made around there is a very good clinical care reason why we don't allow places just to have lab results when they're released from the lab. Isn't there some kind of policy influence that we could ask people to bear so that providers are able to make a pre-released decision? There are a large number of lab tests, which are noncontentious if they would be released to a patient early. I fully admit that there are some, which would not be appropriate. So, can the provider not be encouraged to make that determination when they submit the order so that, actually, that pre-release could happen in a large number of cases?

Steven Lane - Sutter Health - Co-Chair

Potentially, allowing a provider to specify a withhold on an order making it more of an opt-out than an opt-in.

Andrew Truscott - Accenture - Member

Either way, because some states will want it one way, some states will want it the other.

Cynthia Fisher - WaterRev LLC - Member

This is Cynthia. Is that necessarily the case? You look at the examples of I can count on my right hand a couple of people that have had Lyme disease that never got their results of testing positive. And the provider just didn't read the results and then, they got into chronic situations or subacute. So, I don't roll this out to say who are we to judge rather than or set up hurdles further for the patient than, as Clem said earlier, with Apple's current mobile ability, patients have the right to their information. And putting obstacles to withhold it, in fact, I don't believe is the job of our task force.

Andrew Truscott - Accenture - Member

But that's the counterpoint to that, Cynthia. We're actually saying we're trying to remove the obstacles because right now the obstacles are there.

Steven Lane - Sutter Health - Co-Chair

Well, thank you for those final comments. We are at the end of our time. And we want to respect everyone's time. This has been very helpful. I think that what we're going to do between now and the next meeting is perhaps having some offline meetings with the presenters to try to pull together all of the great input that was provided in the spreadsheet and come back with the set of specific recommendations for the task force to consider. If people have additional input that they'd like to add to the spreadsheet, feel free to do that over the next few days. And then, we'll try to summarize all of that back to the task force at our next meeting. Thank you all for your time and we will see you next time.