Interoperability Standards Priorities (ISP) Task Force

Transcript
February 5, 2019

SPEAKERS

Name	Organization	
Kensaku Kawamoto (Co-Chair)	University of Utah	Co-Chair
Steven Lane (Co-Chair)	Sutter Health	Co-Chair
Andrew Truscott	Accenture	ISP Task Force Member
Anil Jain	IBM Watson Health	ISP Task Force Member
Arien Malec	Change Healthcare	ISP Task Force Member
Clement McDonald	National Library of Medicine	ISP Task Force Member
Cynthia Fisher	WaterRev, LLC	ISP Task Force Member
David McCallie	Cerner	ISP Task Force Member
Edward Juhn	Blue Shield of California	ISP Task Force Member
Leslie Lenert	Medical University of South Carolina	ISP Task Force Member
Ming Jack Po	Google	ISP Task Force Member
Raj Ratwani	MedStar Health	ISP Task Force Member
Ram Sriram	NIST	ISP Task Force Member
Ricky Bloomfield	Apple	ISP Task Force Member
Sasha TerMaat	EPIC	ISP Task Force Member
Scott Weingarten	Cedars-Sinai and Stanson Health	ISP Task Force Member
Tamer Fakhouri	One Medical	ISP Task Force Member
Terrence O'Malley	Massachusetts General Hospital	ISP Task Force Member
Tina Esposito	Advocate Health Care	ISP Task Force Member
Valerie Grey	New York eHealth Collaborative	ISP Task Force Member
Victor Lee	Clinical Architecture	ISP Task Force Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Good morning, everyone. Thank you for joining us today on the Interoperability Standards Priorities Task Force call. We'll call the meeting to order starting with roll call. Ken Kawamoto?

Kensaku Kawamoto – University of Utah – Co-Chair
Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health – Co-Chair
Good morning.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Arien Malec?

Arien Malec – Change Healthcare – ISP Task Force Member
Good morning.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Andy Truscott? Not yet? Clem McDonald? Not yet? 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
Good morning. Edward Juhn?

Edward Juhn – Blue Shield of California – ISP Task Force Member
Good morning.

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

Ram Sriram – NIST – ISP Task Force Member
Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Ricky Bloomfield? No? Sasha TerMaat?

Sasha TerMaat – EPIC – ISP Task Force Member
Here.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Scott Weingarten? Cheryl Turney? Tamer Fakhouri? Tina Esposito? Valerie Grey? And, Victor Lee? I believe he may be –

Victor Lee – Clinical Architecture – ISP Task Force Member
Here.

Kensaku Kawamoto – University of Utah – Co-Chair
I think Cheryl is on. I think she just joined the call, but I see her on the panel. Cheryl is on.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Great. Thank you, Ken. With that, I will turn it over to our co-chairs, Steven Lane and Ken Kawamoto.

Steven Lane – Sutter Health – Co-Chair
Well, good morning, everybody, and welcome back. Happy February. Everybody has gotten through the wild weather as best they can. I guess we're missing a number of people today, so hopefully, they'll all doing well. Ken is going to need to leave us a little early today for a conflicting meeting, so I'll be carrying the baton through the end of the meeting. We wanted to go over the agenda first. We're going to be reviewing the prioritization process that we've been going through and trying to make sure that we get all of the votes possible. There's a couple people on the phone this morning who haven't had a chance to register their priorities, so we'll actually call you out, Arien and Ram, and ask you to provide that information here. I don't want to surprise you when we do that. And then, we're just going to talk briefly about the priorities as they exist and how we think they will orient our work going forward this year.

We're then going to go back and pick up where we left off last time regarding the draft recommendations regarding orders and results. We ran aground a bit on the issue of free-of-cost for access to data, so we'll pick up there. There have been some additional edits offered to the document. Victor Lee did a really nice job providing some granularity, and we got some additional input from one of the large vendors that we've included, and I hope that we can get through that before we go to public comment and adjourn. So, that's the agenda as it stands. Does anyone have any additions or questions regarding that? Ken, do you have anything to add?

Kensaku Kawamoto – University of Utah – Co-Chair
No, that sounds good.

Steven Lane – Sutter Health – Co-Chair
Great. All right. So, we did do – you'll recall that we've highlighted five potential areas of focus going forward: Evidence-based disease management, social determinants of health, prior authorization, price transparency, and medication and pharmacy data exchange. We spent some time going through those last time and we invited everybody to establish or specify their first through third priorities based on

the areas they thought they wanted to personally focus on and where they thought we would have the greatest input. So, 22 of our task force members have voted. One person voted only their first priority, but that person is not here, so we can't ask them to weigh in, and we've got six people who have not voted at all, and two of you are on the phone. So, I wanted to invite Arien first – if you can offer up your first through third priorities, we will add them to the list and utilize that going forward.

Arien Malec – Change Healthcare – ISP Task Force Member
First of all, my apologies. I thought I went to the page, and maybe I just didn't hit "save" on the issues. Medication and pharmacy data exchange would be my No. 1, evidence-based disease management would be my No. 2, prior authorization would be my No. 3, social determinants No. 4, and No. 5 would be price transparency.

Steven Lane – Sutter Health – Co-Chair
We're only asking you to go one through three, so we've got you there.

Ram Sriram – NIST – ISP Task Force Member
Yeah, I'm sorry. This is Ram here. I just came back this week from the federal government shutdown, so I'm sorry we couldn't be here last time. Mine are 1). Medication and pharmacy data exchange, 2). Evidence-based disease management, and 3). Prior authorization.

Steven Lane – Sutter Health – Co-Chair
Thank you so much for that. And, just to confirm, have we been joined by Tina, Valerie, Les, Raj, or Scott?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Clem's here, too.

Steven Lane – Sutter Health – Co-Chair
Hey, Clem. I'm so glad you're here. We did get your vote, so that's great. Well then, let me do this and see if I can share my screen. I'm trying to do this in a way that – there we go. That gives us all the meaningful data here. Good, all right. Let me try sharing here. I think we can do this successfully. Please let me know when you can see my screen here.

Kensaku Kawamoto – University of Utah – Co-Chair
We see it. It's a little bit small, but we see it.

Steven Lane – Sutter Health – Co-Chair
Okay. So, what we have here is the summary of the votes that we've received, so you can see here that medication and pharmacy data clearly tops the list as the highest priority for the group with nine people listing it as first, 11 as one or two, and 13 listing it at all. The total score based on the math that Ken baked in is 53. Second in line is, again, evidence-based disease management, and you can see how that was voted and how that breaks down. And then, things definitely cluster together down here with price transparency, prior authorization, and social determinants in that order.

So, I think this is really helpful. We did have a robust discussion about social determinants last time, and learned that a lot of people are doing some great work on that, and that's already being supported by the ONC, so I suspect that this prioritization reflects the fact that that's being well addressed. We've also gotten some input from a number of folks, both on and off the task force, about the importance of

prior auth and price transparency, and Ken, I think you had a good way of thinking about how these would link together, so maybe you could talk about that.

Kensaku Kawamoto – University of Utah – Co-Chair
Yes. I think based on our voting, it's pretty clear that medications and pharmacy data exchange is No. 1, so unless there are objections, I think that's clearly the next topic to go after. And then, actually, Steve Posnack from ONC had the insight to say that at least evidence-based disease management, prior auth, and price transparency can be thought of as basically amalgamating data, communicating data, and providing guidance. So, evidence-based disease management may say things like, "For their severity of COPD, this patient should have a long-acting muscarinic agonist added," prior auth may say things like, "If you want to order this medication, then you need to make sure these things are true about the patient," and price transparency may say something like, "If you want to order that medication, this is what the patient's copay might be, and insurance will cover this one, but not that one," that kind of thing.

So, I thought that was a great insight. Certainly, the data elements involved are different, but potentially, the mechanisms used to service and provide this information are quite similar along the lines of technology. One potential thought is we should start with medication and pharmacy, but for the next one, perhaps we can seek to combine those three, and if we have time, we can also tackle social determinants of health after that.

Clement McDonald – National Library of Medicine – ISP Task Force Member
This is Clem. Could I just comment on the medicine one? So, the first slide you showed this morning had it at the bottom, so I don't know how that changed, and the second thing is –

Kensaku Kawamoto – University of Utah – Co-Chair
Sorry, did it have a what?

Clement McDonald – National Library of Medicine – ISP Task Force Member
The initial slide, which I think is from the people who had voted earlier, didn't have –

Steven Lane – Sutter Health – Co-Chair
Clem, that initial slide was not in any rank order. They were just listed for information.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Okay. Well, the second thing is of all the things that are working now, it's pharmacy. E-prescribing is home free, so I don't know why that needs a lot more attention.

Kensaku Kawamoto – University of Utah – Co-Chair
Maybe the folks who voted it No. 1 can comment, but I believe it was around things like getting dispense data. Maybe the folks who voted it a priority can comment on that.

Steven Lane – Sutter Health – Co-Chair
Clem, one of the things I discussed last time was the issue around discrete SIGs and the value that that brings to providers and patients in terms of the ability to deliver medication-specific decision support and the ability to understand what narcotic dosing is being used, et cetera.

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

Well, I would disagree with that. It'll kill physicians because you can't put the comment – "Let the pharmacist figure it out." He puts it in his text and lets the pharmacist do it. It's just a small percentage of prescriptions, but it can be really burdensome to click, click, click to pick a decreasing dose rather than just pick a menu that says it in text.

Kensaku Kawamoto – University of Utah – Co-Chair
Those are getting into discussions, but I think along these lines, there's also the issue that even when a clinician does initially select discrete SIGs, oftentimes, in the process of going back and forth with pharmacy – for example, for refills – it gets converted into free text. So, even though the clinician went to the effort using structure, it gets lost during the transaction processes.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, I would argue physicians shouldn't have to be burdened with putting it in discretely.

Steven Lane – Sutter Health – Co-Chair
Clem, I think these will be good things to bring up. The purpose of this discussion is simply to clarify our priority, and clearly, the majority of the group feel that this is the first priority to work on.

Ram Sriram – NIST – ISP Task Force Member
This is Ram here. Actually, I voted for it, but after thinking about it, I agree with Clem. A lot of these pharmacy things are done reasonably well nowadays, although there is scope for improvement, so that needs to be discussed further. I voted for medication and pharmacy, but I will submit my apologies because I was thinking when you said to rank the importance, I misread the intent.

Steven Lane – Sutter Health – Co-Chair
Ram, you're welcome to change your votes if you like.

Ram Sriram – NIST – ISP Task Force Member
Maybe I'll change.

Steven Lane – Sutter Health – Co-Chair
Medication and pharmacy could – go ahead.

Steven Lane – Sutter Health – Co-Chair
I'd probably put evidence-based disease management first, then I will go for prior authorization second and social determinants of health third.

Arien Malec – Change Healthcare – ISP Task Force Member
And, just as a note, I was interpreting this and medications and pharmacy, not medications and pharmacy – that is, with a tight coupling or association between the two of them, and so was basing my vote on general access to med lists and decision support about medications.

Steven Lane – Sutter Health – Co-Chair
And, I think that could certainly be included. Again, we're not going to plumb the depths right here. We're just trying to clarify prioritization. So, do you want to make a change, Arien?

Arien Malec – Change Healthcare – ISP Task Force Member
No, that was my interpretation, and I'm sticking with it.

Steven Lane – Sutter Health – Co-Chair
All right. We're trying not to spend too much time calling out individual votes here, but just clarifying where the group is. Again, I think we have a pretty clear prioritization. Our plan is to do some planning and do our deeper dive starting on the 26th of February, after we get through what is hopefully the finalization of our recommendation around orders and results, as well as the closed loop referrals and care coordination. So, any other comments on the prioritization process or outcomes?

Kensaku Kawamoto – University of Utah – Co-Chair
My question is – it'll be after medication and pharmacy, so it's going to be a little bit off, but does anybody have any particular objections to seeing if we could combine disease management, prior auth, and price transparency, at least in terms of the general approach that we want to provide some guidance at the point of care?

David McCallie – Cerner – ISP Task Force Member
This is David. There's a ton of activity in all these spaces already underway by appropriate standards bodies. I was thinking that maybe the committee's work would be to prioritize or vote in favor of the ones that we thought were most important, so I'm not sure that lumping them together will change much. I would think we're going to find out what's going on in each of these domains and either support it or suggest that priorities be shifted elsewhere.

Steven Lane – Sutter Health – Co-Chair
I think that makes sense, David. I also think we'll have the opportunity to highlight gaps where perhaps there is not enough focus presently and where the ONC could encourage further development or, as we've done before, harmonization or rationalization of competing programs. I think that's a good plan.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I would support Ken's position because we would get to those things sooner.

Steven Lane – Sutter Health – Co-Chair
Great. Any others? Good. All right, let's proceed, then. We'll shift now to further review of our orders and results draft recommendations. I've just switched over. Can you all see our spreadsheet with our recommendations?

Kensaku Kawamoto – University of Utah – Co-Chair
It is a little bit small. Is it possible to hit the "maximize" button on the top right of your window?

Steven Lane – Sutter Health – Co-Chair
Does that help?

Kensaku Kawamoto – University of Utah – Co-Chair
That's a little bit better. It's still quite small onscreen.

Steven Lane – Sutter Health – Co-Chair
How about that?

Kensaku Kawamoto – University of Utah – Co-Chair
I can read it. If anybody else cannot read it, I think we can try to maximize the screen or something.

David McCallie – Cerner – ISP Task Force Member
We can open it directly on the Google page, right?

Steven Lane – Sutter Health – Co-Chair
That's true. How's that, Ken? Is that any better?

Kensaku Kawamoto – University of Utah – Co-Chair
That's very good for me, but I'm nearsighted.

Steven Lane – Sutter Health – Co-Chair
Hopefully, this will do the trick.

Clement McDonald – National Library of Medicine – ISP Task Force Member
It's good for me.

Steven Lane – Sutter Health – Co-Chair
Thanks, Clem. So, you'll recall that last time, we went through the first couple, and I accepted the changes that were there, so my intent was not to go through those again. This one here – this priority for all results being sent to clinicians – we did receive a comment toward the end of our discussion about whether device data should be included with the recommended or required metadata, so I added that just to be sure that people felt comfortable with that. Do we have any considerations or concerns about the way this has been incorporated into the recommendations?

Clement McDonald – National Library of Medicine – ISP Task Force Member
So, when you say "device data," would that be Fitbits and things like that, or are you talking about Holter monitors that are ordered and put on the patient?

Steven Lane – Sutter Health – Co-Chair
Well, in this case, we're talking about results sent to clinicians very specifically, so I think this would have to do with the devices that were used to generate those results.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Okay. I just would worry that it automatically includes everybody's body-monitored things that the physician may not expect. So, you're saying these would be ordered test results.

Steven Lane – Sutter Health – Co-Chair
That's what this document is about. Whoever recommended this, can you comment? I believe that this had to do with the devices used for the generation of the results, and I can add that clarification.

Kensaku Kawamoto – University of Utah – Co-Chair
I forgot who put it in or commented, but their comment was the kind of notion that you may want to know that this was a Theranos device versus a Siemens device. So, that was their comment – that in those cases, the LOINC code may not be sufficient.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Okay. So, you're just testing the product.

Sasha TerMaat – EPIC – ISP Task Force Member
Would it be more clear to call it "resulting equipment" or something that is a device that isn't – "medical device" has so many other meanings.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think so.

Kensaku Kawamoto – University of Utah – Co-Chair
Yeah. "Resulting equipment data"?

Sasha TerMaat – EPIC – ISP Task Force Member
If that was the intention, yeah.

Kensaku Kawamoto – University of Utah – Co-Chair
"Data regarding device-generated result" – the equipment.

Clement McDonald – National Library of Medicine – ISP Task Force Member
But, just be aware that laboratories don't typically do that now. I think it's a nice thing. I think it's probably –

Steven Lane – Sutter Health – Co-Chair
Right, that's why we listed it as under consideration. So, if everyone's comfortable with that, we will finalize that change and move on. So, now, we're down to where we were before, and just to be clear, this has to do with making results available to patients and their proxies. I'm going to come over here so that we can see the comments. So, you can see again that we've got subtractions in red, additions in green, and then we've got some comments over here, which is where we left off last time. Sasha had submitted a comment here, and it led us to suggest striking out this specific note here regarding augmenting program requirements to include receipt of information in either standardized or structured formats similar to API requirements, and I think the thought was – and, we discussed this briefly – that it was hard to – Sasha, I'll let you clarify your comment rather than try to state it myself.

Sasha TerMaat – EPIC – ISP Task Force Member
I just wasn't sure what it meant to do that, so I thought it should either be clarified or… I didn't understand what it meant to augment program requirements to do that.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I agree with it being unclear.

Arien Malec – Change Healthcare – ISP Task Force Member
Well, given that it's a policy lever, I think it would have probably been talking about defining criteria for incentive programs, right?

Steven Lane – Sutter Health – Co-Chair
Yeah, that was the idea. We have a program today that says patients need to be able to access their data via APIs. We do not have a similar policy requirement that says patients need to be able to access their data via CCDA. So, the suggestion was that if we have one, we should have the other, and that was the –

Sasha TerMaat – EPIC – ISP Task Force Member
I don't think that's right. That doesn't make sense to me because aren't there policy requirements to require CCDA access in the view/download/transmit criterion and in the API criterion? Both of those also include a CCDA payload.

Steven Lane – Sutter Health – Co-Chair
If that's the case, then this isn't required, but thanks for clarifying that, Sasha. I consider you a subject matter expert in that area, so that's great. So, we've struck that, and I'll make that official here. I'll take it out so it's not distracting us anymore. And then, again, we got hung up on this notion of "free of charge," and I've thought about this a lot since we met.

Arien Malec – Change Healthcare – ISP Task Force Member
Hey, I remembered the comments that I was supposed to provide, and I just provided them via email, but again, my perspective is that OCR has already very well covered this ground, and I provided links to the relevant, pretty voluminous OCR guidance in this area, but it nets out to – 1). Patients have a right to access, 2). Patients have a right to request a form and format, 3). If that form and format is readily available, it must be provided to the patient, and 4). The cost to provide access is limited to the actual direct costs incurred by the covered entity and don't include, for example, covering the cost of capital for infrastructure, servers, and that kind of thing.

And, when you add this all together – again, this is well covered through both the access language and the FAQs on the access language – in the case where a covered entity has access to the API form and format and the patient makes a request, which may be made electronically – for example, through an app – that covered entity is obligated to provide the specified form and format, and the costs – if any – that could be charged to the patient would be the actual direct costs, which would really be the marginal cost of electricity, which would be so close to zero as to be indistinguishable from zero.

So, that's the guidance that OCR has already provided under HIPAA and under their regulatory and statutory powers that lead to an "in the world" reflection of a policy mandate that API access be provided for free. It's possible that there are enforcement gaps, that there are provider organizations that aren't following the rules and guidance that have been established by OCR – in fact, it's probable. I know that the CARIN Alliance is working on additional policy framework and enforcement language in this area, but I do think this is an area that's fairly well covered and where policy recommendations add up to what it is that we're looking for. And, I dropped all the language in an email and sent it out.

Steven Lane – Sutter Health – Co-Chair
Great. Thank you so much, Arien. I think that provides a nice backdrop for us completing the discussion of our recommendation, so I just want to make sure – maybe we'll go through these recommendations one by one. The first one was requiring that ordering providers make results available within a reasonable timeframe, accounting for state laws as appropriate, and the need for the provider to have time to review that. And, we just made one little word change there. Does anyone have any concerns about this first recommendation? Great. We'll go ahead and go on.

The next one – making all results that are in the EHR available to patients via the API, and initially, we just said whether or not they are mapped to standard code sets – this was a point that Clem was making repeatedly – we should at least make all the results available. Now, here, we introduced this "free of charge" concept, and Arien, it sounds like you're saying a lot of this has already been covered, and there are some opportunities for some marginal costs to be charged, but it doesn't – one of the

concerns that was raised last time is we don't want to disallow the opportunity for folks to provide value-added services if they're going to do that. The question here is whether this "free of charge" is needed here or has any value.

Kensaku Kawamoto – University of Utah – Co-Chair
David has his hand up.

David McCallie – Cerner – ISP Task Force Member
You finished your – I didn't mean to interrupt the sentence there, but I just wanted to clarify that when you say the word "results," it's kind of a vague term that some people may mean to be more than just lab results, and the APIs that exist today don't necessarily cover everything that you might consider a result in the EHR. The expectation, of course, is that the set of APIs that are required for certification will be expanded over time through the USCDI, but I just want to point out that the language is a little ambiguous here when you say "all results." I think in this context –

Steven Lane – Sutter Health – Co-Chair
I think we do mean all results. We have been very generic in our discussions. We're talking about imaging results, procedure results – I think that's intentional.

Arien Malec – Change Healthcare – ISP Task Force Member
And, I thought we did have recommendations to add textual reports and other kinds of reports to the list of reports available to the patient via APIs.

Clement McDonald – National Library of Medicine – ISP Task Force Member
And, it's required by law – by the Cures Act.

Kensaku Kawamoto – University of Utah – Co-Chair
Sasha has her hand up next.

David McCallie – Cerner – ISP Task Force Member
Again, to clarify, we need the APIs in the first place, and we don't have those yet, so…

Clement McDonald – National Library of Medicine – ISP Task Force Member
Is that true? Diagnostic reports are in an API.

Kensaku Kawamoto – University of Utah – Co-Chair
Just to keep the hand-raising order, maybe Clem can go after Sasha.

Sasha TerMaat – EPIC – ISP Task Force Member
I would agree with David's point that this would have to be contingent on API development being available for all types of results. But, my concern was actually that we can't say "all results" here without the "as allowed by state laws" that we have in other bullets because it would not be feasible to release things that are prohibited to be released electronically through state law.

Kensaku Kawamoto – University of Utah – Co-Chair
Clem? Did you have a follow-up comment, too?

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

No. I think that's a very good qualification, but I don't… I should have an offline discussion, but I don't think everything is available as an API, but I don't think they're restricted to a laboratory right now.

Kensaku Kawamoto – University of Utah – Co-Chair
David?

David McCallie – Cerner – ISP Task Force Member
I just wanted to finish the point that I think we need to connect this to other work underway to expand the APIs through the USCDI proposal, and we're waiting for more details on what that means. I don't think we want to – I think we'd like to endorse – we should endorse that that is the right approach – a staged, carefully piloted approach to expanding the scope of the domains that the APIs have access to, eventually leading to the full designated records set, which we're a long way away from. So, I'm just saying link it to the efforts underway and endorse those efforts.

Kensaku Kawamoto – University of Utah – Co-Chair
So, David, what you're saying is within… Probably under "recommendations," through USCDI process, or something like that. What you're saying is until we actually define them, it may be counterproductive for every vendor to have different ways of packaging all their data. If you say "all data," then it could get very voluminous because you could potentially even interpret that to mean… Anyway, it does seem like specifying what we mean is good.

David McCallie – Cerner – ISP Task Force Member
Maybe a way to think of it is our recommendation stands as it's written, but then, on the policy lever responsibility, we would encourage the aggressive pursuit of the USCDI staged approach to expansion of CDIs to eventually cover all data, as required by the Cures Act, as Clem points out. The Cures Act is the statute, but we don't have regulatory language around what that means and at what pace it will be required and enforced.

Kensaku Kawamoto – University of Utah – Co-Chair
And, doesn't "free of charge" via patients – according to what Arien said as well, if a patient brings an app rather than a health system or provider, that access cannot result in a charge?

David McCallie – Cerner – ISP Task Force Member
That's correct.

Kensaku Kawamoto – University of Utah – Co-Chair
Interesting.

David McCallie – Cerner – ISP Task Force Member
That's the current understanding. That's how most of us operate.

Arien Malec – Change Healthcare – ISP Task Force Member
It's not how the world operates, but that's what OCR specifies.

David McCallie – Cerner – ISP Task Force Member
For patient-facing APIs, not for release of information through your HIM department. You still pay dearly for that.

Kensaku Kawamoto – University of Utah – Co-Chair
Okay, that's great.

Steven Lane – Sutter Health – Co-Chair
So, in terms of the language that I've added here – again, in green, just to be clear – David and others, are you comfortable with this as a policy lever expanding the scope of API requirements to include access to all results through the USCDI process, to eventually include all data as required by the 21st Century Cures Act?

David McCallie – Cerner – ISP Task Force Member
Yeah. There's a big debate about what "all data" means because Cures doesn't specify that. Some people think it's the equivalent of the designated record set protected by HIPAA, which would be clinical and financial data, but not, for example, provider performance data, et cetera. There's a landmine there that's not well defined yet as to what "all data" means, but I would think all clinical data or clinical and financial data would be within the scope of what most people think will be eventually required. Sasha, do you agree with that? I haven't thought about it a whole lot recently. I may have missed recent trends.

Sasha TerMaat – EPIC – ISP Task Force Member
Yes, I would agree with that, David.

Steven Lane – Sutter Health – Co-Chair
Okay. So, are we comfortable leaving "free of charge" in the recommendation, as recommended last time, and where we have that?

Clement McDonald – National Library of Medicine – ISP Task Force Member
I am.

David McCallie – Cerner – ISP Task Force Member
Yeah.

Kensaku Kawamoto – University of Utah – Co-Chair
Yeah. "Via APIs" is fine.

David McCallie – Cerner – ISP Task Force Member
For the APIs.

Steven Lane – Sutter Health – Co-Chair
Okay, very good.

Clement McDonald – National Library of Medicine – ISP Task Force Member
The qualification of no codes – I don't disagree with it as stated, but if it intends to encompass everything, it won't go anywhere reasonably if there's some code to find its right home in the patient CH, so I don't know how extensive that qualification will be – how much it flows into the other recommendations.

Kensaku Kawamoto – University of Utah – Co-Chair
I think there are some –

Steven Lane – Sutter Health – Co-Chair
Actually, Clem, that was your recommendation, your point being that we really needed to free all of the data whether or not we've already mapped it or whether or not the individual source has done the mapping.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I don't remember that, but I don't disapprove of it. I just think if it's taken as unidentified data except for the patient, it's going to be a shoebox the patient won't be able to use very well. That's all.

Kensaku Kawamoto – University of Utah – Co-Chair
Yeah, and I think Row 5 – at least, it's in the CCDA context, but there have been additions that maybe we can review a little bit later that get right at what you're saying. They identify whether this is lab versus radiology, or whatever.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think it needs a date, too, but anyway…

Steven Lane – Sutter Health – Co-Chair
That's in there. But, let's go on. I really want to get through this one. We have a lot to cover here. The next recommendation here is now – at Sasha's suggestion, we changed this to "encourage," and eventually require resulting agencies to make results available directly to patients. This could be encouraged by CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies. So, here, again, the question of "free of charge," whether the resulting agency that has already been paid to perform the test should also be encouraged and potentially required to make those results available free of charge to the patient.

Clement McDonald – National Library of Medicine – ISP Task Force Member
The "CLIA" thing means "lab," and that's already required, I think.

Arien Malec – Change Healthcare – ISP Task Force Member
OCR did note that HIPAA access… When labs are covered entities – and, they almost always are because they charge CMS – access requirements already apply to them. What isn't there is the requirement that every lab host an API. So, if you think of the two-part test that OCR established for free access, the "access" part is there, but the "readily available form and format" isn't.

Steven Lane – Sutter Health – Co-Chair
So, we did not specify in our recommendation that this was via an API. We are simply saying that the resulting agencies need to make the results available. So, are we comfortable with this change as specified? Very good. We will –

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
This is Terry. Do we need to specify either the format or the fact that it's standards-based…? So, they can make the results available on paper, but are we presuming this is electronic and that it meets minimum standards?

Steven Lane – Sutter Health – Co-Chair
You're suggesting adding the words "making them available electronically."

Clement McDonald – National Library of Medicine – ISP Task Force Member
What about using the same wording that's been used in other contexts for the providers?

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
Yeah, that makes sense.

Steven Lane – Sutter Health – Co-Chair
What do you mean, Clem?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, there is fixed text that's required in terms of the HIPAA thing. I think it says API – I don't know what it says, but we shouldn't be different for the result providers as we are to everyone else, and I think there are words out there that we could use, but I don't know what they are.

Kensaku Kawamoto – University of Utah – Co-Chair
Well, this is kind of a big-picture comment, especially as we get into medications as well. APIs are now required at the EHR level. Do we want to start including ancillary aspects of healthcare and encourage or require that they make their data available through APIs as well?

Clement McDonald – National Library of Medicine – ISP Task Force Member
I would think so, if we can feasibly do it.

Steven Lane – Sutter Health – Co-Chair
So, do we want to introduce the concept that this is via APIs?

Clement McDonald – National Library of Medicine – ISP Task Force Member
That'd be my goal.

David McCallie – Cerner – ISP Task Force Member
I think that makes sense. Which line are we discussing? I've lost the context a little bit.

Steven Lane – Sutter Health – Co-Chair
Sorry. We're discussing this "encourage" line here.

Kensaku Kawamoto – University of Utah – Co-Chair
I think the only question is – an EHR establishes a PHR relationship with patients and can do identity management. For example, how is a lab going to know that the person trying to request it is, in fact, that patient? I guess they would have to go through some sort of – how do they positively identify this is who you are or who you say you are?

Arien Malec – Change Healthcare – ISP Task Force Member
This is a really good question that is probably outside of our scope.

Steven Lane – Sutter Health – Co-Chair
Okay. Any other changes to this one – the blue one?

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

Well, what we could say is that… So, sometimes labs just get a specimen number. They don't know anything about the patient. So, I think we could say something about if they have – qualify it that if they know who the patient is, the patient could get the data, but that may destroy it. I don't know.

Steven Lane – Sutter Health – Co-Chair
They know who the patient is. They had to have patient identity to do the test.

Clement McDonald – National Library of Medicine – ISP Task Force Member
No, that is not true. They'll just send out a specimen number.

Steven Lane – Sutter Health – Co-Chair
Okay. I'm not sure that level of granularity is going to add to this. But, did we want to say "via APIs"? I want to be clear on that before we leave this.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I'd still like that.

Kensaku Kawamoto – University of Utah – Co-Chair
I think it's good – should we weaken this a little bit to say "…and consider eventually requiring"? I'm just afraid of saying "eventually require it" when we don't know whether it's even feasible to do this.

Steven Lane – Sutter Health – Co-Chair
We know that LabCorp and Quest have already made their data available via API to patients, so we know it's feasible for the lab results. I guess the question is whether imaging, cardiopulmonary, and other sorts of results – pathology – would also – this could be done. It's hard to imagine that it couldn't.

Kensaku Kawamoto – University of Utah – Co-Chair
Well, how does LabCorp know who you are? How do you register to say "I am this person"? I guess you upload –

David McCallie – Cerner – ISP Task Force Member
I've done it. You go to their site.

Arien Malec – Change Healthcare – ISP Task Force Member
Weirdly, they have to go submit claims and bill you, so at some point, they need to know who you are.

Kensaku Kawamoto – University of Utah – Co-Chair
Well, if folks feel comfortable, this is reasonable. I'm okay with not weakening it.

David McCallie – Cerner – ISP Task Force Member
I think the clinical concern you might have about bypassing the ordering clinician is whether the results will be understood in the context of what the clinician was working on. That's an old argument that may seem patronizing to some, but it is the basis behind some of the state regulations around delays in releasing of results. So, it's not totally clear to me that there's a net advantage of going directly to the source as opposed to the ordering clinician.

Kensaku Kawamoto – University of Utah – Co-Chair

Should we just add that comment "as allowed by state law"?

Steven Lane – Sutter Health – Co-Chair
Sure, that's fine.

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
By specifying APIs, are you eliminating other possible mechanisms, or is that…?

Kensaku Kawamoto – University of Utah – Co-Chair
I don't think we're saying you can't, we're just saying we… There's nothing that says you may not use another method of providing data, so I think this is just saying – we're basically saying as a floor, you must provide API data.

Steven Lane – Sutter Health – Co-Chair
Okay. I added "state laws." Okay, let's go on. The next recommendation was to – and again, we've added "encourage and eventually require the use of standard, patient-friendly order and result display names to the patient based on LOINC standards that are already being developed." And, Sasha made the comment that she just wanted to add the "encourage" or "suggest adoption," so we weakened that language a bit, but again, this is getting at the patient-friendly names. Any concerns about that?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Sounds okay.

Steven Lane – Sutter Health – Co-Chair
Great. All right. We do want to pick up the pace as best we can here. The next one is the recommendation to align state and federal policies to ensure consistent and predictable data accessibility to patients, beginning with the development of a catalog of varying state and territorial requirements, followed by specification and promulgation of national standards to promote maximal data-sharing with patients in both human- and machine-readable formats. Any concerns about that? Great, all right. We got through that. I'm very excited by that, so I'm just going to standardize all that display, and we will move on.

The next is an addition, which came to us related to the practical experience of vendors that are trying to exchange this data, highlighting that there is currently no standard way to differentiate the type of result sent in a CCDA document. So, this is CCDA-specific as opposed to dealing with FHIR, but the recommendation is if CCDA specifications were – or, the observation, really – if the specifications could differentiate different types of results, vendors could better integrate outside data into the chart, and the specific recommendation to make an expansion in the CCDA standard in order to include result types, and then, the comment here that – and, this is really a question for those of you who know more about FHIR than I do – whether this is already included in the FHIR spec or whether it's worth identifying that as a potential need as well.

Clement McDonald – National Library of Medicine – ISP Task Force Member
FHIR does have a result type, though I don't know that it's obligatory at the present time. I think it's optional.

Steven Lane – Sutter Health – Co-Chair

Okay. So, we can say "ensure that the FHIR spec include and require an exchange of result type metadata."

David McCallie – Cerner – ISP Task Force Member
Some of this is the kind of work best left to the low-level experts that understand the space as to what should be required or not. I'd be leery of getting that detailed in our recommendation here.

Kensaku Kawamoto – University of Utah – Co-Chair
Yeah, USCOR has categories of required items, so I don't really think we need to touch this in FHIR.

David McCallie – Cerner – ISP Task Force Member
What would happen is people would just have a type called "unknown," and you could put in there "unknown." There are workarounds, but we're getting too detailed for our level of subject matter expertise here.

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
I think that's fair.

Steven Lane – Sutter Health – Co-Chair
So, are we comfortable with this as it exists here?

David McCallie – Cerner – ISP Task Force Member
My perspective is if you properly identify at the granular level what the result is, you can easily infer the type from it.

Steven Lane – Sutter Health – Co-Chair
Well, what we've found is that that's not happening.

Clement McDonald – National Library of Medicine – ISP Task Force Member
It's pretty junky now, so I don't know if we should think of that as a guide. He's right. If you've got an exact code for it, you can work it up to what it really is. I think the real problem with CCDA is the problem of this "no unique identifier" results. So, you get six of them from different places –

Steven Lane – Sutter Health – Co-Chair
We've got that in another spot, Clem.

David McCallie – Cerner – ISP Task Force Member
I'm totally comfortable with the spirit of this. It's just a level more of detail than what might be warranted by our level of research on the subject. But, just so people know what they are, for sure.

Steven Lane – Sutter Health – Co-Chair
Does anyone object to including this in our recommendations as it stands here?

Clement McDonald – National Library of Medicine – ISP Task Force Member
No.

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
That's fine.

David McCallie – Cerner – ISP Task Force Member
I'm okay with it.

Steven Lane – Sutter Health – Co-Chair
Great. Thank you so much. The next one is similar, based on the observation – again, we may be down in the weeds, but I think of real value is the notion that when they come in the CCDA and are exchanged between vendors, results are not grouped by procedure, and that makes it difficult for receiving systems to be able to present those. So, the suggestion is that result components be grouped by procedure to keep the context together. Again, it's rather down in the weeds, but it's something that's missing at this point.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think that's well stated.

Kensaku Kawamoto – University of Utah – Co-Chair
Is this referring to a CBC and its components, or something else?

Steven Lane – Sutter Health – Co-Chair
Yes, precisely.

Kensaku Kawamoto – University of Utah – Co-Chair
Is that usually considered a procedure?

David McCallie – Cerner – ISP Task Force Member
Yeah, that's very ambiguous language.

Kensaku Kawamoto – University of Utah – Co-Chair
Maybe it should be grouped by ordered item, or something like that.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I don't think I'd include it. We should start over. What are we trying to do?

Steven Lane – Sutter Health – Co-Chair
I believe what this is saying is don't send the sodium, potassium, and creatinine separately if it all came from a CHEM-7. I think that's what it's saying.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, but is that for human visibility or computer use?

Steven Lane – Sutter Health – Co-Chair
It's really both.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think it's off target. If it's coded right, you could put them all together anyway.

David McCallie – Cerner – ISP Task Force Member

I think some of us would argue if you have a proper timestamp and the proper code, it shouldn't matter what else was drawn in the same tube.

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

David McCallie – Cerner – ISP Task Force Member
It may be a deficit in your display system if it's not able to line things up properly by drawn date and time. I'm not sure requiring the way it was drawn or the way it was ordered is relevant to interpreting the results.

Steven Lane – Sutter Health – Co-Chair
All right. Any other thoughts? Otherwise, we'll just remove this.

Kensaku Kawamoto – University of Utah – Co-Chair
I can see how this could be useful. I'm a little torn on it. Of course, you could recreate all this, but it'd be much easier if the sending source would group it for you. It's easier to just walk through the components rather than recreate the grouping.

Clement McDonald – National Library of Medicine – ISP Task Force Member
But, who are we serving and who's reading CCDAs today?

Steven Lane – Sutter Health – Co-Chair
Patients and providers.

Sasha TerMaat – EPIC – ISP Task Force Member
This feedback comes from providers about studies we've done with some of our users about how to make interoperable documents more useful, and certainly, there's plenty you can do with date and time filtering, but that has not totally satisfied provider feedback in our experience, and they would like to see a grouping by how it was ordered for their own human interpretation. So, I think if the group feels this isn't a priority – obviously, we're trying to put together priorities – I'm comfortable with removing it and focusing on other places, but the backdrop of this was provider feedback to improve usability, so that might give it some background context.

David McCallie – Cerner – ISP Task Force Member
Sasha, does the CDA permit the grouping and people just don't take advantage of it, or is it a question of just changing the CDA spec to permit the grouping?

Sasha TerMaat – EPIC – ISP Task Force Member
That's a great question, and we'd need a CDA expert. My impression is that it permits but does not require it.

David McCallie – Cerner – ISP Task Force Member
Which would be my guess as well, and what we're then talking about is encouraging the group that produced the CCDA to preserve any grouping information they have.

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

Well, if we specified it as orderable, but I'm not sure the orders are put in the same place in CCDA. Are they? Do you start with an order?

Sasha TerMaat – EPIC – ISP Task Force Member
No, orders are separate, but within the section on results, I guess there's interest in some amount of grouping by orders, which are actually in a separate section.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, it seems like someone else should be deciding this. We don't know enough.

Steven Lane – Sutter Health – Co-Chair
Okay.

David McCallie – Cerner – ISP Task Force Member
I think we would agree it's not a regulatory or policy issue.

Steven Lane – Sutter Health – Co-Chair
So, it sounds like we have consensus that it doesn't really belong here. So, unless somebody objects, I'll take this one out.

Kensaku Kawamoto – University of Utah – Co-Chair
The regulatory policy issue might be to recommend convening stakeholders using the CCDA data exchange to identify enhancements that should be made, given that CCDA is going to stick around for a while. That would be the recommendation, right?

David McCallie – Cerner – ISP Task Force Member
And, ONC is aggressively supporting improvements to the quality of CCDAs. That is an appropriate ONC activity, and it is underway, and HL7, Commonwell, and Carequality are all participating in that effort. It's at a higher level than this one. I think it's more focused on what kinds of clinical content should be in the CCDA, what ties to encounters, and what ties to current summaries. There's a lot of work being done in that space already. So, maybe the policy thought here is just to encourage work to improve the readability and clinical content of the CCDA, like Ken just suggested, as a broad principle.

Sasha TerMaat – EPIC – ISP Task Force Member
That seems to be the driver for what is in Row 5, and potentially some of these other rows. A lot of them are aimed at that same goal of, in the current state, what are relatively small things the system could do to improve the clinician experience or patient experience.

David McCallie – Cerner – ISP Task Force Member
To improve the consistency, quality, and readability of CCDAs.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, if these things will take three or four years, will it matter?

David McCallie – Cerner – ISP Task Force Member
Clem, everything in this space takes three or four years.

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

That's my point. Something else might supplant it in that time frame.

David McCallie – Cerner – ISP Task Force Member
Yeah, look at X-12.

Steven Lane – Sutter Health – Co-Chair
All right. So, I've made some changes based on the comments that I've been hearing. Do we feel comfortable with this? Should we make these Priority 2, perhaps? Would that be appropriate?

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

David McCallie – Cerner – ISP Task Force Member
I like your language.

Steven Lane – Sutter Health – Co-Chair
Okay. So, we'll move those down to Priority 2 and leave them as specified here. We're comfortable with that. All right. The next one was a Priority 2, and there was a suggestion to move it up to a Priority 1: The need for standard interoperable methodology to specify what has been ordered and what is the status of an order. And then, we had some recommendations, one of which was advised to remove. Again, here, we have all orderables and requiring order status as a piece of metadata. Any concerns about this? There wasn't a lot of discussion, but I just wanted to finalize this.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Why did we take out the coding? Again, you're just going to get a pile of stuff you can't organize if you don't have a code on it.

Steven Lane – Sutter Health – Co-Chair
I don't recall why that was advised to remove. We could certainly leave that in if it –

Clement McDonald – National Library of Medicine – ISP Task Force Member
It's not very severe. It's "priority orderables." SNOMED results shouldn't be in orders, so I don't know if SNOMED is relevant there.

David McCallie – Cerner – ISP Task Force Member
Can someone remind me what problem we're trying to solve with this one? Who is this targeted at? Who is consuming this?

Steven Lane – Sutter Health – Co-Chair
The problem is that you place an order in one system, and the fact that an order has been placed or that an order is in a status of pending or in process – the status of the order – that information is not interoperable at the moment.

David McCallie – Cerner – ISP Task Force Member
It is, though, isn't it? HL7 supports it.

Steven Lane – Sutter Health – Co-Chair

If I look across to another system, I don't know what orders have been placed. I only know what orders have been resulted.

Sasha TerMaat – EPIC – ISP Task Force Member
Steven, are we talking about labs in particular? I would think that some of the upcoming procedure things would say that there is a scheduled lab or a forthcoming procedure where the order was placed, but it hasn't happened yet.

Steven Lane – Sutter Health – Co-Chair
I think you're right. In some cases, if someone is scheduled for a colonoscopy, that might be available, but the fact that somebody has already had a PET scan ordered or a set of labs ordered – this is what was raised when we went through this the first time. Ken, I'm pretty sure you were part of bringing this forward.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Part of the problem is a provider doesn't know he should be looking for results if he doesn't know what's ordered from another place.

Steven Lane – Sutter Health – Co-Chair
Or doesn't know that someone else has already taken care of something.

David McCallie – Cerner – ISP Task Force Member
But, this is in the context of connecting to a system from the outside or something, because within the system, obviously, you see clearly what's been ordered.

Steven Lane – Sutter Health – Co-Chair
Absolutely. No, this is about the interoperable nature of data regarding what has been ordered. And again, we had originally had this as a Priority 2. Somebody suggested bumping it up to 1, but we could certainly leave it as a 2. It sounds like it's a bit more future-focused.

David McCallie – Cerner – ISP Task Force Member
I'm not clear what the gaps are here.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, I don't think the LOI standard has been strongly supported yet, right?

David McCallie – Cerner – ISP Task Force Member
But, LOI would not be used to look into another system.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, it has the content that could be delivered to somebody.

David McCallie – Cerner – ISP Task Force Member
Right, and that can be done today. If you get an HL7 feed from another system, it can absolutely communicate orders pending review, verified, corrected – those statuses are all communicated with HL7. But, you have to be a subscriber to the stream. This sounds like you're querying in through APIs or something, in which case I think FHIR APIs would support this. It just seems like a functional requirement, not a standards gap.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, I don't think you can easily find orders from other systems at the present time.

Steven Lane – Sutter Health – Co-Chair
I don't, either. I have no way of getting this data today, whether it's via a FHIR query, via a direct message – again, unless you have an established HL7 interface.

Clement McDonald – National Library of Medicine – ISP Task Force Member
It doesn't seem horrible to ask for it.

David McCallie – Cerner – ISP Task Force Member
Yeah, but I think what's more of a gap is you don't have a good, standard way to peek into another system and get the status of a patient in another system. A real-time query into another system is not something that's widely supported, right? We support APIs with finished products that are generated via messages that are sent out or CCDAs that are produced, but the gap here is what's the way that you could peer into another system and see the chart in its live state? That's a much bigger problem than just seeing order status.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Are you against this one? It doesn't seem that offensive to me.

David McCallie – Cerner – ISP Task Force Member
It seems like a BB gun shooting at a random target.

Steven Lane – Sutter Health – Co-Chair
As a clinician, David, I would disagree. As a clinician, it's important for me to know what has been ordered and pending in another system.

David McCallie – Cerner – ISP Task Force Member
I just think there's a bigger gap than this specific thing. So, the ability to see into another system and see the complete status of the workup of a patient, which could include orders –

Steven Lane – Sutter Health – Co-Chair
But, we're just talking about results and orders. That's the scope of these recommendations. So, we're not going to try to boil the ocean. Do you object to including this as a second-priority item?

David McCallie – Cerner – ISP Task Force Member
No, not unless anyone else does. If I'm not expressing my concern, I'm fine to withdraw it. That's good. Let's move on.

Steven Lane – Sutter Health – Co-Chair
Anyone else? Great. All right. Sorry, I don't mean to be harsh, I just want to get through our work.

Clement McDonald – National Library of Medicine – ISP Task Force Member
You're doing a good job, Steve. Keep pushing.

Steven Lane – Sutter Health – Co-Chair

The next one was another suggestion, and this really relates to what we talked about above. Above, we were very clear to state that we wanted all of these results to be mapped to SNOMED, LOINC, et cetera, but what we've heard back again from some of the users and vendors is that that's not quite enough, that the current coding is not quite sufficient to get us to where we want to be, and that there are additional needs where we have these many-to-one and one-to-many relationships. So, this is a general Priority 2 suggestion to create a means of interpreting different codes and information available so that when received, they can be uniquely identified. This is adding a greater level of granularity than is today available through LOINC, SNOMED, and CPT.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think this is confused. CPT is clearly not always granular. The criticism of LOINC is that it's too granular, and SNOMED and LOINC work in different spaces. So, unless someone wants to put them together in the same space, I think this is ill-defined. There are always criticisms that will apply in this space. It'd be better – who asked for it? We need a clearer, more specific thing that they're complaining about.

Steven Lane – Sutter Health – Co-Chair
I've been involved in a lot of these discussions, and it really has to do with the ability to exchange data, whether you're talking about within a single-vendor system or a cross-vendor system. This has come up in the Carequality/Commonwell context as well, that even if you have consistent LOINC and SNOMED coding of the results and result components, as we've said, because of different methodologies and machines, you cannot consistently uniquely identify which result components should map together.

This is simply an acknowledgement that that granularity – again, some people say things are too granular, but as they exist today, they still aren't working to allow us to say that this serum sodium and this urine sodium are truly two different things, or this methodology – you might have organizations using the same LOINC and CPT codes to actually map two different things, and what we have today is a situation where you need individual, laboratory, and clinical subject matter experts holding things up and determining them. You can't fully rely on the current metadata.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, I think you could criticize any individual code, but CPT and LOINC shouldn't go together. They really have different purposes. If you look – there are maybe 2,000 CPT lab codes, and you might have to put them in five times to represent one test. They're just not mixable. So, I think a criticism on LOINC would be fair, but I don't know how to mix CPT and LOINC, or if you're trying to, you don't understand what they really say.

Steven Lane – Sutter Health – Co-Chair
A good example on the CPT problem, Clem, is that in my organization, we might have four different MRIs that all map to the same CPT. The CPT itself does not fully clarify the specificity of the ordered test.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, but the LOINC and RSNA codes are very granular. CPT is just not going to cut it.

David McCallie – Cerner – ISP Task Force Member

And, CPT is used to group them for billing. It has no real clinical validity. Unfortunately, we're stuck with it in some cases.

Steven Lane – Sutter Health – Co-Chair
Sasha, do you want to comment on this at all?

Sasha TerMaat – EPIC – ISP Task Force Member
I have a suggestion. I think that the goal for this – the recommendation, in a sense – would be the same one we talked about earlier, which is ongoing work on improving the usability of current exchange. One of the weaknesses of current exchange today is sometimes we use code sets which are nonequivalent at different healthcare organizations or insufficiently granular. I think there is a lot of opportunity for people who are deeper into exactly how to fix it than we are to discuss, but it does sound like even from the comments we've just heard, there is general consensus that there is a problem that affects the usability of order and results interoperability, it's just that we're not in a position to clearly dictate what exactly the fix should be right now, and I don't think that's this group's role, anyway.

David McCallie – Cerner – ISP Task Force Member
My concern is that these code sets – certainly, SNOMED and LOINC are extremely granular, and the problem we run into is how to lump them back together. For example, how can you line them up on a flowsheet when they're coded with granular differences? It may not be clinically relevant. The problem is they're relevant to somebody – to the pathologist, to the person that runs the lab – somebody wants to see them separated, which is why they are highly granular LOINC codes. The difficulty is in grouping them back together. Now, CPT is a different problem because it's a grouper code set – grouping for billing. It's not intended for granular clinical use. So, I think this is a really tough space, and it's not simply that they're not granular enough.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think what would really be helpful – since some of the critics are people who want something to happen which probably isn't physically possible, there really should be some concrete specifics to fix it. I know there are problems at LOINC, but it's not related to CPT. You can't map it. We've tried to.

David McCallie – Cerner – ISP Task Force Member
Each of these code sets has different problems, but to lump them together is confusing. CPT has a completely set of problems than LOINC, which has a different set of problems from SNOMED, and solutions are going to be very different in the three spaces. So, I agree with Sasha's high-level thought that these are all about improving readability and usability of the results, but the actions necessary are going to be quite different for each of these three domains.

Sasha TerMaat – EPIC – ISP Task Force Member
I don't think we need to get too fixated on the three examples that are listed. Those are ones that my coworkers had listed as particular examples, but it's not intended to imply that those have the same problems, or that the fixes all have to be approached similarly, or even that those problems are limited to those three code sets. So, maybe we should just cut the EC, avoid some of the swirl that's coming from that, and focus on – the consensus I'm hearing is that there are improvements to be gained from working on the code sets in terms of, in some cases, making them more granular and able to be expressed, and in other cases, providing better mapping and consistency for clinician experience when the code sets are more granular.

Clement McDonald – National Library of Medicine – ISP Task Force Member
It's really helpful – when you get feedback, you get more specifics, like mapping of what to what, and in what context? Some of these things are very vague, and it's hard to deal with them.

Sasha TerMaat – EPIC – ISP Task Force Member
Clem, we have more specifics, and I just didn't think that was the right place to try to summarize work that we've done for many years into a couple pages. I don't think this group can solve it specifically. It has to go to other experts.

David McCallie – Cerner – ISP Task Force Member
But, the overall goal is readability and usability of the clinical information, so it should be codified at an appropriately granular level to be accurate, but also groupable for clinical readability, and those are both hard problems. A lot of work has been done; a lot of work still needs to be done.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I agree with that.

Steven Lane – Sutter Health – Co-Chair
So, how do you feel about the way I've modified the text here?

Sasha TerMaat – EPIC – ISP Task Force Member
I'm supportive.

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

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

David McCallie – Cerner – ISP Task Force Member
Looks good.

Steven Lane – Sutter Health – Co-Chair
Excellent. All right, let's move on. Sorry, Clem?

Clement McDonald – National Library of Medicine – ISP Task Force Member
You're a magician.

Steven Lane – Sutter Health – Co-Chair
I'm trying. Now, I think we are getting toward the end here, with very few changes in this one. "Need for a standard methodology to integrate external decision support for clinicians, patients, and other stakeholders into the full range of order and results workflows." I'm pretty sure that this – I think most of us agree on this, so there are just some minor changes there in the wording. "Support the advancement of the CDS Hooks standard, support the development of a hook that can be activated or utilized when a provider or patient receives and/or is reviewing a result." It's a pretty granular recommendation, but there it is.

"Support the development and use of standards to determine and display net pricing." We'll obviously be coming back to this. And, "Suggested alternative order information to relevant stakeholders, including organ providers, clinical support staff payers, and patients." So, there's a lot there with regard to external decision support and how it integrates into the orders and results process. Any objections to the suggested changes?

David McCallie – Cerner – ISP Task Force Member
Steven, I would suggest "standards such as CDS Hooks" because I think there will be more than one way to do certain types of external decision support – for example, the prior authorization and the drug pricing may be done with discrete APIs through NCPDP rather than through something like CDS Hooks. The point is that there are multiple standards here. You don't want any more than are necessary, but you might want more than just a single standard.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, I think the NCPDP thing is on its way.

David McCallie – Cerner – ISP Task Force Member
It's in use today in the real world by Cerner, Epic, and probably others.

Steven Lane – Sutter Health – Co-Chair
So, shall I say "such as CDS Hooks and NCPDP"?

David McCallie – Cerner – ISP Task Force Member
Yeah, the "such as" part.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, because NCPDP is very targeted, so they're not equivalent.

David McCallie – Cerner – ISP Task Force Member
No, they're not equivalent. My point is that you may need more than one tool in your toolbox to solve this problem.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Right. Well, maybe the way you originally said it, as "such as," might be the right answer.

Steven Lane – Sutter Health – Co-Chair
I've got that. How do you feel about the text we have here? Do you like it? Great. Next one. Again, this one is "There is a need for standards to support the integration of prior authorization into EHR-based ordering workflows."

Clement McDonald – National Library of Medicine – ISP Task Force Member
Could I just – making CDS Hooks and NCPDP paired – NCPDP is a very hard-coded thing. It's not a general solution. I don't like how that thinks that it is.

Steven Lane – Sutter Health – Co-Chair
Can you suggest alternate language?

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

"General standard sets of CDS Hooks and specific…" No, I don't know how to do it. Sorry. I don't know if you need to mention NCPDP in that context.

David McCallie – Cerner – ISP Task Force Member
The reason it's there, I think, is because of the net pricing and suggested alternative order information – that kind of concreteness – the net pricing is probably not best set uniquely by CDS Hooks.

Clement McDonald – National Library of Medicine – ISP Task Force Member
No, I like it, it just makes them sound like they're alternatives, and they're not.

Steven Lane – Sutter Health – Co-Chair
Okay. Again, I think we're getting a little deep. We're running short on time. So, I'll take it out, Clem. Again, it's just "such as," so I don't want to upset anything. We've got a few more to go here – that's curious. Oh, this is the one that others have worked on. But, I am sensitive to the time. I think we are committed to open to public comment at this point, so let's do that and see if there's any, and if not, we will come back and keep going.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thanks, Steven. It looks like we're at a breaking point. Operator, can we please open the line for public comment? Let me just take a couple of seconds here to pull up the phone number. While we're doing that, I just wanted to confirm – I saw that Les Lenert has joined us online, but have any other members joined us since the top of the call that did not acknowledge themselves? Okay, great.

Steven Lane – Sutter Health – Co-Chair
Les, hopefully, you'll still be here after public comment and we can ask you to provide your prioritization of your five topics.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thank you. Okay, operator, can you please open the public line?

Operator
Yes, thank you. 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. 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 *.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thank you. I just wanted to mention – Les, are you on audio, by chance? Okay. If not, if you want to provide your prioritization, you can also do that in the comment feature. Operator, do we have any commenters in the queue at this time?

Operator
No commenters at this time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Okay. I will give back about 12 minutes to our co-chairs.

Steven Lane – Sutter Health – Co-Chair

Great. Let's make full use of the time. If I can re-share my screen – I don't see the "share your screen" button. There we go. Thank you so much. I'll go back to where we were and pick up where we left off, which is another recommendation – or, the observation that "There is a need for standards to support the integration of prior authorization into EHR-based ordering workflows, the need for a standard methodology to integrate external decision support for clinicians, patients, and stakeholders into the full range of orders and results workflows." Sasha said, "I agree. There are multiple effort underway. Not certain it's essential to standardize all of these use cases to a single approach. Reusing similar approach where useful certainly makes sense, but certain of these use cases might require unique approaches." It's a good point. So, it may not be a single standard methodology that is needed, so perhaps we should expand that.

David McCallie – Cerner – ISP Task Force Member
I think the "such as" approach that we took above might be appropriate here – "appropriate standards as necessary to integrate" or something like that. There could certainly be more than one.

Steven Lane – Sutter Health – Co-Chair
Okay. So, I just changed it to a plural. How do you feel about that? "Standard methodologies."

David McCallie – Cerner – ISP Task Force Member
Yeah.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Ken, what's your thought on that?

David McCallie – Cerner – ISP Task Force Member
Ken may have had to leave.

Steven Lane – Sutter Health – Co-Chair
Yes, Ken did have to leave. Unfortunately, we're on our own here. Sasha, does that satisfy your concern?

Sasha TerMaat – EPIC – ISP Task Force Member
It does, yes. Thank you.

Steven Lane – Sutter Health – Co-Chair
Okay, great. There was another suggestion that came from Epic about provenance metadata. We actually had this, but I separated it. We had **[audio cuts out] [01:18:52]** and reference IDs in one line, and I separated them into two for your consideration. So, this is pretty much what we had before. We're not getting sufficient provenance metadata to understand the source of the data, and this was simply to say that that should be required. I think we're all aware that this has been added in the USCDI. Jack did include a comment. "Should the provenance data include device information?" I think we did capture that above, so I think that was where this came from. Jack, I think we handled that.

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think the request in the first column is good. I think we've made it too complicated. It's really a unique instance identifier for the results, and it really screws things up that you don't have it, and it also applies to prescriptions and things. But, I think it's gotten really big. I don't know if you have to say as much as we said, but again, I'm not good at refactoring.

Steven Lane – Sutter Health – Co-Chair
Again, we're talking here specifically about orders and results, and the recommendations are that provenance metadata should be required when these results are shared – and again, that's already been suggested in USCDI – and that the provenance data inclusion should be independent of the transport link. So, does anyone object to the way that we have phrased this?

Clement McDonald – National Library of Medicine – ISP Task Force Member
I guess I was looking at Row 12. That's the one I was concerned about.

Steven Lane – Sutter Health – Co-Chair
Okay, we'll get there in a sec. I separated out of the reference IDs. So then, reference IDs made it into its own category because we added a little bit more detail here. Many vendors do not consistently send unique reference IDs for discrete results data. This makes it difficult to identify and accurately update data previously received, and the recommendation, then, is that all systems – and again, we had this before, we just fleshed this out a bit – "All systems should generate, use, and send unique reference IDs" – David, this was originally your idea – "for all orders, procedures, and result components, require interoperability of the reference ID metadata with orders and results such that the receiving systems can recognize a specific order or result as having been received previously.

If the received data represents an update, the receiving system should be able to identify and addend the earlier version. Internal identifiers must not change over the life cycle of an order or result, and the internal identifier data should again be independent of the transport mechanism," as we noted above. So, again, this is a slight expansion of David's original recommendation, and since we hadn't considered this as a group, I wanted to make sure we didn't have any further input on this.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, it seems like Bullets 2 and 3 are excessive, and they just say the same thing. They're just explanatory. I think it'll impede getting it done.

David McCallie – Cerner – ISP Task Force Member
I think 11 and 12 are essentially the same.

Steven Lane – Sutter Health – Co-Chair
Well, provenance and discrete identifiers are really different things, which is why I separated them. You did have them together initially, David. So, I appreciate that you think they're the same thing, but I don't, so that's why I put them on two lines.

David McCallie – Cerner – ISP Task Force Member
Provenance is a superset, and provenance would include the reference ID. I'm not sure what your point is, Steven. What were you worried about?

Steven Lane – Sutter Health – Co-Chair
I think of provenance as being the source of the data. The reference ID is down in the weeds of the individual results and their stability over time. That's all.

David McCallie – Cerner – ISP Task Force Member

Yeah, but provenance is not only the source, it would include the unique identifier, and to some people, it would include every person that has touched it or seen it along the way. It's a complex topic to define what provenance is, but I certainly think it would include reference IDs. So, I don't mind having these separate, but I think they are substantially saying the same thing.

Clement McDonald – National Library of Medicine – ISP Task Force Member
My position was to extend Item 12 to make it clear what's got to be done. The other things are just reasons for doing it, and I think it's got to be –

David McCallie – Cerner – ISP Task Force Member
They're still requirements.

Clement McDonald – National Library of Medicine – ISP Task Force Member
The other thing is a persistent ID, because people can always send another ID out each time they send them, but it's not what you want.

Steven Lane – Sutter Health – Co-Chair
So, that second sub-bullet – "The internal identifiers must not change over the lifecycle" – that's the idea of persistence, right?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, okay.

David McCallie – Cerner – ISP Task Force Member
And, that's necessary for provenance tracking. You know where it came from.

Steven Lane – Sutter Health – Co-Chair
Yes. So, Clem, you were suggesting that the first sub-bullet, "If received data represents an update," is unnecessary? Is that your suggestion?

Clement McDonald – National Library of Medicine – ISP Task Force Member
I think the next two are true – they're not wrong. It's just that it makes it too much to read to get to the point. If you get the identifiers and treat them right – you're saying the next two bullets explain why you'd like them, but I don't know if that's helpful.

Steven Lane – Sutter Health – Co-Chair
Are you suggesting removing the red text here?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, I'm not sure – it's the one above.

Steven Lane – Sutter Health – Co-Chair
Just the first one.

Clement McDonald – National Library of Medicine – ISP Task Force Member
No, the first and second. These are the second and third.

David McCallie – Cerner – ISP Task Force Member

Clem, I think these are just requirements that we're trying to solve for. These are problems that we're trying to address. Enumerating them or not – I don't really care, but…

Clement McDonald – National Library of Medicine – ISP Task Force Member
Well, what happens is you get a big pile of text, and people don't pay attention.

Steven Lane – Sutter Health – Co-Chair
So, I'll take out this red one here, Clem. Is that your thought?

Clement McDonald – National Library of Medicine – ISP Task Force Member
That'll simplify it.

Steven Lane – Sutter Health – Co-Chair
Okay. Any objection to this as it stands?

Clement McDonald – National Library of Medicine – ISP Task Force Member
No. That's mana from heaven.

Steven Lane – Sutter Health – Co-Chair
Okay, that's great. All right. Let's see. We've got a few more minutes. We may be able to get through one more – oh, okay. So, this is actually the big one where we got some very useful input from one of our task force members, which was really meant to simply clarify. Victor, are you still on the phone? Can you provide a little context here?

Victor Lee – Clinical Architecture – ISP Task Force Member
Yeah, I just wanted to flesh out some details around our recommendations. I agree with the problem in Column B. So, the recommendations – I just wanted to add a little bit of meat on the bones.

Steven Lane – Sutter Health – Co-Chair
But, I don't think you changed the actual recommendations themselves so much as provided clarification, correct?

Victor Lee – Clinical Architecture – ISP Task Force Member
Right, because I think the original recommendations had broad brush strokes, and I feel like in some cases, there are pretty good standards that we can use for orderables. For medication orders, I think RxNorm generally does a pretty good job, but where we're missing some standards is perhaps in medication order details. A lot of things aren't actually truly coded terminologies, and so, it makes interoperability of that a little bit more challenging. I don't know if it makes sense just to let the group read what's on the screen rather than me insulting everyone's intelligence.

Steven Lane – Sutter Health – Co-Chair
And, it's hard to get it all on the screen. I'm going to see if I can shrink a little bit. We are almost at time, but I think we actually have a chance to get through this. I'm just shrinking this down. Actually, given the time – again, I think this is really just improved wording, so I doubt that we're going to have objections. If people are comfortable, I will wordsmith this, and we can send it around with the notes.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Just be aware that shrinking it down makes it invisible.

Steven Lane – Sutter Health – Co-Chair
Sorry about that, Clem. I don't know if that helps. There is one more – in the last minute and a half, I want to see if we can just – this is another one that David suggested that I thought was quite useful. "Results and other externally sourced observations may pass through many systems, including consumer and unregulated vendor-controlled systems where tampering or other data modification may occur." The recommendation was to explore the value of digital signatures on appropriate order and results data that would allow the originating system to be confirmed and the values to be verified. Jack commented that he thought this was super important, and Tamer agreed. So, again, we haven't talked about this in great detail, but I wanted to give people a chance to say whether they're comfortable including this. Any objections?

Clement McDonald – National Library of Medicine – ISP Task Force Member
I like it. I think it's a go.

Steven Lane – Sutter Health – Co-Chair
Hearing no objections, we will add that to the list. If everyone's comfortable, I will work with Victor to refine this language here, and we will consider this a wrap.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Thank you, Steve.

Steven Lane – Sutter Health – Co-Chair
Thank you all so much. We are going to be hosting – or, Cerner will be hosting – a face-to-face opportunity to get together at HIMSS next week. Thank you very much, David, for making that happen, and others for supporting that. We will be meeting again as a group on the 19th in two weeks to do a similar freshening of our recommendations around close of referrals and care coordination, and then we will meet again on the 26th to jump into the meds and pharmacy data domain.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Hey, Steve? If someone can't be at HIMSS, is that something that's important to get on the Compass call, or is it not going to deal with –

Steven Lane – Sutter Health – Co-Chair
No, it's meant to be a meet and greet and a chat opportunity as opposed to a formal meeting of the task force.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Okay, thank you.

Steven Lane – Sutter Health – Co-Chair
Thank you, everyone, for your participation. Great meeting.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thank you, everyone.

David McCallie – Cerner – ISP Task Force Member
Thanks, Steve.

Sasha TerMaat – EPIC – ISP Task Force Member
Thank you.