Interoperability Standards Priorities (ISP) Task Force

Transcript
February 19, 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
Sheryl Turney	Anthem Blue Cross Blue Shield	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
Carmen Smiley	Office of Technology, ONC	IT Specialist

Transcript

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

Good morning, everyone. Welcome to the ISP task force meeting. This is our second meeting in the month of February here. We have a pretty full agenda today, hoping to wrap up some draft recommendations and start to explore the next topic area that the task force will address. So, with that 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 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 – ISP Task Force Member

Good morning.

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

Arien Malec? Not here? Andy Truscott?

Andrew Truscott – Accenture – ISP Task Force Member

Present.

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

Clem McDonald? Cynthia Fisher?

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member

Yes. Good morning.

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

David McCallie?

David McCallie – Cerner – ISP Task Force Member
Here.

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

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

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

Leslie Lenert – Medical University of South Carolina – ISP Task Force Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Jack Po? Raj Ratwani? Ram Sriram? Ricky Bloomfield.

Ricky Bloomfield – Apple – ISP Task Force Member
Good morning, I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, Ricky. Sasha TerMaat? Not yet? Scott Weingarten? Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – ISP Task Force Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning…Tamer Fakhouri?

Tamer Fakhouri – One Medical – ISP Task Force Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Oh, thank you. Tina Esposito? Not yet? Valerie Grey? And Victor Lee.

Victor Lee – Clinical Architecture – ISP Task Force Member
Yep, here and on mute.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Okay, I will turn over to our co-chairs Ken and Steven.

Arien Malec – Change Healthcare – ISP Task Force Member
Hey, Arien's here. Arien Malec.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Oh. Hi, Arien. Thank you.

Steven Lane – Sutter Health – Co-Chair
Thanks, Arien. Great.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anyone else I missed? Okay. Thanks, everyone, let's circle back.

Steven Lane – Sutter Health – Co-Chair
Well, thank you all for joining us. I wanted to acknowledge that David McCallie and I met at HIMSS last weekend and had a very nice little social hour together. Not too many other people showed up, so that… we were learning on our part, about how that went. I know everyone was very busy during the week, and it is good to be back together again. Lauren, I think we wanted to spend a little bit of time talking about the current plan for the task force. Did you want to go over that, or do you want me to?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure, sure. So, as many of you know, ONC released a proposed rule on 21st Century Cures Act last week. So, we expect to charge the full committee with reviewing the rule and providing their recommendations. So, with that, we are going to pause for a bit on the ISP task force so that the high-tech members on this task force can shift their attention to the rule. When the committee is charged, they'll have about a 60-day comment period. In which case, this task force will resume after that. So, if all goes according to plan, we're looking at perhaps

resuming towards the end of April or first of May.

Steven Lane – Sutter Health – Co-Chair

Perfect. So again, our goal today is really to finalize some of the domain work that we did last year. And then, as time allows, begin the discussion of medication and pharmacy data based on the comments that folks have submitted. The other housekeeping item was Tamer Fakhouri has had a slight change in his position and representation, and we just wanted to give him a chance to mention that.

Tamer Fakhouri – One Medical – ISP Task Force Member

Sure. Thanks, Steven. So, I've joined Livongo Health, which is a digital health company focused on building solutions that empower people with chronic conditions. I'm still continuing to practice primary care at One Medical in San Francisco, so I feel this new position allows me to work on solutions that are highly complementary to the mission of primary care. So, I'm very excited about that.

Steven Lane – Sutter Health – Co-Chair

Thanks, Tamer. We just wanted people to have a chance to know how that change went. Ken, do you have anything to add before we jump into the next task?

Kensaku Kawamoto – University of Utah – Co-Chair

No, that sounds good. We won't meet in this capacity for a while, so let's give as much time as possible.

Steven Lane – Sutter Health – Co-Chair

Great. So, what we're going to be doing is opening up the draft recommendations on closed-loop referrals and care coordination that we have all worked on together. And, unlike the work we did over the last two meetings on the orders and results recommendations, we hear that the edits have been modest, and I'm anticipating that we will go through these pretty quickly. So, I am in the document, hoping that people can see that pretty well. For me it's readable, even on a laptop screen, here in the Adobe Connect. So hopefully everyone can see. I guess Clem is not with us, so he usually keeps us honest in terms of screen resolution. But our first recommendation, you will recall, observes that current referral workloads are inefficient and fail to leverage available interoperability tools, and this leads to increased cost, laze in care, and poor coordination.

So, we have a pretty extensive set of recommendations regarding some of the details of the steps involved in closed-loop referrals. Acknowledging that the 360x project has done a lot of work in this space and has a number of vendors already doing this, based on direct transmission, that we acknowledge that the use cases can be expanded to include prior authorization and request for information. I think a lot of us heard a lot about these use cases at HIMSS, and we made a point about patient identity management and the importance of that. We called out message context as an area where there are conflicting standards that are still evolving, and we encouraged efforts to harmonize or unify those approaches – the addition of the word unified really came from Clem. He didn't like the word harmonized, so

we supplemented that.

And then we all felt that FHIR was an important evolving standard that also should be leveraged, as possible, to support closed-loop referrals, and we called that out, including support for the Argonaut scheduling implementation guide. So those were our recommendations, again, very minor change there. And then we called out some policy levers for both ONC, and then we had the addition of CMS, suggesting alignment of relevant programs to reward activity that improves care through electronic closed-loop referrals. Which we know that they are doing, in fact, through their quality measures. So, not a lot of changes there, but just wanted to make sure that everyone is comfortable with that. Any thoughts or comments before we move onto the next one? If not, let's scroll down. Again, we're just going to be calling out some small changes along the way.

The second one has to do with the collection of the clinical data that is required to – actually if you can scroll down one in the display here, we want to go to the next item. Perfect. All right, great. So, this has to do with standards for collecting the clinical data that should be collected prior to referring a patient. And Terry, I believe, added this text here: This need is also relevant to transitions between care settings, such as from acute to post-acute care – I see I missed a 't' there. And then, on the recommendation, there was really just some minor change in the language here that was suggested: Identify an organization or convenience; support a collaborations development; involve recommendations for what clinical data consulting or receiving providers should be sent in order to optimize efficiency, etc.

Again, just clarifying that the provider receiving a referral isn't always a consultant. It could be from a consultant to a primary care doctor, for example. That happens, too. Or, as we said, from an acute setting to a post-acute care setting, where they wouldn't be really referred to as a consultant. And then, we added again some clarifying language around the standard data elements necessary for collection and transmission, as including those necessary to support prior authorization. And then, on the policy levers, again we called on ONC to convene stakeholders to look at minimal standards for clinical and administrative data required and desirable for clinical referrals, calling out exemplars of CCDA and FHIR, our best friends here, as well as guidance for display of those standards, and then aligning this process with USCDI.

I think most of us are aware that USCDI has had new life breathed into it by the proposed rules that came out last week. We're all very excited about that and look forward on working on that together with ONC. So, any questions or comments about the minor edits that were made in this second observation and recommendation? Sasha found a typo – thank you, you're so good. I hope that was the typo that Sasha found, the one that I fixed. All right. And again, we're just going to keep blowing through these. Again, doubting that much of this is controversial, but wanting to be sure that the final recommendations that come out of our task force that we will be bringing forward in our report to the ONC will reflect the consensus agreement of this group. So, let's go ahead and scroll down to the next one. They get a little bit shorter now, so we'll probably be able to fit more than one on a screen. Perfect.

The next one is talking about clinician to clinician-patient specific messaging, and the fact

that we are lacking for standards to support this very important workflow, especially when it goes beyond the walls of a single institution using a single EHR. We suggested that this be supported and incentivized, including user adoption. We know that a lot of these tools exist. Arien and others have spent years building out the direct protocol and putting them in place, but we know that in reality, it's often not utilized extensively. And then also, again, investigating how FHIR-based approaches could be developed and leveraged to support this important workflow. Any thoughts on that? Great. Now, we will just keep on moving here. These are all priority one recommendations that came out of our earlier work. The next one has to do with the ability to reliably identify and locate providers that don't understand the messaging capabilities...

Kensaku Kawamoto – University of Utah – Co-Chair

Sorry to interrupt, I totally missed it. David raised his hand. Maybe when you're at a good stopping point?

Steven Lane – Sutter Health – Co-Chair

Oh no. No, that's fine. Let's go right ahead. David.

David McCallie – Cerner – ISP Task Force Member

Yeah, I just really, maybe, comment relevant more to the first two points which is I think – and I am not sure this needs to be reflected anywhere else, I just need to say it again; that we should consider our smart app style approach for managing complex referrals. That this notion that you can do it with predefined templates and predefined data exchanges strikes me as unreasonable, and you need a more flexible approach. I made that point in our early discussions, and then we didn't really pursue it, which is fine by me. But I think in the long run, I would call these approaches sort of halfway technologies. They're not going to be sophisticated enough to be flexible. Maybe they're where we should be to get started, but we'll need something more sophisticated in the long run.

Steven Lane – Sutter Health – Co-Chair

I think that's a really good point, David and I do think we have time to add that in, if you like. I am thinking about where it goes, and we've got the closed-loop referral communication in the first instance…

David McCallie – Cerner – ISP Task Force Member

I think where it might fit is in the very first one, which is, I think, line two the spreadsheet. At the very last part in column B, it says FHIR supports provider directories, clinical work for messaging, and could potentially provide an alternate transport mechanism. Maybe it goes there or something; also, consider actual referral management apps that are embedded in the workflow as smart apps.

Steven Lane – Sutter Health – Co-Chair

Okay.

David McCallie – Cerner – ISP Task Force Member

Go ahead.

Steven Lane – Sutter Health – Co-Chair

And let me - Go ahead and just say that again. how would you like to phrase that? I'll see if we can get that in there.

Arien Malec – Change Healthcare – ISP Task Force Member

David, just to be clear, I don't think you are talking about – are you talking about a third-party referral management app? Or are you talking about something like the questionnaire approach that we settled on, where you send the information, but there may be some additional detailed information that you want to capture and send back?

David McCallie – Cerner – ISP Task Force Member

I'm talking about the former. About a third-party referral team management.

Arien Malec – Change Healthcare – ISP Task Force Member

You're talking about a bespoke and referral management app?

David McCallie – Cerner – ISP Task Force Member

Yep. Which has the flexibility to use FHIR to reach into the record to get data that it needs without bothering the clinician, but the ability to interact – update, provide, glimpse back into the history of the conversation and so forth. It's not – it would be a network-based approach. Obviously, the referral management services would be around a network, but that network could be as broad as the VA if you wanted, for example. Or as narrow as would be necessary. Steven, I can send you a snippet. It doesn't look like I can edit this cell.

Steven Lane – Sutter Health – Co-Chair

Here, David. Here, I just popped something in at the bottom of the recommendations in 3C. If we got that displayed – if you can scroll up one level? And we might need to widen the column in order to show on this screen, so let's try that.

David McCallie – Cerner – ISP Task Force Member

I see it, it looks good.

Steven Lane – Sutter Health – Co-Chair

Okay, yeah. So just reading it out to folks, I said, "Explore the use of referral management apps, e.g. using smart technology solutions to support referral management workflows and the associated information exchange."

Kensaku Kawamoto – University of Utah – Co-Chair

That sounds good, and just one thing to add. University of Utah did actually work on ONC-funded – I think it was a High Impact Pilot – to develop a smart app, SMART on FHIR app, for helping with the referral process. I think along the lines of what you were saying, where we

can pull data from the record using FHIR to facilitate gathering and communicating the information without providers having to type it in or whatnot. So anyway, there has been some work on it. Probably the biggest issue we found is that a lot of the data points we needed just were not available in the U.S. Core FHIR profiles. But yes, we tried that, and I think it makes sense, too.

David McCallie – Cerner – ISP Task Force Member

Yeah, Ken, that's great to hear, and I think the advantage of the smart approach is if you can't find the data with a query into the database, you can just ask the clinicians on the screen.

Kensaku Kawamoto – University of Utah – Co-Chair

Yes, absolutely.

David McCallie – Cerner – ISP Task Force Member

And that gives you kind of a flexible fallback. Don't bother the doc if you found what you need, but if you didn't, you can ask a question.

Kensaku Kawamoto – University of Utah – Co-Chair

Yeah, you could even just show the recent, relevant data like the imaging and just ask the user: "Do you want to just click on the ones that you think are most relevant for the person being referred to?" Things like that, rather than, well, you figure out what they are and copy and paste it into the referral.

David McCallie – Cerner – ISP Task Force Member

Right, and then I think maybe some of you saw the paper from Vanderbilt about Wikifying clinical documentation, which is something that I proposed years ago. But you could imagine, these apps actually manage a focused conversation about the referral in a flexible back-and-forth way that doesn't require the complexity of trying to embed specific things in direct messages. Anyway, thanks for capturing that. I will rest my case, un-raise my hand.

Steven Lane – Sutter Health – Co-Chair

Excellent, thank you. Any other comments before we move on? I don't see any hands. And I apologize since I am popping back and forth between applications, I'm a little behind. So thanks, Ken, for calling that out. So we are on row five, where we were discussing provider directories and the recommendation changes that we made that are still here in red, that are – again, trying to flesh this out: to support the development and advancement of a nationwide standard for provider directories and their management; to support referrals and care coordination, including cross-organizational clinical messaging. This should include information regarding – and then we list some key data fields that were identified as being needed. Any thoughts about those additions there? Great.

We then go on our last top priority recommendation which has to do with governance for information sharing, which should enable referral scheduling, among other things. This is a current barrier, we observed that, that DirectTrust and TEFCA, and other governance frameworks exist. And we wanted to recommend that the access to and governance of push

messaging and the associated technical and workflow requirements be included in the scope of the final TEFCA. And again, the only change there was simply adding a little header text. Moving on to the priority-two recommendations. Again, on row eight, simply added the header there, so no substantive change to the text. In row nine, we have the recommendation about patient-to-clinician messaging, which today is primarily supported inside of portals. But there are certainly other opportunities to look at that.

We've made recommendations to support pilots of patient-to-provider messaging using multiple available technology solutions, e.g. direct FHIR, provide flexibility to individual patients to select messaging tools of their choice and to manage messaging with care team members utilizing disparate IT solutions, and to call out the importance of having messaging solutions integrate with established clinician workflows. I think this is all pretty straightforward, but these were additions that were made since the last time we reviewed these. So, any questions or thoughts on these? Ricky, I know that you are on the phone. You and I have had the chance to discuss patient-clinician messaging from the perspective of your employer, which certainly supports a lot of messaging between individuals. I'm just curious how this recommendation kind of jives with your view of the world.

Ricky Bloomfield – Apple – ISP Task Force Member

Obviously, this is a really hard problem, and very workflow dependent. So, I think this recommendation is fine for now. It's going to take a pretty concerted effort with relevant stakeholders to come up with something that's universally useful.

Steven Lane – Sutter Health – Co-Chair

Great, thanks. On row ten, we have an observation regarding… Cynthia?

Sasha TerMaat – EPIC – ISP Task Force Member

Oh sorry, this is Sasha actually.

Steven Lane – Sutter Health – Co-Chair

Oh, great.

Sasha TerMaat – EPIC – ISP Task Force Member

On row nine, are there policy questions open about messaging and its role, for example, in the legal medical record that would also need to be considered?

Steven Lane – Sutter Health – Co-Chair

It's an interesting question. Do you feel that we have challenges there? I know that I use your vendor's product, and patient-provider messaging is considered a part of the legal medical record. I know that there is some confusion out there about people who use email. I don't know how other vendors address that. Do you feel there is a need for us to make a recommendation in that regard?

Sasha TerMaat – EPIC – ISP Task Force Member

It is something that I was under the impression there is not consistency in how folks approach that today. And so, I was wondering as we were investigating larger pilots, if it's not

just a different technology question, but if there's also a sort of policy question of implementation? Perhaps not. Maybe – or maybe that could be solved as part of a piloted technology as well.

Steven Lane – Sutter Health – Co-Chair

Any other thoughts on that?

David McCallie – Cerner – ISP Task Force Member

I just think that at this point, the notion should be that the result of patient-physician secure messaging should be charted or should become a part of the clinical record. In some ways this feels a little bit like a blast from the past, because my company – 15 years ago? 17 years ago? – had pluggable patient messaging that plugged into, among others, EPIC at UC Davis. So, it's not clear that the issues here are primarily technology so much as they're the integrated workflow needs that have been solved through more proprietary approaches to secure messaging. I'm not sure where that comment goes, but I suspect that workflow – physician workflow – and the ability to plug-in third-party applications into that workflow will be the major enabler or impediment to successive, separable patient-physician messaging.

Steven Lane – Sutter Health – Co-Chair

Sasha, and others, what do you think of the line of type I added there at the end: Encourage consistency of policy solutions regarding the inclusion of patient-clinician messaging as a part of the legal medical record?

Sasha TerMaat – EPIC – ISP Task Force Member

That's fine with me, I guess. With the one caveat that I know, if we're really talking about messages like things the patient wrote, more like an email, I think people have different policy feelings about automated messages. Like if you would consider, for example, connecting a device that messages the EHR with maybe large volumes of some sort of step counts, or something. That would, I think, in many clinician's eyes be different. Is that fair?

Steven Lane – Sutter Health – Co-Chair

It is. Would you want to include a caveat about that here?

Sasha TerMaat – EPIC – ISP Task Force Member

Are we specifically thinking of more narrative messaging here and would want to say that just for clarity?

Steven Lane – Sutter Health – Co-Chair

How about something like acknowledging that this may – that these policies may vary…

Kensaku Kawamoto – University of Utah – Co-Chair

We're maybe a little granular?

David McCallie – Cerner – ISP Task Force Member

Can I suggest we are maybe out of our lane? This is a really good discussion for, I think, what's these days called patient-generated health data or device data. And there are definitely a set of issues involved in how much data should be in the chart. That is probably a task for somebody else's worker.

Steven Lane – Sutter Health – Co-Chair

I think that's fair. Again, we really were specific to the messaging. So, I think we can leave it here. Thank you.

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member

Okay, this is Cynthia. Just speaking from the patient perspective, I think it's really important that at 30,000 feet, we really look toward usability and opportunity for two-way dialogue. So, as we look at the world, the movement of open notes, and the ability for that open interaction. I think we can look at – much like in other industries, there are secured dialogues in the apps once you're in, that can enable that empowerment of that voice in two-way, and corrections to a two-way type also on usability for the patient when they need to correct some errors that might be recorded about their health data.

Steven Lane – Sutter Health – Co-Chair

Thanks, Cynthia, and I think that's consistent with what we have here. That's a good point. Alright, sensitive to the time, I want to get through the rest of this. On row… sorry?

Ming Jack Po – Google – ISP Task Force Member

This is Jack. Can I also make one quick point, also on number nine?

Steven Lane – Sutter Health – Co-Chair

Sure.

Ming Jack Po – Google – ISP Task Force Member

Is it possible to say something about making sure that different secure messaging applications have some standards so that they can talk to each other?

Steven Lane – Sutter Health – Co-Chair

Good point.

David McCallie – Cerner – ISP Task Force Member

This is David. I think there's a direct analogy there with the emergence of Direct, which emerged at a time when there were a number of non-connectable secure email systems beginning to penetrate into the industry, and Direct was an attempt to create a unified capability across all of the systems. It ended up becoming the system itself, but I think there is a direct analog here for the secure messaging.

Kensaku Kawamoto – University of Utah – Co-Chair

Yeah, I think right now, even in the hospital I've had to use multiple different secure messaging apps. And I can't even imagine what it would be like to get to the patients, if it's

completely different.

David McCallie – Cerner – ISP Task Force Member

On the other hand, how many airline apps do you have on your smartphone? As many as airlines as you fly.

Kensaku Kawamoto – University of Utah – Co-Chair

I guess this is why we have a problem.

Ming Jack Po – Google – ISP Task Force Member

Yeah. I think it needs attention. I agree.

Steven Lane – Sutter Health – Co-Chair

So, I just added a little text there, Jack, in response, as you can now see on the screen. Dial messaging solutions will integrate with one another as well as with established clinician workflows for portal-based messaging. Does that help?

Ming Jack Po – Google – ISP Task Force Member

Yeah, that looks great. Thank you.

Steven Lane – Sutter Health – Co-Chair

Okay, good. All right. Moving on, minor changes on row 10: standard patient-centric multi-stakeholder multi-institutional care plan is needed. So, the addition of the word patient-centric – Jack, you had a comment there. I feel like this might belong in the general observation section, though this is super important. It seems to be a moon-shot type thing that isn't really bound by technical issues at the moment. I certainly appreciate that comment. We do have it as a level two priority, knowing that it is a bigger lift. I'm not sure, were you uncomfortable with it where it is here?

Ming Jack Po – Google – ISP Task Force Member

No, I just think some of the – a lot of the other priorities seem to be very specific. This just seems to be more general. So, it just strikes me as very different in detail and feasibility.

Steven Lane – Sutter Health – Co-Chair

Okay. Well, unless you specifically object, I think we'll leave it here and leave it as a priority two. In the recommendations, again just a minor textural change, ensure that patient caregiver and family goals and wishes are incorporated into the care plan. Again, a minor change there. On… Yes?

David McCallie – Cerner – ISP Task Force Member

Steven, it's David. I would register the same general observation with respect to interactive care plans as with respect to referral management. That in the long run, we will probably need an app-based approach. The notion that you could exchange static documents to capture the fluidity of an evolving care plan strikes me as profoundly impractical. Or, let's put it this way, practical but useless, because things will change out from under you so quickly. So again, I would make a similar observation that I think just in the long run, we should explore

app-based approaches for managing care plans.

Steven Lane – Sutter Health – Co-Chair

All right, I've captured it, David. Thank you so much. Okay, and on row 11 we refer to real-time text messaging. Here again, a whole body of work which, like Jack, you pointed out in your comments, is fragmented across different services. I think we made that point, both with regard to patient-provider messaging and real-time text messaging, regardless of those who are involved. So, thank you for that. And our recommendation here, again, we just added a single word to try to clarify that a little bit more. So, I really appreciated how carefully folks read these and provided edits. After our recommendations, we had some general observations, which really again, just where we added unification along with harmonization in response to Clem's response. So, those were added on rows 13 and 14 without any other substantive changes having been recommended.

On row 15 – I know I'm speeding up a little bit here – again, we had just some minor editorial changes in the recommendation to the ONC. Not a substantive change, so just calling those out. And then, a bit more changes in the final observation on row 16: that we added this ONC policy lever suggesting convening practicing physicians, HL7, DirectTrust, Argonaut, EHR vendors, and other relevant stakeholders to identify specific use cases that would warrant a standards evolution path to allow optimal functionalities currently available in Direct to potentially also function in FHIR; develop certification criteria and associated CNS programmatic changes to allow a flexible transition to the appropriate use of the FHIR standard where this technology is being superior for given clinical use case.

And again, this is trying to spell out the appropriate path for bringing FHIR into this use case and assuring that that's done in a way that is thoughtful and appropriate. But I think we've all acknowledged how beneficial it would be to move some of this from, or have at least the option of using FHIR in addition to using Direct, as we've seen for some of these workflows. Any comments about any of that? Great.

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

Stephen, this is Terry. Just a really general comment, where does ISPTF go from here, and how does it get institutionalized in the process? Meaning, shouldn't there always be an ISP function somewhere that says here are some upcoming issues that we see in the future, here's how we prioritize them, here's the approach? I am just wondering about institutionalizing this approach.

Steven Lane – Sutter Health – Co-Chair

I think that's a great comment, Terry, and I'll make one response, which is that I think it provides almost a perfect segue to Carmen from the ONC, who's going to be talking to us about the ISA, and how it is evolving and how it has evolved in its most recent annual iteration. Steve Posnack made a comment at HIMSS in one of the early sessions, where he referred to a standing committee or task force focusing on identifying priority uses and use cases, and I actually had a little dialogue with him and it leads subsequently, saying, "Did you mean to say that the ISP task force was going to be a permanent task force?" And he said, "Oh, no, no. You guys have a timeline, you've got a certain set of deliverables that were

specified by 21st Century Cures."

But I think your point is well taken, that reviewing and gaining this kind of stakeholder input into priorities is a critical function. And, as we have said from the beginning, it should occur in coordination with the evolution of USCDI. So, I think that it's a really good point, and we should come back to that with ONC leadership as we gear up the next round of work of USCDI work. All right. Having said that, the next on our agenda is Carmen, who we've asked to do two things for us today. One is just to give us a brief update of the changes that have been made to the ISA in its annual iteration to the 2019 reference edition, and then to begin us on the path of our discussion of medication and pharmacy data, and the standards that exist to support its exchange, to then lead us into a consideration of that topic area.

Carmen Smiley – ONC Office of Technology – IT Specialist

Thank you so much. This is Carmen. I'm an IT specialist in the office of technology at ONC. Next slide, please. Thank you. All right, so updates to the ISA are inspired by primarily public comments. Sometimes it's inspired by rulemaking, including a ruling that affects the ONC Health IT Certification Program, and other factors, such as stakeholder interoperability needs and HHS and ONC mission support. I've highlighted just a few, but not all of the updates that we've made to the e-prescribing ISA over the last year, and those were included in the reference edition ISA for 2019. I'm including the link to the ISA in the chat, if anybody would like to go there to figure out and explore this section as I'm going through it, if I'm unable to provide a live demo.

So, some of the new pages in the ISA that are included in the reference edition include weight-based dosing, especially for pediatric patients, and the prescriber requests to a PDMP twist date. PDMP was built out quite a bit, including emerging standards. And since and although the reference edition was published in January of 2019, there have also been some additional updates since then that will be included in the 2020 edition reference ISA. But as you know, this is a continuously evolving site, and we rely a great deal on public comments, and input from each of you on the call, and all of our stakeholders. And as – next slide, please. One of the new functionalities that were added more recently was actually a specialty care and settings functionality that highlights opioids and pediatric pages that are relevant to those specific use cases.

And the top highlight is where you can actually download the reference edition. And a few other new interoperability needs pages were also added, included one that supports EPCS, the ability for a prescriber to communicate drug administration events, and the ability of a prescriber to communicate with a REMS administrator, and also for the exchange of PDMP data across the PDMP ecosystem. So, as you click on – I'm sorry, forward? There you go. Thank you. If you click on the specialty care and settings button for the opioids, just click on the opioids button, it will highlight a number of interoperability needs pages that are specific to that, or that support opioids efforts, including a number of e-prescribing pages. Next slide, please.

Thank you. And, as was mentioned earlier, the 21st Century Cures NPRM was released, and it inspired additional changes to the e-prescribing pages. And one of the prime changes in the

NPRM is the update of the script – PNCPDP script standard from version 10.6 to 2017071. And as I'm sure that you are aware, CMS finalized their adoption of 2017071 for e-Rx and medical history to be effective January 1st, 2020. Historically, ONC and CMS have harmonized our policies and aligned standards to ensure that the current standard for certification at ONC also permits the use of Part D standards. So, if the new standard will be adopted in our final rule, it will eventually be our new baseline for Health IT Certification.

So, our approach is – actually, next slide, please – we create a new criterion for e-prescribing called B11, and B11 includes all of the transactions that were in B3. Some of them will be built out to accommodate the new standard, and those are highlighted in green. Next slide, please. And as you can see, lots of additional transactions will be included in the criteria, or are proposed to be included in the criteria, and I'd like to just highlight that this includes REMS transactions. And many of you may be aware of REMS transactions coming from the FDA, which is the risk evaluation and mitigation strategies. And the REMS transaction page, or the interoperability needs page, is also tagged for opioids, as they recently updated their opioid analgesic REMS in September 2018. Next slide, please. I apologize this screenshot is so small.

I did just want to highlight that on many of the pages on the ISA, you'll see on the bottom of some of the standards tables, some of the new emerging standards. And even for a new prescription, which has been included in the e-prescribing certification criteria since the 2014 edition, we're now adding more emerging standards that are addressing this specific need. And in the limitations, dependencies, and pre-conditions, you'll see the differences, where there are differences, between script 10.6 and script 2017071.

Again, I encourage you to dig around the electronic prescribing ISA, as well as the ISA overall. We do continue to accept public comment throughout the year and work very hard to incorporate those comments. Sometimes we might have to reach out – thank you. There's my contact information, in case anybody has questions, or has any suggestions for any of the ISA pages. You can also go to the comment section at the bottom of any page to follow that formal process for providing comments. Are there any questions that are specific to e-Rx?

Steven Lane – Sutter Health – Co-Chair

I really thank you for that, Carmen. That was a fast and remarkably detailed discussion, which was very helpful, and I think that has set us up for our discussion. I don't think – has Clem joined us? I don't think that he has.

Kensaku Kawamoto – University of Utah – Co-Chair

I don't think so either.

Steven Lane – Sutter Health – Co-Chair

Clem shared a comment, at least with me. I'm not sure – I don't recall who else was included. That he was really questioning our decision to do a focused cycle on medication and pharmacy data, because he felt that so much progress was being made. I think he's shared with us as a group before that he thinks e-prescribing, EPCS, a lot of these things are going well, that they're more standardized than many other areas in our industry. And that when

you look at the proposed rules and really, the harmonization that is going forward, that his take was that things are moving along well. So, he's not here to represent it, but I think that in some sense he did challenge us to say, were we really right? Were we on target when we identified the meds and pharmacy data area as the one in greatest need of further evaluation by this task force? So, I'll just sort of put that on the table.

We did receive from all of you substantial amount of input into the Google doc that was posted, and perhaps we can bring that up to stimulate our discussion of this area. I still don't have editing capabilities for that document. I can't even change the width of columns to make it fit better on the screen. So, the folks from Excel, can you bring this one up? I can send you, if you don't have it, the link that I have. I'm not going to bother sharing my screen, because…

Kensaku Kawamoto – University of Utah – Co-Chair
Do you want me to share it? I have this on mine.

Steven Lane – Sutter Health – Co-Chair
Yes, if you can. Can you get into it, Ken?

Kensaku Kawamoto – University of Utah – Co-Chair
I can.

Steven Lane – Sutter Health – Co-Chair
And maybe you'll have the editing capabilities that I don't yet have.

Sheryl Turney – Anthem Blue Cross Blue Shield – ISP Task Force Member
It looks like someone is sharing now. Is that the Accel team sharing?

Kensaku Kawamoto – University of Utah – Co-Chair
Oh, is it? Okay. That works too.

Excel Team Member:
Yes, that's us.

Kensaku Kawamoto – University of Utah – Co-Chair
Okay, please. Go ahead and share that then.

Sheryl Turney – Anthem Blue Cross Blue Shield – ISP Task Force Member
Maybe it's just taking a second to load? Are you guys still seeing just where it says, "Share my screen?"

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

Steven Lane – Sutter Health – Co-Chair
Yes, I am.

Accel Team Member:
Yes, give us one moment. Sorry about that.

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member
Yeah, this is Cynthia. I'm having trouble getting into it as well.

Steven Lane – Sutter Health – Co-Chair
Here we go.

Kensaku Kawamoto – University of Utah – Co-Chair
I think it's starting. I see it.

Steven Lane – Sutter Health – Co-Chair
Ah, good. That's the one.

Kensaku Kawamoto – University of Utah – Co-Chair
Maybe we can zoom it in a get a bit.

Steven Lane – Sutter Health – Co-Chair
Ken, do you want to guide us through this segment? Walk through some of the…?

Kensaku Kawamoto – University of Utah – Co-Chair
Yeah. That sounds good. I'm going to just on my end zoom it a little bit. Let me see – change view… I'm going to maximize on my screen, let me know if that causes problems for anyone else. Okay.

Steven Lane – Sutter Health – Co-Chair
Hopefully that did it.

Kensaku Kawamoto – University of Utah – Co-Chair
Okay. So, the first comment was from Clem, and it's basically exactly what Steven just discussed, but let's just say it in his own words. So, we had asked folks to identify issues in this area that they see, and challenges in what needs to be done. He said, "I think this category had the very least needs and should not have been on the list. The current requirement was at least 10U, and CDPD functions to cover almost anything anyone would want. The one new function mentioned by the committee was structured sigs, and that is a bad idea. For declining doses, and other complicated sigs, better to allow – interesting spelling, by the way – allow systems to send prepackaged texts and/or for physicians to type it unstructured.

Sigs will be a big burden on providers, take more time, and better for the pharmacy to read the text than do that complicated structuring. Prior mission is meant to reduce prior burden, not to increase it. Challenge pharmacy is at the most complete attention." And then, he said, "No gaps. MPRM already handles it." So that's Clem's comments. I don't think there's really

anything more to discuss other than he thinks it's well-handled, and he's asking people to please not require physicians to use more structured sigs. Let's move onto the next one. And then maybe – I had some too, but maybe the folks who commented can comment on their own. Terry, can you comment on yours?

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
Yeah, just – I guess this is all use case based. So, structured sigs is sort of a use case beyond what long-term post-acute care and home and community-based services probably need at this point. So, I'm just thinking that more simple, basic use cases, if they're well-established, might be the baseline where we want to achieve rather than excellence to the 99th percent. I'm just – it's really a question of at what level of adequacy are we going to declare victory and move on? So, I think it's a pretty low bar for post-acute care, and perhaps not as high a bar as was established, as Clem alludes to.

Steven Lane – Sutter Health – Co-Chair
You know, it's interesting, Terry, because you call out in your comment dose frequency, time of last administration, kind of the preparation instructions… and to me, that's structured sig. Right? That a structured sig is what allows a computer to actually know how much of what medication a patient is getting at what time, so that things like full reconciliation can be performed. So, my comment, which I shared last time when Clem raised this verbally, is that I'm still a big believer in structured sigs. I think that it allows – it would systems to provide more detailed decision support and alerting that could improve patient safety, that it could substantially improve the efficiency of the refill process, and it's interesting, because you called out issues of ramping doses, and changing doses over time.

And again, at least the EHR vendor that I use now supports all of those in a structured format, in a way that allows providers to specify their preferences for their commonly used sigs, etc. Again, my counter to Clem's and perhaps even your comment is that I think that there are still opportunities here to support these very workflows if we choose to go there.

Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Member
And, sorry, apologies, because I didn't do my homework. But in many cases, the med histories that we're getting back are coming from PBMs, which come off of adjudicated claims data, and don't include any sig information at all, where such information is available from pharmacies. So, I do think even in the area of med history from pharmacy and PBMs for med reconciliation, there are gaps in use of even existing data fields and standards relative to sig information, structured or unstructured.

David McCallie – Cerner – ISP Task Force Member
This is David. I would add, the other distinction that maybe is worth thinking about is the distinction between templated sigs and truly structured sigs. I know a lot of vendors have the ability to create a template – a physician can basically say, "This is the text I want to paste in to describe the tapering dose," or whatever. That's not a structured sig. A structured sig is considerably more complicated.

Steven Lane – Sutter Health – Co-Chair
And structured – maybe the better word is computable, right?

David McCallie – Cerner – ISP Task Force Member

Well, I think it is structured in the sense that the NCPDP message has structured fields that the information has to go into. I think computable is yet another variation. We, for example, and I am sure of many others, have written parsers that can read free text sigs and tease them apart into structured components. So, it's computable in the sense that we can actually write a parser for it, but it's not structured in the sense that it fits into slots and a message defined by NCPDP.

Arien Malec – Change Healthcare – ISP Task Force Member

And again, this is – healthcare is always a power law field. My point being, that right now I don't believe physicians are routinely getting textural unstructured sigs where such exist, because they are getting from the PBM side and not from the pharmacy side. Even when you get into structured sigs, there's a tremendous amount of utility for structured sigs that allow you to compute the total dosing in relatively simple cases, and then very clearly, there are cases of titrating doses of IV drugs, etcetera, that are really complicated, and they get fractally more complicated the further on you go. The point being, there is utility to capture marching up the stack at each level, even if there are some areas that are just too hard that you punt.

David McCallie – Cerner – ISP Task Force Member

Are you arguing for or against structured sig, Arien?

Arien Malec – Change Healthcare – ISP Task Force Member

I'm arguing number one for let's make sure the unstructured sig that exists in pharmacies gets to physicians. Number one. Number two, I'm arguing that as we take on – or if we take on – structured sig, that there's a natural marching order by which there's utility that we can capture taking on structured sig that are relatively less complicated cases. And we don't have to jump to titrations, or tapers, or IV drugs, or some of the other corner cases that are incredibly complicated. We can capture some value and utility in some of the easier cases upfront, as we march down towards some of the fractally more complicated cases.

David McCallie – Cerner – ISP Task Force Member

So, you're arguing for us to program… structured sig?

Steven Lane – Sutter Health – Co-Chair

I think that's a really good point.

Arien Malec – Change Healthcare – ISP Task Force Member

Yep.

Steven Lane – Sutter Health – Co-Chair

Hey, and it may well be that structured sig is really the next frontier. You know, it may be, as Clem says, that so much of this is being taken care of that the proposed rule really covers a lot of what people have been wanting, and that laying out briefly a path forward to – as you said, Arien, bring back the data that does exist in whatever form it is, so that providers can

see that. I think your point about the history data from PBMs and pharmacies is key. And then structuring what can be structured readily, and then moving along that path. Because I think it doesn't sound like there's any disagreement about the potential value for being able to calculate total daily doses and being able to provide some decision support around sig.

Kensaku Kawamoto – University of Utah – Co-Chair

And I suggest – I think we have a dozen of these. Maybe we can do at least a quick pass through all of them and then I'll come back, since we'll be departing from this topic for a while. Maybe – can we move onto the next one? And Victor, I know you may be muted. Please speak up if you want to comment on yours, otherwise we can read it for you.

Victor Lee – Clinical Architecture – ISP Task Force Member

Yeah, hi. Just a quick comment. I think Arien said it best. Just, in my experience, especially working on opioids, is it's very difficult to do for certain calculations. But again, to the extent that it makes sense to either define standards or help people understand where there are standards that are not being used. I think it might be multifactorial. But I think that's – I'll leave it at that. Thank you.

Kensaku Kawamoto – University of Utah – Co-Chair

Thanks, Victor. Okay, and I can't see the hands raised, if anybody has hands up or whatnot, please just raise your voice.

Steven Lane – Sutter Health – Co-Chair

I'll watch for those, Ken. I'll watch for the hands. You can go ahead.

Kensaku Kawamoto – University of Utah – Co-Chair

Okay, thank you. The next few are from me, if you can go down rather than up. I think we are in row four. Okay, I think we skipped a few. I think row four was my next one. Let's see if we can make that one. Or five.

David McCallie – Cerner – ISP Task Force Member

Five is short.

Kensaku Kawamoto – University of Utah – Co-Chair

Five, okay. Perfect. So, I'll just quickly go through these. So, my first comment was on the exchange of prescription medication order data. So, the challenge – so again more information in the medication identity may be needed, such as dose quantity/frequency etc. But, one issue we found was current U.S. Core FHIR protocols don't require the transmittal of even free text sigs, and many meds are prescribed as free text sig only. So, a clearer requirement, I think, is require U.S. Core FHIR profiles to transmit free text sigs. I put this in the last cycle about comments. But it seems if we have a sig, you should send it. It's inadequate for the standards to say even if you have it, you don't actually have to send even the free text sig. We do run into this, for example, in some of our point-of-care opioid use cases where we could parse the free text sig, but it's just not sent, so we just can't provide guidance.

So anyway that's, I think, pretty straightforward. If somebody bothered to write a free text sig or if there is a sig, just require it to be sent as part of the transmission. Row six: med dispense data. I see there's an amendment from David including outpatient mail-order pharmacies, so med dispense data is not universally available, and currently not available in FHIR. So, for example, FHIR has this notion of what has been ordered and what has been patient reported, but in the U.S. Core FHIR profiles, there is no "How do you describe dispense data" such as PDMP data for opioids. So, I think the need here is for U.S. Core FHIR profile for medication dispense. There is a U.S. implementation guide for medication dispense that I think was meant to transition to the CS Core.

Probably the biggest thing looking at that is whether to use NDC and/or RxNorm codes because a lot of dispense data's in term-spend DCs. But a lot of U.S. Core requires RxNorms, so that has to be reconciled, otherwise, every single potential user would need to do those mappings. This would include PDMP data and could leverage existing ONC efforts in this area. And then, of course, share scripts could be a good source, but could miss data not in its network. Talking to folks in different health systems, I think the coverage can range from anywhere from 60 to 95 percent in their local area. For us, it's closer to 60 to 70 percent. Which is great, but you're still missing a bunch if you're relying just on that network.

So, solutions could involve defining the U.S. Core file profile for medication dispense, and then the state PDMP should use that for PDMP data, and Rx dispensing sources should support the profile as well, and EHR should support their use. I comment on people's spelling, but apparently, I can't spell either. So, maybe this could be an area of discussion. I know Ricky, for example, previously had discussed the need for the dispensing sources to provide this data as well. So, I'll pause there and see if anyone has comments on this.

Ricky Bloomfield – Apple – ISP Task Force Member

Ken, this is Ricky. I just have one comment related to the use of NDC versus RxNorm. I don't know that there needs to be a reconciliation there. We could simply ask that they send both and have them do the work on their end. I know in general, for Argonaut, we required one main coding system, but this may be a case where having both, if available, would be much more useful.

Arien Malec – Change Healthcare – ISP Task Force Member

Yes, this is Arien. I would say that having RxNorm in all cases would be much more useful than having NDC in all cases. NDC is in many ways a legacy standard. It's a packaging unit standard that's really intended for tracking of manufacturer packaging units, not really well intended for the use case of, for example, med reconciliation. I would also point out that again, this issue of medication dispense data is in an interesting one, because in many cases the med history that people get through some of the prescribing networks is PBM data, which is really claims data, and only contains the data available in order to justify the claim, which doesn't include, in many cases, the sig. The pharmacies have access to the actual fill and dispense data, and we should also note in many cases, there's a fairly complex workflow pharmacy side where it is important to understand whether the medication's been ordered.

In many cases, the medication's ordered and claimed before the patient picks it up, so it is useful to know what the patient actually came in and picked up, which may or may not map to what comes off of a PBM file. So, and particularly, as the Cures defines provider in a very broad way and requires information exchange access and use from a broad range of providers, including pharmacies, this area of pharmacy fill data and dispense data is a really ripe area for improving patterns of access into full medication history in ways that are really useful for coordination of care.

David McCallie – Cerner – ISP Task Force Member

This is David. I would second that. I think this is the biggest area where we need a systematic approach to as opposed to this kind of piecemeal, cribbed together approaches that we have to live with today. We also have warring standards that will need to be resolved. The pharmaceutical – pharmacy side typically uses NCPDP and some even older arcane standards, and we're talking about FHIR here, which is not in use between pharmacies and PBMs. So, this is an area I think where there's a lot of patient safety, patient adherence, all sorts of opportunities for improving. And it's not a standards problem, there's plenty of standards. It's a system problem.

Kensaku Kawamoto – University of Utah – Co-Chair

Okay. Maybe if I can I'll move on to the next one. Just go down to seven. Okay, so, the need here is to identify whether patients were on a particular drug in the past. The challenge here is one of the core resources available for this is the National Library of Medicines, Rx Nav, and related tools. The issue here is that they don't return RxNorm codes for discontinued drugs, so after about a year after a drug goes off the market it's no longer retrievable. So, for example, this is fine if you say "Hey, has the patient been on this drug over the past year?" But if you want to say, "Hey, has the patient ever received, say, chemotherapeutic drugs, or other medications?" and it's now off the market, you could have issues where you erroneously think the patient has not been on it. It's just a known issue.

The gap to fill is to support pulling of archived RxNorm codes in the National Library of Medicine, Rx Nav APIs, and NLM is aware. So, I think this is just a matter of resourcing, so the solution here would be to fund NLM to get this work completed. I don't think – I'm not sure how many folks realize, using this resource, that this is a hole. I ran into it when we were doing opioid-related work and realized opioids that existed in the National Library of Medicine six months ago no longer were present in our data set. That – I didn't expect that. So, it seems like something that could be easily solved if it could be resourced.

Row eight is medication reconciliation, we 've touched on this, but the challenge here is similar medication data entered by different sources are difficult to reconcile. This is obviously a big deal, right? So now that we have a lot of data connectivity coming in, it's true also for things like problems, but now clinicians are being asked to do enormous amounts of reconciliation, and it's just daunting when you look at it – the amount of time and effort required to look at slightly different or free-texted or whatnot. And I think this is a clear part in terms of clinician burden, too. How can we make this experience more efficient? Because it is pretty painful. So, for example, a gap is effective approach this knowledge-driven medication reconciliation, and for that reconciliation effort to persist through systems. So,

there's going to be quite a bit of human effort going into reconciling. There needs to be ways to make sure that the effort that was spent isn't lost the next time.

Potential solutions would be fund deeper analyses and potentially ref med solution development for med rec so it's not overly burdensome to providers. This could be a product differentiator for folks, but maybe at the baseline there could be some public good kind of things that could be created here that could be built upon. But it does seem like a major pain point. Let me just quickly go through some others, unless someone has a comment? Go ahead.

David McCallie – Cerner – ISP Task Force Member

Ken, it's David. On your last point there about med reconciliation being a hard problem, you're not really identifying a standards gap here, it's really more that it's – you would just say fund more research into how to automate it?

Kensaku Kawamoto – University of Utah – Co-Chair

Well, I don't know. Because, for example, the gap could be that people don't use structured sigs, right? So, it's harder to say these two are the same things.

David McCallie – Cerner – ISP Task Force Member

That would make it even harder.

Kensaku Kawamoto – University of Utah – Co-Chair

Yeah, I don't know… I assume standards will have some aspects of this. For example, if you want to transmit and keep the results of reconciliation, right? If you see three different drugs from three different sources and somebody actually went through and said, "This is the actually the same as these two," I think that the only place where that's kept potentially is in that system. There is no way for that knowledge to reach, I think currently, the other two healthcare systems that a physician – health system A concluded that this med is reconciled with these two other meds.

Arien Malec – Change Healthcare – ISP Task Force Member

This reminds me of an area of my deep, deep past, but that's exactly right. That the assertion that X is a reconciled med list is very different from the assertion that Y is a list of meds, and in many cases the standards – and I don't know where we are with FHIR, but in many cases, the standards aren't capable of distinguishing between those two assertions. The second issue is that many standards don't carry persistent identifiers, which makes re-reconciliation in the case of updates very difficult or needlessly difficult, because you aren't able to say, "Okay, I saw that thing already, I already reconciled that thing. I don't need to go through the duplicitous work." So, I think both of those are really useful observations for automating some med reconciliation work.

David McCallie – Cerner – ISP Task Force Member

I agree, particularly the provenance point that Arien made there a second ago. I think that's maybe worth calling out, because it would help with reconciliation. But the reason this is a

hard problem, is we're trying to solve – this is analogous to instead of having a bank account to track how much money you have, you just keep a running tab with all of the vendors that you deal with, and you hope that you can somehow reconcile all those transactions into a consistent number. The only approach that will really solve this is to give charge of the current medication profile of a patient to a controlled source, PCP or whatever, and have transactions flow through that source. But that's not going to happen.

Arien Malec – Change Healthcare – ISP Task Force Member

Well, that's the point, though. That even in cases where somebody, for example, for discharge meds or admit meds where somebody actually has taken the work to reconcile the med list, there's no way of making that assertion or distinguishing that assertion from this is a list of random meds.

David McCallie – Cerner – ISP Task Force Member

Right, and anybody else who wants to prescribe for that patient has no way to connect to that data, because they don't know it exists. They're not aware that someone did a reconciliation two days ago. How would they know?

Arien Malec – Change Healthcare – ISP Task Force Member

Exactly. So maybe we should help them know.

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

This is Terry. I'm wondering if it's likely that there will be a central source of truth for medication. I mean, obviously the pharmaceutical pharmacies are pushing hard to become that, and they're probably better positioned than the PCP to do so. Under the assumption that some central source of truth will emerge, so what are the standards that we would need to support that central source, whatever it is?

David McCallie – Cerner – ISP Task Force Member

I think it's mostly the system gaps. You would have to rewire everybody's system to talk to whoever that authority was. The standards probably are pretty good.

Arien Malec – Change Healthcare – ISP Task Force Member

Yeah, the standards are not pretty good because they don't establish, as we noted, provenance, and they don't establish the status of reconciliation.

David McCallie – Cerner – ISP Task Force Member

But if I have to update a central authority every time a prescription is written, you could solve that problem trivially. It's that connection to that system, matching the patient, understanding you have the authority to do it, all those system issues.

Arien Malec – Change Healthcare – ISP Task Force Member

Yeah, and again, all I am asking for is a much simpler level of that, which is that if the discharge meds from a hospital have already been reconciled, and a poor attending has gone

through the laborious task of assembling that reconciled list, and it gets sent down to the PCP. At least annotate that that laborious clinical task has been taken, and that the attending has asserted that this is, in fact, the discharge list.

Kensaku Kawamoto – University of Utah – Co-Chair

Okay, let's keep going. Can you move to row nine, please? I think we just have a few more I just want to cover before we go. So, row nine, I think, was next. Okay. So, row nine – so here's where we've also touched on this – interpretation of calculations using the medsit components. So, the challenge here is a lot of sigs are in free text. So, my comment here, as Clem notes, is I don't think the solution is to ban free text sigs. That just doesn't seem like our role, probably. Maybe professional studies could come up with some recommendations, but that would be a big deal. So EHR systems could provide mechanisms to facilitate this, but that is probably a vendor-dependent issue, and not really appropriate for government or standards regs. Like making it easier to write structured tapering scripts, that's, for example, something that's become recently easy to do in our vendor system.

So, perhaps what could be done here is to develop public good resources for converting free text sigs into structured sigs. So, I actually worked on this last Christmas, this was like my personal project. I was working on a CDC-ONC project on opioids and guidance there. So, the issue there was that for our health system, in about a one-year period, about 15 percent of our opioids were free-texted, about 10,000 unique sigs were what I found. And I looked for, "Hey, somebody must have run into this." I'm sure there are ones, but I couldn't find any that were free or open source and usable.

So I did create one able to capture about 80 percent by volume of these and convert them with confidence into structure. So, we used this for more per-milligram like the ones that we use in production right now, and that was government-built, it's already open-source. I don't know if there are others like that, but so one solution here would be to fund public good free text to structured sig converters, and an alternative addition would be to define functional requirements for how this kind of interface for that kind of part would be, like inputs, outputs, metadata generation and then let the market compete, maybe in addition or as an alternate. But I was surprised that, given how obvious this need is, that there was nothing really available in the public domain to use for this. I'll just move on… Yes, go ahead? There was a comment?

Okay, I'll go into row ten: PDMP use. So, the challenge is access and cost. So, row ten. Yeah, so issues: PDMP access is regulated in the patchwork of state regulations, such as some states not aligned; PDMP had been incorporated into the EHR for distant support; and PDMP access, particularly for downloading data into the HER, can be cost prohibitive from a health system perspective. So, some solutions potentially could include: streamlining regs across states for PDMPs, such as federal regulations, or perhaps model state regulation; and providing FHIR-based access to PDMP data at a low cost directly through state PDMPs. And, there is actually an ONC project in the pile on this currently, so I think that sounds pretty promising. Seems like this is something that could have a real impact on things like addressing the opioid epidemic.

And then, I think if we go to the next one, I think that's David, I think maybe?

David McCallie – Cerner – ISP Task Force Member
No, Cynthia Fisher is the next one on the file.

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

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member
Yes, hi. Yeah, we just did a bit of changes here in real time. So, the point that we bring up is really about patients and physicians needing to know the real price of their prescriptive care. So that it's inclusive of their net negotiated price, so that you would see the employer plan coverage as well as their deductible or their share of plan, and their out-of-pocket, as well. And a lot of this has come from cases where patients, for instance, I can give an example of the metformin combination new combination drugs, that if you take the – patients were actually getting metformin and glyburide typically under $15 per month, and the new combo drug came out with a name brand that, until was after the fact, many patients were discovering it was costing them out of pocket. The price out of pocket to them was $500 a month and became unaffordable.

So, patients oftentimes embarrassingly either don't comply adherence to drugs and then it might take them months to be able to go back to see their doctor to change their prescriptive care back to an older combination. So, bringing that as just one example of many, as we look forward to transparency being part of the equation and decision-making, what is realistic based upon a patient's plan as well as their financial circumstances, I think it behooves us to take a forward position to enable readily available visibility into these prices at point-of-care so that it can be decided in combination with the clinician and patient choices of care. And finally, to have it be open, so that as we look to the marketplace as we have a competitive marketplace in so many other fronts, that we can look at cost-effective pharmaceutical management downstream, and we can look at that.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Cynthia? This is Clem. So NCPDP has been actively working on a plan to transmit back by insurance plan the various cost differentials. I don't know exactly where it stands, but you keep an eye on it. The second thing is this combination thing has been discouraged, at least in my medical school days for a long time, but it's ridiculous that you put two drugs together and it explodes the cost, so I fully agree with your sentiments.

David McCallie – Cerner – ISP Task Force Member
Not a standards problem.

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member
Thank you, Clem. And I think we behoove it to allow this pipe, or pathway for what will make for competitive forces in the marketplace and greatly improve the quality of patient care in a timely way at the appropriate times, so I'd thank you all to consider that.

David McCallie – Cerner – ISP Task Force Member
This is David. There are commercial services.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Sorry, this is –

Steven Lane – Sutter Health – Co-Chair
Yeah, we're going to need to go to public comments for a couple of minutes, and then we can come back and pick up right there, David.

David McCallie – Cerner – ISP Task Force Member
Sure.

Steven Lane – Sutter Health – Co-Chair
Okay. Suit up.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thanks, Steven. So, if we could just get the phone number up? Great, thank you. And operator, can you please open the lines for public comments?

Operator:
Certainly. If you would like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate when your line is in the question queue and you may press star two 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 using the star keys. Again, star one to make a public comment at this time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Thank you, and I just want to confirm – Clem, I heard you jumped on the call, I know Jack and Sasha, Valerie as well… did anyone else join?

Clement McDonald – National Library of Medicine – ISP Task Force Member
Yeah, I just got off a plane about five minutes ago, so I'm sorry.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
That's okay. Do we have either Raj or Ram, Scott, or Tina on the call? Okay. Just wanted to confirm. And then, operator, do we have any comments in the queue at this time?

OPERATOR:
We have none at this time.

Lauren Richie – Office of the National Coordinator – Designated Federal Officer
Okay, thanks. So, I think I'm going to hand it back to David. We kind of caught you mid-

thought there.

David McCallie – Cerner – ISP Task Force Member

Thank you. I just wanted to point out on the actual costs front, for providers there are a couple of commercial services that now provide that capability that a number of the vendors have embedded. I don't think they currently use standards, so that's something that could potentially change. And then CARIN, C-A-R-I-N, the group that is pushing hard for consumer access to their health record data, has a very active project to establish appropriate standards and structures to use those services to report directly to consumers, without requiring that they go through their physician. So, there are two efforts underway to address these problems, is all my point.

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

Well, David, do you know about the NCPDP effort?

David McCallie – Cerner – ISP Task Force Member

Well, I think that the NCPDP stuff would be used in the future, but it's not in the commercial products today. They're using…

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

Yeah. I'm not sure if it is cooked yet.

David McCallie – Cerner – ISP Task Force Member

Yeah. It may not be, I don't know. I'm just saying that the commercial stuff is not standards-based, but it works. It's got high demand from providers, they really like it.

Kensaku Kawamoto – University of Utah – Co-Chair

Just for the sake of time, do we want to move on?

Cynthia Fisher – WaterRev, LLC – ISP Task Force Member

This is Cynthia, I just think we're at the very beginning of this, and to whatever we can do to make it open, that we allow the pipes for the competitive forces, I think we benefit – the patients and providers across the board and the consumers.

David McCallie – Cerner – ISP Task Force Member

Yep. I agree.

Kensaku Kawamoto – University of Utah – Co-Chair

David, do you want to go through the – I think the last two are yours? I think on row 12 and 13?

David McCallie – Cerner – ISP Task Force Member

Yeah. And, again, this may be redundant to work that's already underway, but just the complex process of prior authorization for higher-tier drugs, restricted access drugs, is

something that creates tremendous physician burden and can be addressed and automated at least partially by appropriate standards. I believe there are good standards in design on this, but I just want to call out the functional need for prior authorization services. And then on the portable prescriptions, this is just something that has come up in the past. Our pharmacy team tells me that there's work underway to address this, but the thought here is that if you have a prescription electronically sent to a particular pharmacy, and for whatever reason you want to have that transcription transferred electronically from one pharmacy to another pharmacy, that has been difficult to do and some of the services to allow that to have happened simply are not present, but I am told those are also under development in NCPDP. So, these may be both being addressed.

Steven Lane – Sutter Health – Co-Chair

Well, I just wanted to say how much we appreciate everybody's input in the time since our last meeting and calling these out. Clem, we were channeling you a bit at the beginning with your overarching question as to whether this area requires or would benefit from the focus of this group. I think what I have heard in these 12 comments that we just went through is that there really is an opportunity, but a lot of the great work has been done, including in the proposed rule. But I, at least, feel like we would be well advised to go ahead and spend some time on this when we're all together.

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

Well, I'm okay with that, but the thing I wish I had the chance to weigh in on was the structured sigs, and there's a bunch of dimensions to that that may not have been discussed...

Arien Malec – Change Healthcare – ISP Task Force Member ???

Yeah, we talked about it in your absence.

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

Good. Did you decide everything?

Kensaku Kawamoto – University of Utah – Co-Chair

No, we decided there was probably still some value. I just wanted to come back to the work that was done, that we did on orders and results draft recommendations, and that was where we incorporated Victor's input. I'm going to try to see… it's on row 13, actually. I'm sorry, whoever's running the slides. It's the second to last row. So I did incorporate, Victor, a number of the details that you had shared, and I promised to do that for the group before we came back. So, this is there. We don't have a lot of time to dwell on it, but we basically took some of the suggestions that Victor made and incorporated them into our recommendations. So I invite people to look at those, especially Victor, to make sure that they are providing appropriately what you had suggested.

I did limit – Victor, you started getting into things like sigs in nursing orders, which I think were somewhat different than the orders and results scope that we had been focusing on, so I dropped those out. So hopefully, no offense taken there.

Victor Lee – Clinical Architecture – ISP Task Force Member
Thank you.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Just wanted to comment in response to David. There is already transfer one in prescriptions, it's called Rx Transfer Request: Response and Confirm in the MPRM. So, it's more than on the way.

David McCallie – Cerner – ISP Task Force Member
Good. All right, so we are at time. I think we have accomplished our task of finalizing our recommendations in the two domains that we touched on, and I think setting ourselves up to dig into medication and pharmacy. I would invite task force members to continue to contribute to the Google sheet that we have, and I think what Ken and I will try to do before we reconvene would be to shorten that and compile it into the format of observation recommendations, policy levers that we've used in the past, and we can pick up our work from that point forward.

Clement McDonald – National Library of Medicine – ISP Task Force Member
Thank you to both chairs, and we appreciate your work.

David McCallie – Cerner – ISP Task Force Member
Yep.

Steven Lane – Sutter Health – Co-Chair
Excellent. We'll see you all in a couple of months.

Ming Jack Po – Google – ISP Task Force Member
Okay, thanks, everyone.

[End of Audio]

Duration: 90 minutes