



Interoperability Standards Priorities (ISP) Task Force

Transcript
May 28, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Role
Kensaku Kawamoto (Co-Chair)	University of Utah Health	Co-Chair
Steven Lane (Co-Chair)	Sutter Health	Co-Chair
Andrew Truscott	Accenture	Member
Anil Jain	IBM Watson Health	Member
Arien Malec	Change Healthcare	Member
Clement McDonald	National Library of Medicine	Member
Cynthia Fisher	WaterRev, LLC	Member
David McCallie	Individual	Member
Edward Juhn	Blue Shield of California	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Google	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Ricky Bloomfield	Apple	Member
Sasha TerMaat	Epic	Member
Scott Weingarten	Cedars-Sinai Health System	Member
Tamer Fakhouri	Livongo Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Tina Esposito	Advocate Aurora Health	Member
Valerie Grey	New York eHealth Collaborative	Member
Victor Lee	Clinical Architecture	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

Operator

All lines are now bridged.

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

Good morning, everyone. Welcome to the ISP Task Force Meeting. I know it's been a while since we last met. But we needed to take a break to focus our efforts on the proposal. So, I want to thank you all for your patience, and for joining us here again today. We'll get started with roll call, and then I will hand it over to the co-chairs. Ken Kawamoto?

Kensaku Kawamoto – University of Utah Health – 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

Present.

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

Anil Jain?

Anil Jain – IBM Watson Health – Member

Here.

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

Arien Malec? I believe Andy Truscott is going to be absent. Clem McDonald? Cynthia Fisher?

Cynthia Fisher – WaterRev, LLC – Member

Present.

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

David McCallie?

David McCallie – Individual – Member

Here.

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

Edward Juhn? Terry O'Malley? Les Lenart? Jack Po? Raj Ratwani? Ram Sriram?

Ram Sriram – National Institute of Standards and Technology – Member

Present.

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

Ricky Bloomfield?

Ricky Bloomfield – Apple – Member

Good morning, I'm here.

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

Hi, Ricky. Sasha TerMaat?

Sasha TerMaat – Epic – Member

Good morning.

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

Hi, Sasha. Scott Weingarten? Sheryl Turney? Tamer Fakhouri? Tina Esposito?

Tina Esposito – Advocate Aurora Health – Member

Here.

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

Valerie Grey? And Victor Lee?

Victor Lee – Clinical Architecture – Member

Here.

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

Great. Okay, Ken and Steven, I'll turn it over to you.

Steven Lane – Sutter Health – Co-Chair

Excellent, thank you so much. And welcome back, everyone. It's been a few months since we've met. And we're very excited to get back to the work that we began and dug deeply into last round. I see we have a number of visitors on the call, which is really excellent. And thank you public, for joining us.

We're going to go ahead and just review the charge of this task force, and then spend this time reorienting ourselves to our third domain, the domain of medication and pharmacy data. You'll recall that in March, now just a couple months ago, we made a presentation to the HITAC with some preliminary observations in this area. And what we want to do is review those. Kind of seeing what people have been thinking about those areas in terms of where we can and should go with them. And then also discuss some potential additional subdomains or areas related to medication and pharmacy data that we think the task force may want to take up.

We then want to talk about the timeline for the rest of the work of this task force, and how we're going to complete our charge later this year. Ken, do you want to add to that?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Nope, that sounds great. I'm looking forward to continuing this work.

Steven Lane – Sutter Health – Co-Chair

Excellent. So just as a reminder to everyone, the charge for our interoperability standards priorities task force is to make recommendations to the HITAC and subsequently to ONC on priority uses of health IT and the associated standards and implementation specifications that support such uses. Which, you'll recall, was a fairly open-ended charge that we started with. This was largely called for in the legislation in 21st Century Cures.

So, we've been doing our best with this. Specifically, we're supposed to make recommendations about priority uses of health IT, consistent with the Cures Act, the standards and implementation specifications to support these uses, or that may be developed for each identified priority. And then, recommended subsequent steps. And then, as we said, later this year, we're going to be publishing a report, bringing that back to the HITAC for formal recommendations to the ONC.

So, you'll recall that initially we focused in on orders and results and did some very good work in that area. We then went on to dive into referrals and especially closed loop referrals, and the necessary care coordination that goes along with that. In that area, we – one of the subdomains that we dug into was the need for standards to support referrals in terms of clinical content and what data needed to be exchanged between referring providers and referred to providers. I'm happy to say that in that effort we reached out to the AMA, and since our last meeting here, we've had a number of discussions with the folks at the AMA about their interest in supporting that work. And that, as I say, is an ongoing discussion. Seth Pazinski and – I'm sorry not Seth, but a number of folks at the AMA have been engaged with us in those discussions. And we're looking forward to seeing that move forward.

Let's go on to the next slide. So again, we intend to start by a review of the work we've done in medication and pharmacy data. Ken, you pulled this together very nicely for the presentation to the HITAC in March. And I was kind of hoping that you would kind of walk us through line by line where we've been. We do have the original spreadsheet from Google Drive with the observations, recommendations, and policy levers that we have discussed. That was about 10 different observations. So, maybe on the next slide, Ken, if you're comfortable, you want to walk us through what we presented?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Sure. Do we have the – yes. Yeah, sure. Absolutely. Can you go to the next slide? Yeah. And we've added some more here that we'll discuss later. And I see in the other Google Doc, there are the details. So maybe we can just go at a high level.

So, the areas – and there are recommendations after this, so I'll go very quickly through this. Where we as a task force discussed the need. Including access to med dispense and administration data in a standard way. The need for a discrete SIGs and how to get to them when there are no discrete SIGs, where it should be texted. PDNP data and how they are accessed and how they are integrated into the workflow and having that available in a cost-efficient manner.

We had discussed price transparency, which in this case is really into medications. But has implications for other types of healthcare costs, in particular with regard to what a patient has to pay. We also discussed prior authorization, again, a cost-cutting concern with some issues in pharmacy

management. Electronic prescription forwarding and the new topics that we'll discuss today include adverse drug event data, other FDA needs, and primary research needs. And Steven will talk to those as potential topics later today. Next slide, please.

Okay. So here were our graphed recommendations in terms of priorities. So, these include, again, I'm going to look here for things that are – yes. Maybe I'll just go through them because there is enough detail here. We first separated into top tier priorities from what we had discussed and second-tier priorities. So, priority 1-A, again, the dispense admin info is not universally available. 1-B, the med racket transition or care is challenging, quite burdensome. 1-C, the lack of transmittal of free text CIGs in the U.S. Core Fire Profiles. 1-D, the cost prohibitive nature of PD NP access. 1-E, the net price of prescribed medications can be challenging to obtain. And I'll make a note that I personally have spending a lot of time on this in my work recently, and it is a challenge. 1-F, the need for standards to negate prior auth in prescribing workflows.

Then as second-tier priorities, the path to discontinued drugs that are not on the market anymore, don't get returned, and the NLN marks norm API. 2-B that free text SIGs are prevalent, but difficult to interpret and use. And 2-C, that there's currently no way to forward any RX to an alternate pharmacy. Next slide, please. Okay. Steven, if you want to take it from here.

Steven Lane – Sutter Health – Co-Chair

Well, maybe before we go into these potential new subdomains, I wanted to kind of back up to the prior slide and give people a chance to just remember this and provide any commentary, modifications, additions, questions, that come to mind. This is a fairly high level, but we have deeper detail regarding our thoughts in the spreadsheet. In fact, maybe this would be a good time to pop back over to the Google Doc, which I know that Luke got ready to go here and remind ourselves kind of what some of the detail here is.

Again, I really thank Ken for pulling this together as he did back in March for our HITAC presentation. One thing that struck me, Ken, as you were going through there, is we mentioned cost related to accessing PD MP data. But in California, we are having some real struggles with the technical integration of the PD MP access into EHR workflows. And a lot of that is sort of at the policy level within the state. We are working on that. But it seems to me that in addition to cost issues, I think there are real opportunities here in the PD MP realm, with regard to standardizing the method by which that data is accessed and integrated into the EHR workflows to make it more convenient for providers to utilize that data.

So, I think that there may be opportunities like that for us to add some more detail to these. So, I guess, I know that we don't have Clem here. Clem has always been an active participant in our discussions about discrete CIGs. We continue to go back and forth. I mean, Clem seems to be sort of a detractor on the discrete CIG information. And a number of us have continued to keep that one alive because of the value that we think it would bring. But I would just invite any of...

Kensaku Kawamoto – University of Utah Health – Co-Chair

Maybe – yeah, sorry. I see David's hand is up. David, do you have a comment on this?

David McCallie – Individual – Member

Just that the generally high level, and it may not be the right time for it, but just looking at that broad list, I had some thoughts. But I don't want to interrupt Steven if he wants to dive into something specific.

Steven Lane – Sutter Health – Co-Chair

No, no, no. Go right ahead. I was just setting us up to try to engage the group, so please do.

David McCallie – Individual – Member

Okay, great. So, I mean it's useful sometimes to take a break from these things and then come back and look at it again and sort of zoom out and see things from a distance. And it strikes me that in this long list, some of these are fundamental policy problems. Policy and/or I'll call them business problems, and not particularly standards problems. And some of them are standards problems for which there is active standards development underway and groups that have taken responsibility for it. And then maybe some of them are truly new and unaddressed problems.

But it might be useful to sort of segregate out which ones are either basically waiting for policy work, like the PD MP stuff. That's not standards problem, that's a policy problem. Or something that is waiting for clarity in the business side, the medication reconciliation. The issue here is nobody is responsible for it. And it's a hard problem, so therefore nobody does it. It's not a standards problem. Things like E-prescribing forwarding is an NCPDP problem. Structured CIG is an NCPDP problem. I just think we could weed some of these out and say they are really not standards priorities problems.

Steven Lane – Sutter Health – Co-Chair

So, just as a reminder, David, we, in our charge, have both the prioritizations of the standards, the identification of the standards, and talking about how they are being implemented. So, even if there is a standard which is not being fully implemented, as we certainly have discussed in our prior domains, that is well within our charge to make suggestions back to ONC as to how perhaps that could be encouraged, incentivized, etc.

David McCallie – Individual – Member

Okay. Then I think at a minimum, make sure we understand which – what are the barriers that need to be addressed for each of these, and clearly identify those. It wouldn't do to hand them over to a standards body and say work harder on this if, in fact, the fundamental barrier isn't a standards barrier.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Agreed. And Terry has his hand up. Terry? Terry, you're muted.

Terrance O'Malley – Massachusetts General Hospital – Member

Oh, thank you. So, David let me disagree a little bit on med rec. This maybe is mislabeled, because the issue is not so much reconciliation although that's part of the process. It's actually getting a medication list that we have used in the hospital to correspond to a medication list that can be used in the next site of care.

And the problems there have to do with, in a sense, payment, and formulary access. And often it's not as simple as just creating a med list from one place and send it to the next. Often you need an iterative process that goes back and forth and says, well, our formulary only pays for Lipitor, but you want Crestor. And you really have to go back and forth. And the reconciliation occurs at that level, which is a different kind of reconciliation. So, long-winded.

David McCallie – Individual – Member

I agree to totally with that. I think that's sort of the problem, is that the entity to host that conversation is not defined. The business entity that would, in fact, manage and coordinate that conversation doesn't exist uniformly. The DaVinci project tried to work hard on the 30-day discharge medication reconciliation project. And it was impossible to find a responsible party. I have no doubt that there are standards gaps, but I think it's fundamentally, no one in charge at that transition. Particularly from acute care back to ambulatory care. Not everybody lives in a system where there is a driving primary care physician that's coordinating the process. And that physician may or may not have access to all of the data necessary to do those iterations. It won't get solved by better fire API, is my concern.

Terrance O'Malley – Massachusetts General Hospital – Member

Okay.

David McCallie – Individual – Member

It's bigger.

Terrance O'Malley – Massachusetts General Hospital – Member

I'll take that last one. So, one of the things, since I'm a post-acute care person, there is a responsible entity and transfers from acute to post-acute. It's the post-acute care site, who is now on the hook for the medication list and expense. So, we may have a responsible party, finally. And we have been looking at the 360 X as a paradigm for a closed loop referral, in a sense, medication reconciliation is a closed loop referral. It's an interactive process with communication that requires to be coordinated and sequenced to get to the end point. And if we look at 360 X in that light, and there are standards gaps, because 360 X is direct, and I'm sure what the Fire researchers are that could support 360 X, and perhaps you do, but I certainly don't. But 360 X will come again on prior auth, so.

David McCallie – Individual – Member

But it won't come as a surprise to anybody that has listened to me rant and rave in the past, that I think, in the long run, these things probably require an app like approach. Where there can be interaction with a system behind it that understands the choices and what is available and coverage limits and all of that. 360 X is a waystation and a step in that direction, but it's cumbersome because it's like trying to schedule a family picnic with email. You got rounds and rounds and rounds and rounds and diverging conversations before you finally get some kind of consensus. Takes a lot of time, a lot of work. So that might be a good step in the right direction, but the long run, I think it's an app-based model.

But I was less concerned about transfer to a post-acute facility because I agree, those really – that is clear responsibility. And more just discharge back to the community. I'm thinking of my father-in-law who had something like eight or ten medicines from three or four different specialists. And on discharge from the hospital, he would have no idea what he was supposed to take, and it wasn't clear who was supposed to tell him. So that was the broader concern. UT we're getting into the weeds, and I'm sorry for that.

Steven Lane – Sutter Health – Co-Chair

Well, I don't think there is any need for an apology. I think this issue of med Rx as people have noted is one that we continue to discuss because it hasn't been solved. And I guess one question, and I would throw this out to the broader task force, is are there concrete suggestions that our task force could make to HITAC and subsequently to ONC. Is there something that ONC could do in their position, or

CMS, to better support better med Rx. Or is there not? I guess that is a question I would – whether we are talking about 360 X. Whether we are talking about the Fire. I mean, separate from the technology standards, but in terms of the implementation of med Rx, what could we do to make that better? To find – to assign the responsibility?

You know, Terry said, well, when you go from acute to post-acute, it's the receiving organization, the receiving provider who is responsible for that. I mean, in some sense, that's always the case. I mean, it's always the receiving or current provider who is responsible for reconciling meds. We have made some efforts with 30-day med rec, to have somebody check a box or somehow document that something was done. But I think that a lot of us feel that that is not really being done thoroughly. And in the spirit of the closed loop, I don't know that that information is going back to the sending organization. Or whether it really even needs to.

David McCallie – Individual – Member

Yes. David again. Just to jump in on that. I mean, I think that is exactly the right way to ask the question. And I'm not familiar enough of the latest changes in the payment structures. But clearly, the process of performing med reconciliation is time-consuming and highly valuable to the patient. Its time consuming for the provider, highly valuable to the patient. So, at a minimum, one would hope you get paid for it. Somebody should take that time and do the phone calling or iterative 360 Xing or whatever it takes to get an agreement on what the right medication is. Somebody, in order to spend the time to do that well, it probably needs to be a reimbursable step. It may be to some degree already, but maybe that is a gap. I don't know.

Steven Lane – Sutter Health – Co-Chair

You know, I think you make a really good point, David. They have created CPT codes, for example, for counseling regarding advanced directives. I think if there were through med rec were reimbursable. And it was meaningful, in so far as reconciling a list of four PRN allergy meds versus a list of 30 complex meds for a critically ill patient. Those are very different things. They're small, medium, and large, med recs.

But if providers were paid for that, whether they were physicians, or advance practice nurses, or pharmacists, that could potentially incentivize people doing a better job.

David McCallie – Individual – Member

I totally agree. And somebody would build the app, I guarantee you.

Terrance O'Malley – Massachusetts General Hospital – Member

There is continuity of care codes following discharge, either from the hospital or from post-acute care, back to PCP that you – that is actually paid at two or three times the regular office visit rate for exactly that purpose. I'm not quite sure how they are being used, but those codes already exist. And if people aren't using them, then they're missing out. But my question...

David McCallie – Individual – Member

Maybe there is an opportunity to connect the dots there as our report back out to HITAC.

Terrance O'Malley – Massachusetts General Hospital – Member

My concern is, and David, I agree 100%, 360 X is really kludgy, but it's a huge first step. Really automating at least part of the communication piece. What I would love to see are the Fire resources

to support 360 X or something like it. I think it would be a tool that we would find valuable in a bunch of use cases. So, let me put a plugin for that.

David McCallie – Individual – Member

Yes, so you are using – the idea would be to use 360 X as the – to use directly as a transport mechanism, but the content would be encoded resources.

Terrance O’Malley – Massachusetts General Hospital – Member

Yes. Or not even use direct. Use whatever you’ve got. But have it so that it supports an app-based exchange. I’m not advocating 360 X as the model so much as advocating as the paradigm. It’s just this is a closed loop referral. How do we support closed-loop referrals with Fire?

David McCallie – Individual – Member

Yes. And I think of it as it’s like if you want to book a flight on your airline, you have an app for that. And you negotiate with the app, back and forth with the airline, or maybe multiple airlines and settle your flight. It’s hard to do that with email, so you probably need something hosting the conversation. Some system or entity hosting the conversation. Keeping track of the decisions. But that’s hard.

Steven Lane – Sutter Health – Co-Chair

Are there any other general observations about the list of items that we brought back to HITAC? Any areas – I mean, it sounds like we have some opportunities to dig deeper into med Rx, and Ken has been capturing some of that here. Any other of these established areas that people wanted to comment on after having this chance to let it settle in for a couple months? If not, let’s go on – oh, sorry, Ricky, go ahead.

Ricky Bloomfield – Apple – Member

Sure. The only thing that I would add, and I think this gets into the med Rx conversation a little bit and it is listed as priority 1-A here, but dispense information is very hard to come by. And having accurate dispense information can help inform med Rx. Obviously, it doesn’t come close to solving the problem, but it is an integral piece there.

And one idea I have heard floating around is requiring the available of dispense information via API, similar to how the clinical information is currently required from health systems. That’s obviously not a technology problem, although further profiling of the medication dispense resource would help with that. But it’s partially a policy problem and an ecosystem problem as well. And I think that is important to bring to the ONC who may want to chat with CMS and others if they have appropriate regulatory oversight over some of those pieces.

Terrance O’Malley – Massachusetts General Hospital – Member

Id dispense, in this case, an ambulatory dispenses. Is that what we are talking about? We’re not talking about hospital-based administration of each dose on the nursing rounds, right? Or are we?

Ricky Bloomfield – Apple – Member

Right. I was referring to ambulatory dispense. I would include inpatient as the administration piece of that, which I think is also important. But exactly, I would separate it in that way.

Terrance O’Malley – Massachusetts General Hospital – Member

I agree.

Steven Lane – Sutter Health – Co-Chair

Ricky, given your interest in this, could you perhaps propose some language at perhaps as a comment or an addendum to the spreadsheet that we are looking at? Not right at the moment here, but between now and our next meeting. I think that especially those on the call who have a deeper familiarity with Fire and just where that is, it would be very helpful. In a response also to what Terry was saying earlier. How can we incentivize the further development of fire resources to support the kind of back and forth discussion or negotiation that is required for med Rx? And for some of the prior auth data that we want to deal with as well? Because we really do want people to contribute to this.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Sorry, Ricky, I cut you off. Go ahead.

Ricky Bloomfield – Apple – Member

Oh, I was going to say, sure that's fine. I am happy to put something in the spreadsheet there.

Steven Lane – Sutter Health – Co-Chair

And Cynthia, you have your hand up?

Cynthia Fisher – WaterRev, LLC – Member

Yes, thank you. And thank you, Steven, for sending us a link or a copy of this med Rx page, because it will be helpful to have the whole copy to be able to comment. We only have it on this small screenshot.

The other question, and it may be in this document, is the ability in the medical reconciliation of medication. Reconciliation but also on the point of care decisions is also the ability to see options on generic, options on choices. Especially in the changes in pricing in insulin and in pre-diabetic, having new medications prescribed that end up costing them on the thousands per month, where they need to go back to their physician after they find out the price and go back to old medication prescriptions have caused significant duress and financial duress.

And I'm wondering if we can look at the ability to provide visibility into generic options as well as pricing options. And there will be many apps. We've been speaking about apps. You know, if we open this up for innovation, there will be many different ways, and there already are some entities that do provide this. But I'm just thinking that it is very important that we provide the open architecture for that type of development to be provided at the point of sale.

Steven Lane – Sutter Health – Co-Chair

That is great input. And it actually is a good segue to where we are hoping to go before the end of the hour, so thank you. Thank you for that.

So, let's move back to our slides just momentarily and talk about kind of what we thought could be added to this. Now again, as a reminder to everyone, our time – we checked with ONC. We have asked the question a couple of times now; would it make sense to keep this task force going? Sort of reinvigorating it in the way that USCDI has now on sort of cycle two or completed cycle two and is now moving on to cycle three if you will.

But, you know, the sense is that we are going to fulfill our charge before the end of this year. So, we need to think carefully about how we are going to spend our time. So, we have discussed several

different areas. We discussed the social determinants of health. We discussed evidence-based disease management. And I think, when Ken and I met with the folks for ONC, our thought was we would probably be best served by really doing the best we could with meds and pharmacy data to a level similar to where we went with our first two domain areas, and then have those three domains suffice as the focus for this work that we have done.

So, with that in mind, let's go to the next slide here and talk about some additional kind of subdomains that we thought it might be worthwhile to explore as part of medication and pharmacy data and see what people think about these.

One thing that has struck me is adverse drug event reporting is still done in a very 20th century kind of get the form and fill it out and send it in sort of way. I think we are all well aware that adverse drug events happen all the time, every day, in every practice probably. And if my practice is typical of those around the country, the vast majority of those never get reported back to the FDA. And it's not clear to me that the FDA really has a process or the bandwidth to make full use of that information. And I think if we're talking about patient safety and trying to optimize our learning health system, that I for one would be interested in chatting with the FDA about standards for adverse drug event data capture reporting utility. So, I wanted to throw that out to the group for comment.

And I'll just run through the list very quickly. I mean, the rest of this clearly is – FDA itself is obviously working with med data all the time. And there have been some publications out recently about the need for standardization in that realm. So, one thought would be for us to chat with the FDA here to learn about what they feel that they need. Is there anything that we could do? That ONC, CMS could do to support their needs. And clearly, that bleeds over quickly into the whole area of drug development and pharma.

I think there has been very little engagement of the pharma industry with the larger interoperability discussion that is going on. I think they are sort of having a parallel set of discussion in pharma about their need to access and share data. But it doesn't, as far as I can tell, really overlap very extensively with what we are doing on the clinical side.

And there again, whether you are talking about adverse drug events, whether you're talking about new drugs that are coming out, or simply research, clinical research on new drugs that are being used in the clinical setting.

So, these were some thoughts on potential new areas to dive into. And I wanted to throw it open to folks to see whether these seem worthwhile or whether you have some suggestions or additions to these. And the public is welcome to use the public comment chat to offer input as we go along, as well as take the opportunity of the formal verbal public comment that will be coming up shortly.

Terrance O'Malley – Massachusetts General Hospital – Member

Steven.

Steven Lane – Sutter Health – Co-Chair

Terry, your hand is up?

Terrance O'Malley – Massachusetts General Hospital – Member

Yes. I think to look at the FDA and what they need is actually a really potentially significant piece, given they are sort of, not the chokepoint, but they are sort of the common final pathway for a lot of the medication issues. Certainly, the development and adverse reporting, and to a certain extent, even pricing. So, I would support this approach in asking them what they need. I think that is actually a very important piece. Thank you.

Steven Lane – Sutter Health – Co-Chair

David?

David McCallie – Individual – Member

Yes. I think it would be great to get their input. They have worked on this problem, obviously, for a long time. They have structured vocabularies, in particular, Meddra, that's WHO mandated for a number of countries to share regulatory information that can be used to codify adverse reactions. So, it's not space where they are doing nothing. There is a lot of activity. But I don't think it is at all integrated with what has been going on in the EHR side of the space. So, would it make sense to have a one click, adverse event reporting app, that a provider could click a button, and it would snapshot the patient's current medication and profile, and pop up a quick question on what the adverse event was and submitted that to the FDA, all actually bundled up for subsequent analysis. Something like that, I think, would make a lot of sense. But they're doing stuff in that space already, we should hear from them, make sure that we stay consistent.

Steven Lane – Sutter Health – Co-Chair

Other thoughts?

David McCallie – Individual – Member

The other, this is just me, one-second thought, which is there have been significant contributions from patient-focused adverse event capture. But it has typically been done by entities that are focused on specific diseases, like ALS or multiple sclerosis, whether either the society or groups like Patients Like Me have created standard forms for assessing the patient's experience with the medication and with the disease process itself. And those websites, they are typically delivered to the patient by a website. Maybe these days by apps on the phone, have made major contributions to understanding the natural history of the diseases as well as the way the patients respond to the medications. So, we shouldn't ignore the patient direct reporting side of the equation.

Steven Lane – Sutter Health – Co-Chair

That's a really good point, David. I'm curious, does anyone on the task force have any specific contacts either with the FDA or within the pharma industry, or folks that you are aware of that you would suggest us potentially outreaching to?

Anil Jain – IBM Watson Health – Member

Yeah, this is Anil. We have done some work on this base. And I'd be happy to connect the committee task force with folks who are in the pharma industry working on the fairs system and looking at adverse drug events from an electronic point of view. But I also wanted to make a quick comment, if it's okay, Steve. That one of the things that we should also be very sensitive to is asking the clinicians who are using these systems to do more and more. And responding to an adverse drug event and making sure that there is a complete picture of what happened is actually not that trivial. And so, we just have to keep the physician burden in mind. And also, the indemnification and protecting the

physicians who do these kinds of reporting, when it may not be related to the drug at all. It may be a complete coincidence.

And so, there is a – I think we need to hear from the pharma industry, we need to look at what they've done. But we also need to keep in mind that the electronic health record has a specific purpose. And part of that, we should be thinking about that exhaust of that EHR use to be used for safety events and for potential research and drug development for pharma. But I'm not sure most clinicians are going to be spending five minutes really thinking through what happened, and there could be an unintended consequence.

Steven Lane – Sutter Health – Co-Chair

You make a really good point, Anil. And I think David was starting to get at it. Saying if there was one button that you would push or even a zero button. The system can tell that I started drug a two weeks ago and the patient's coming back in. And now I'm stopping drug A and starting drug that is either a different drug in the same class or another class for the same indication or associated diagnosis, etc. I mean, a lot of this, as you say, it's sort of the exhaust of the system. And while it may not be the job of the clinician to do more than say, oh, yes. It seems like you're changing drugs, perhaps because of an adverse drug event. Would it be okay if we reported this? You know it could be as simple as that. But I think our points are very well taken. We need to watch the burden side of the equation.

Anil Jain – IBM Watson Health – Member

Yes. One quick additional comment. We may want to start with something that I think we are hearing, at least on the IBM Watson Health side of things, is a really important part of where pharma needs data. Which is on the deidentified retrospective data. And just focusing simply on making sure we have minimum data sets coming out of the electronic health records and deidentifying them. And making sure that we can look back and look for signals and things of that sort, may be a good way to sort of step through this before we start getting clinicians to inadvertently collect data that could be used to look for signals that may be an issue down the road. So that's just another thought, which is can we sequence the needs of the FDA and pharma. And really just think about the data and the standards that are required for them to have the highest fidelity signals.

Steven Lane – Sutter Health – Co-Chair

So, great suggestions, Anil. And what I would really appreciate it if you could maybe shoot us a quick email sort of outlining some of your thoughts and offering specific suggestions or contacts, either from within your company and/or the FDA that we might look to for subject matter expertise in this area to educate us further.

I think we should jump to – oh, public comment's not for a little while yet, I'm sorry. Lauren, would it be okay if we got some public comment now before we went on to the timeline?

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

Sure. That's fine. Let us get the number up. And operator, can we open the public line?

Operator

Certainly. If you would like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star two if you would

like to remove your comment from the queue. For participants using speaking equipment, it may be necessary to pick up your handset before pressing the star keys.

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

And do we have any comments?

Operator

We have none at this time.

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

Okay. Steven, we may just circle back in a few minutes, since we started a little early, just to see if we get any additional comments.

Steven Lane – Sutter Health – Co-Chair

That's fine. Yes, I see that in the public comment chat Dr. Miller, thank you, Holly, offered the suggestion that patients, caregivers, family members, may also be well positioned to initiative reporting regarding adverse drug events, which I think is a great idea. Obviously not exclusively back to the FDA but making it easier for patients to report back to their clinical care team. That's a great suggestion. What's on our next slide? I think this is where we go into the timeline. Can we go to the next slide?

There we go perfect. So, the thought here was to look ahead at the rest of our time together and to start thinking about how we could best use this time to finish our work. So, this is today. We are starting at the top, May 28th. We just did a brief recap of the recommendations to date and some additional subdomains. And these are just some high-level thoughts. We're really interested in people's suggestions.

We thought that perhaps in our next meeting, we have two meetings scheduled in June two in July, and two in August, and then we are really going to be looking at finalizing our recommendations back to HITAC.

And we have obviously expressed a lot of interest prince transparency related to medications, and I think to Cynthia's point, not only are we interested in generic options or options within the same drug class. But I think there is also the issue of alternative treatments. You know you pick the class, and every drug in that class is unaffordable for your patient. But did you think about perhaps this other alternative approach to therapy? So, there is a lot that could be done there. We thought that it could be very helpful to have NCPDP and or Sure Scripts, a vendor that had done a lot of development and implementation in this area come and present what they are doing. And in the process, share with us where standards could be developed and/or implemented differently to support that. So, we cured that out as a possibility.

We talked about perhaps having FDA or some other expertise come in and talk to us about adverse drug events and reporting. And then I think potentially, also, a session focused on the needs of the pharma industry. Anil, you mentioned the FAIR system. I think I heard that acronym from a patient of mine recently who works in the pharma industry and is actually very much involved in their interoperability

efforts. Which is where I learned that what they are doing is completely unconnected with what we are doing. So, I think having somebody coming in perhaps in July to discuss that would be helpful.

And then obviously, more ideas are going to come up. There is the whole area of evidence-based guidelines specific to meds. I mean, we talked about opening that up as an area of focus unto itself, but I think with both price transparency, prior auth, providing the best clinical evidence, these are all things that really fit into medication uses, prescribing, etc. And as such we could explore them here without having to take them on as a domain unto themselves. So, Ken, do you want to sort of add to this about the work plan and the month ahead of us?

Kensaku Kawamoto – University of Utah Health – Co-Chair

Yes. I think my understanding is we may be able to continue this past this cycle recommendation. So, we don't necessarily have to fit anything that could be a priority before then. I think there is going to be ONC focus on prior authorization separately as well. So, I think to focus on the aspects of medications that sort of overlap with that, including prior auth and price transparency make a lot of sense. I do think perhaps scoping it down, like you say, to medications for this initial round, makes a lot of sense to make headway in this rather broad topic that we can tackle.

Steven Lane – Sutter Health – Co-Chair

David, your hand is up?

David McCallie – Individual – Member

I was going to make a comment back when Anil's point about the adverse medication event is really a subset of the broader patient safety reporting space. And I think he covered that. So, I think that was the comment. Just think of it in the broader context of safety events in general.

Steven Lane – Sutter Health – Co-Chair

Yes. That is very much where that thought came from. In fact, it was a recommendation from Raj that we consider that here in the task force. So, I think if there are experts, Raj or others, in the areas of ADE as a piece of patient safety, I think we should take advantage of them. Recommendations would be welcome. Cynthia, your hand is up? Cynthia Fisher, are you on mute?

Cynthia Fisher – WaterRev, LLC – Member

Sorry, I was on mute. You know, I just wanted to also suggest for the July visits, that we also look at bringing in innovators, too, in the space. So maybe a good Rx or someone like that would also be good to bring in.

And then, the other part is both on price transparency and choices and decisions, thank you, Steven, I agreed with the point on looking at options with generics or other modalities of therapeutic or medicinal care as choices based upon affordability by the patient and per their EOB. And I also think one of the things that we also want to look at is payment information. There are standards for payment information, and as we move to the digital world, it will be even more important to have both price and payment be on our mobile device, like the rest of the world in which we manage, so we will have consistency toward that end.

So not just price, but also on payment and benefit considerations. Because often, even employers will have no – some may incentivize for the generics by having no co-pay or deductible of generic or more

cost-effective regimen is chosen. So, I just wanted to throw that out there as looking that whole decision making along with the patient and caregiver team.

Steven Lane – Sutter Health – Co-Chair

I see no other hands up, and I think we wanted to pop back to public comment here at five minutes before the hour.

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

I do not think we have any, but I will ask the operator.

Operator

We have none at this time.

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

Okay.

Steven Lane – Sutter Health – Co-Chair

Perfect. So, a lot of people are on the call. People both members of the task force and the public who have been very quiet. I really want to encourage others who have thoughts in this area to pipe in. We, again, we would plan to work together with the ONC to put together these next couple of meetings, really largely to focus on educating the task force, as we've discussed, around price transparency, ADE, and probably some of the pharma data exchange. So that we can understand those realms in more detail and what the needs may be. And then that would set us up for some writing, and editing, and arguing, about the final recommendations later in the summer. Any specific thoughts or recommendations that people have about that plan? All right. Well, hearing none, we will proceed.

A number of you have offered to provide us input offline, and we are thrilled to get that. We actually have a meeting of the task force leads later today. I think a few hours from now. So, if people have time to put their thoughts together, and we can consider that as we're doing our planning.

Also, any specific recommendations for subject matter expertise. I think, Cynthia, your comment about good Rx is a good one. I don't know a lot about them, but I've heard good things about what they do. Sure Scripts, I think we have some contacts there. Again, Anil, your suggestions on the pharma side would be most helpful. And I think that perhaps we maybe be able to draw, as discussed on some of the other experts that we have within the HITAC, Raj Ratwani in particular, to help educate us around the patient safety side of this.

I'm curious from the EHR vendors on the call, any thoughts about work that you all have done or have contemplated to push us along this path in the area of drug information?

Sasha TerMaat – Epic – Member

Specific to medications?

Steven Lane – Sutter Health – Co-Chair

Yes.

Sasha TerMaat – Epic – Member

I think a lot of what might be covered by NCPDC and Sure Scripts would be very similar to the representative of what EHR developers have done. Because much of the work to integrate medication, price information, comes with the services – the standard, the NCPDB standards, and the services that Sure Scripts is offering to provide prices that way. I think that will cover a fair amount of the work and is already queued up for the agenda.

Steven Lane – Sutter Health – Co-Chair

And Sasha, has your team done any work in the area of adverse drug events and/or interaction with pharma round research?

Sasha TerMaat – Epic – Member

Like reporting directly from the EHR?

Steven Lane – Sutter Health – Co-Chair

Yes, or facilitating that.

Sasha TerMaat – Epic – Member

Typically, in my experience, typically when people are going to report a safety incident, they want to do it out of a risk management system and not an electronic health record, so that it enters the sort of patient safety protected workspace and is not part of the medical record. So it's like you would have the patient's medical record in the EHR, and then when you are going into, oh, I'm going to report a safety incident, you would want to make sure that that is part of your protected workspace with the PSO you are reporting to, or I guess other entity if you report it to FDA, and that moves out of the medical record and the EHR into another space. That's my experience. And so, certainly, I think there are users of electronic health records that do both things. I think there is some intentional segregation in some cases.

Steven Lane – Sutter Health – Co-Chair

That is a fascinating comment, Sasha. And I wonder how much of that is driven by regulation or requirement. How much of it is driven by paranoia or fear on any actor's part? Who do you think would really understand that space well?

Sasha TerMaat – Epic – Member

I would feel like we would get the best maybe sense from a safety officer who organized their investigations and reporting in that way. They might have the most insight as to why they structure their systems in the way that they do.

Steven Lane – Sutter Health – Co-Chair

Yes.

David McCallie – Individual – Member

This is David. I am no longer associated with a vendor. But from my memory, I would agree with that separation. And I think it is driven predominantly by liability concerns and the channel that was created to protect disclosure of that information both from a patient privacy point of view as well as a provider liability point of view. But it has been researched quite a bit, so there is a lot of knowledge in that space.

One of the thoughts that I had around the use of the one push button way for a provider to sort of snapshot what was in the record at the moment that the putative event occurred, pull it out of the record so that it can be analyzed separately. The context could be snapshotted pretty easily these days with the APIs, which was not nearly so easily done four or five years ago.

Steven Lane – Sutter Health – Co-Chair

Well, thank you, David, for that closing comment. We are a minute over time. And thank you all for your participation. We will plan to meet on June 11 and hopefully have a rousing agenda focusing in on price transparency and medications. Have a good day.

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

Thank you, everyone.

Kensaku Kawamoto – University of Utah Health – Co-Chair

Thanks, everyone.

Sasha TerMaat – EPIC – Member

Goodbye.

David McCallie – Individual – Member

Thank you, bye.