Health Information Technology Advisory Committee

Transcript
March 19, 2019
In Person Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Individual	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Health Care	Member
Cynthia Fisher	WaterRev	Member
Brad Gescheider	PatientsLikeMe	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin	Member

Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Patrick Soon-Shiong	NantHealth	Member
Sasha Termaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
ARWG Speakers		
Name	**Organization**	**Role**
Carolyn Petersen	Individual	Chair
Aaron Miri	The University of Texas at Austin	Chair
ISP TF Speakers		
Name	**Organization**	**Role**
Ken Kawamoto	University of Utah Health	Chair
Steven Lane	Sutter Health	Chair
IACC TF Speakers		
Name	**Organization**	**Role**
Michael Adcock	Individual	Chair
Andrew Truscott	Accenture	Chair
CMC TF Speakers		
Name	**Organization**	**Role**
Raj Ratwani	MedStar Health	Chair
Denise Webb	Individual	Chair
USCDI TF Speakers		
Name	**Organization**	**Role**
Christina Caraballo	Audacious Inquiry	Chair

Steven Lane	Sutter Health	Member
HITCC TF Speakers		
Name	**Organization**	**Role**
Carolyn Petersen	Individual	Chair
Christoph Lehmann	Vanderbilt University Medical Center	SME
ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Steve Posnack	ONC	Executive Director, Office of Technology
Jon White	ONC	Deputy National Coordinator for Health Information Technology

TRANSCRIPT

HITAC Speakers

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All lines are bridged.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Good morning everyone. Welcome to the HITAC members and members of the public. Thank you for joining today's HITAC meeting. We have a very full and interesting agenda today so we will formally call the meeting to order starting with roll call. Carolyn Peterson?

Carolyn Petersen - Individual - Chair
Here.

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

Robert Wah?

Robert Wah - Individual - Chair
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Michael Adcock? Christina Caraballo?

Christiana Caraballo - Audacious Inquiry - Member
I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Tina Esposito?

Tina Esposito - Advocate Healthcare - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher?

Cynthia Fisher - WaterRev - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brad Gescheider?

Brad Gescheider - PatientsLikeMe - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valerie Grey?

Valerie Grey - New York eHealth Collaborative - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anil Jain?

Anil Jain - IBM Watson Health - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
John Kansky?

John Kansky - Indiana Health Information Exchange - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken Kawamoto?

Ken Kawamoto - University of Utah Health - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steven Lane?

Steven Lane - Sutter Health - Member
Here.

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

Leslie Lenert - Medical University of South Carolina - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien Malec?

Arien Malec - Change Healthcare - Member
I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denni McColm?

Denni McColm - Citizens Memorial Healthcare - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Clem McDonald? Aaron Miri?

Aaron Miri - University of Texas at Austin - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brett Oliver?

Brett Oliver - Baptist Health - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley? Raj Watwani?

Raj Ratwani - MedStar Health - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready?

Steve Ready - Norton Healthcare - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Patrick Soon-Shiong? Sasha Termaat?

Sasha Termaat - Epic - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andy Truscott?

Andrew Truscott - Accenture - Member

Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sheryl Turney?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb?

Denise Webb - Individual - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Kate Goodrich, I believe she's absent. Chesley Richards? Not here. Ram Shriram?

Ram Shriram - Individual - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Lauren Thompson? And with us today we have our National Coordinator, Dr. Rucker, Elise Sweeney Anthony, Executive Director of Office of Policy, Steve Posnack, Executive Director, Office of Technology at ONC. And at this time, I would turn over to our National Coordinator for remarks. Dr. Rucker?

Donald Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
Thanks, Lauren. It's great to see everybody in person. As you know, with weather and other Washington-types of issues, we've been a little shy in the meetings but I know everybody has been working hard on the various taskforces. I wanted to thank the folks both for the general work on the taskforces but also the HITAC annual report, which we're going to have available soon and send along to Congress, as is required by the Cures Act.

So, obviously it's been an exciting time for ONC with the long-awaited interoperability rule, out for public comment now. As folks know, that took a while to get out the door, long processes there. But we really feel it's a very, very good starting point to get the American public back into control of their healthcare and to do that by having true control over the medical records.

Obviously when portals came in, the portals were the best technology that I think there was to

empower patients. But clearly, we have moved a lot in the greater computing sphere to smartphones. So, to get patients control of their medical data on their smartphone is really a powerful step and we think that the proposed rule does that.

We obviously look forward to your comment here. As you know, CMS has a companion interoperability rule. As you might guess, it was not an absolute coincidence that they came out on the same day and have the same comment period. I think that would probably violate the laws of probability, I'm guessing. But seriously, it represents our belief that this is really the next step for the American public. So, we're very excited about that.

For HITAC, you are welcome to as individuals comment on these CMS rule, but obviously, per the congressional charter, we would really like you to focus on our rule because that is basically a legal requirement here. So, we won't specifically get into the CMS rule.

Now, Seema Verma said our rule was much longer and one could say many things about long rules, but I think the basic constructs in there are very fairly simple. There's one specific thing that has garnered some public attention. There's an RFI around price transparency. So that's really an RFI, as folks know. There's not really a good really computational framework to figure out how to get price information out because of the odd ways that we pay for healthcare in America.

So, that is really, I think, a first step in trying to understand how we actually start shopping for care in America, right? I mean, when you think about it, it is sort of bizarre that in the rest of our lives we can find prices and in healthcare, it's just an inscrutable mystery.

To that into the broader goal of how we measure value and get rid of some of the sort of friction in the healthcare system, tomorrow we're going to have a number of sessions that are geared around prior authorization and some of the data flows there. We will save a discussion of that for tomorrow morning, but there is more to come there.

So, I think with that I will turn it over to Elise.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

Good morning. Thank you so much. I just want to thank you to reiterate what Doctor Rucker has said in terms of the amount of work that I know all of you have contributed to the workgroup and to the taskforces in preparation for developing recommendations for the rule. We know it's a huge amount of work and each a taskforce has a substantive bulk of the rule to address. So, we really appreciate all the work you have been contributing to that effort.

I want to thank the co-chairs and chairs of the taskforces and the work groups for their work as well as to the staff leads at ONC and to the SMEs at ONC for providing support to you in helping put the words down on paper or where we can provide some explanation of where to find things in the rule. So, thank you for all of that as well.

And I also want to thank, for the annual report that's coming up – actually has been some questions whose animal report it is. It's the HITAC Annual Report. It's not ONC. I know that sometimes gets mischaracterized from other stakeholders, not you guys, of course. But I do want to thank you for all that work. I think it will be helpful in terms of as we think through our next steps for the coming years where we can help address and where we can help think through how health IT can help and engage stakeholders across the spectrum. So, very much thanks for that work as well.

And then I also wanted to think about the prior authorization hearing tomorrow. It's going to be a wonderful opportunity. I know it has come up in some of the taskforce discussions in the past around prior authorizations and many thanks to Dr. Tom Mason and Dr. Andy Gettinger for their work in that regard. I think it's a wonderful agenda of witnesses who will share their perspective. So, I'm looking forward to that tomorrow.

And for today, obviously we have a pretty packed agenda. Much of it includes discussion of the rule and where the taskforces are to date. One thing I will always reiterate, as you guys know me well at this point, is that the rule is still in the public comment process, so we cannot interpret the rule, obviously. But where we can point you to where discussion in the preamble may touch on in issues that are raised, we are happy to do that, as well as if there are any points we can provide feedback on, we are happy to do that. But that may be limited in many ways.

But that provides an opportunity for comment. So, as you're thinking about your recommendations, if there are areas where we were not clear or we could have been clearer, that's part of what we are hoping to get from the HITAC because that helps us put together a final policy that really can work on the ground.

So, huge thanks for all the work you are doing so far. I think we mentioned that a meeting last year that there was much work to come. So, hopefully you guys see that we are true to our word that there was a lot of work to come, but I really appreciate all the work. I know the day jobs that all of you have. This takes time away from that. So, we appreciate the public service you are doing by providing this work for us. So, thank you so much in advance and I guess we will go ahead and pass it to our Chair.

Robert Wah - Individual - Chair

Thank you, Elise. Good morning, everyone. Great to see you all here in person again, as has already been said. Thank you all for your patience with all the machinations that happened earlier in the beginning of the year and acknowledgment about how everyone stepped up and has taken a rule on the taskforce, many taskforces and workgroups. I think we are off to a great start with some significant rule-making commentary here. We appreciate Don being here as our National Coordinator and getting us started.

I want to just say a couple of things about the agenda. I think everyone has gotten it. There has been a number of batches that have come out. I think batches are good for cookies. They're not necessarily good for documents. So, you've gotten a lot of documents there.

We apologize for that, but thank you all for being patient and understanding about the need to

get these out. The timing – we have been trying to get them out as early as possible for you to digest, just like cookies, but ass you can imagine, it has been hard to get the timing down to do that. We will continue to try to get them out as much as possible so that you have the maximum amount of time to prepare.

On the administrative side, I want to remind everybody – at the break for lunch, please stay in the room. We have got to get a photo. It's a visual age, so we have to have a photo of this great group. So, please be present for that. Also, on the administrative side, we are told that the microphones only work four at a time. So, when you're not speaking make sure your microphone is off. So, your little red ring is not there. We can't turn on more than four at a time. So, I guess we have to watch out for that.

What else do I have here? On a personal, I just want to say that I have now left DXC Technologies. So, I will join Carolyn as a personal member of the HITAC as opposed to representing an organization.

And with that, I think the next order of business is to approve our February minutes, which have been distributed. I will open first any comments, questions or suggested changes to the minutes that have already been proposed out there. All right. I'm seeing none, all those in favor of approval of the minutes, please say aye. All those opposed, say no. Okay. So, we have accomplished the approval of the minutes we had on the phone call in February.

And I think with that, I will turn it over to Caroline and Aaron to review the HITAC annual report. As has already been stated, this is our committee's annual report and we appreciate the great work that has been done. And again, we tried to get this out to you to review and we have gotten comments and I think you've seen all that listed. But at this point, I will turn over to Carolyn and Aaron.

Carolyn Petersen - Individual - Chair

All right. I want to welcome everyone to the first in-person meeting of the year. We appreciate your diligence in getting through the weather issues and look forward to a great meeting today. We also appreciate your diligence and interest in working through the annual report with us. We have spent several months as a workgroup preparing this document and, as Robert and Elise and others have reflected, it is a document to reflect our views of the HITAC. So, with that, we will launch into our slides.

So, we started here, again, with our list of the members – myself and Aaron as co-chairs, Christina Caraballo, Brett Oliver, and Chesley Richards as our members. We're supported by ONC, Michelle Murray as a lead and others helping with the preparation of the report. We owe them a great debt of thanks for all the efforts they did in helping to resolve our changes, locate resources, bring on speakers, and generally help us create a comprehensive document on behalf of the committee. Next slide please.

Our overarching scope is to inform, contribute to, and review drafts and final versions of the annual report, which will be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress. Next slide, please.

So, in a more detailed look at our scope, we are analyzing HITAC progress related to the priority targeted areas. We are assessing the health IT infrastructure in advancements in the priority targeted areas. We are analyzing existing gaps in policies and resources for the priority target areas and we're bringing forward ideas for potential HITAC activities to address these identified gaps. All of this is required under the 21st Century Cures Act. Next slide, please.

So, we will go on now with our next steps and meeting schedules. Our next step for this particular draft – the full HITAC committee reviewing this report and suggesting any further edits. We already started that process in February and have incorporated your comments and suggestions into the current draft. Today, the HITAC full committee is approving, we hope, our revised report. The HITAC will be forwarding this final report to the National Coordinator and the National Coordinator will bring this to the HHS Secretary and Congress. Next slide, please.

So, we have here a list of all of our meetings and the work you have followed along with us through the last several months. Today, we are bringing forward what we hope will be the final report for your approval. And then in a couple of months, we will be starting on the fiscal year '19 annual report. We decided we could give ourselves a couple months off because of the other important taskforce workgroups and we are ready for a vacation. Next slide, please.

We have had several reports to this committee, and again, today we'll be looking at that final draft and moving that forward. Next slide.

So, our goal today, really, is to discuss the updated draft of the annual report and to see if we have consensus and are comfortable with where we are at or if we need to do additional work and make further changes. The structure of this report is an executive summary followed by a foreword and overview. We look at the HITAC progress in fiscal year 2018. We have a landscape analysis of the health IT infrastructure as well as the gap analysis of the infrastructure.

We have made some recommendations for addressing the health IT infrastructure gaps and there are suggestions for additional HITAC activities that we could undertake this year or in the future. We have a conclusion and also several appendices listing resources and our citations and other documents that may be of use to HITAC as we go forward this year and in the future. Next slide.

So, again, our priority target areas, as noted in the section 4003 of the 21st Century Cures Act, cover three areas three areas in particular – interoperability, that would be achieving health IT infrastructure that allows for electronic access, exchange, and use of health information. Privacy and security – that's the promotion and protection of privacy and security of health information in health IT.

Patient access – that's the facilitation of secure access by an individual in his or her caregivers to such individuals as protected health information, and then finally, any other target areas that are related to these three main areas that we identify as appropriate targets to be considered on a temporary basis with adequate notice to Congress. Next slide.

So, at this point Aaron and I are going to host a discussion of the report. As you saw from one of the batches that arrived in the inbox, we sent several drafts. Our goal was to provide you with documents that show the changes we have made, a complete listing of all of your comments and how we resolve those. We believe in transparency and because this is a product of the committee as a whole, we really wanted everyone to be very comfortable that you know what we have done in our work bringing something to you and in your comments back to us about how to improve that document.

We want to talk today if there are any questions or comments about this latest draft we have sent you, if there's anything else that should be added to the draft, and then hopefully to discuss approving the draft.

At this point I will pass the mic to Aaron for his comments.

ARWG Speakers

Aaron Miri - University of Texas at Austin - Member

Yes, good morning. Hopefully, you did get it in one of your batches of emails and not cookies, but to the degree of it, the latest report and feedback should be your inbox now if you have it open. We will go into it. Next slide, please. I do want to say one more thing I want to thank, again, Elise, your team, and Dr. Rucker. Their team is very fantastic to partner with. So, what we got to hear was a summation of all their comments, all their feedback, and what not.

Let's go into the report itself and let's ask, first of all, are there any general questions that people have from the final outcome of that? One, does everybody have it?

Carolyn Petersen - Individual - Chair

I think it came out last Friday. We tried really hard to get it out early because we knew you would have lots of documents to look at and many slide presentations. So, it would be the one that came out last Friday.

Aaron Miri - University of Texas at Austin - Member

All right. Next slide.

Carolyn Petersen - Individual - Chair

So, discussion – what can we address for you about the report? What would you like to talk about? Are there any additions that you feel are missing from the report? Andy?

Andrew Truscott - Accenture - Member

No one else was, so, I thought I would. It's great. Thank you ever so much and thank you for the work that's obviously gone into this. It would be great, I think – my sentiment, I don't know whether that's shared with colleagues on the committee, just to say over the next 12 months how can we help? How can we actually be a more effective committee in support of ONC and the agenda? think that would be useful comment to get in. Sorry I haven't mentioned provide that to you previously. But I'd be interested to know whether colleagues also agree with that as well.

Aaron Miri - University of Texas at Austin - Member

It was interesting. This is the first time the annual report obviously was put together. So, we were kind of figuring out as we're going along with great guidance from trusted partners. So, I think this upcoming year we plan on getting the report earlier, which will help and I think at that point, we can bring more iterations in front of this group to discuss and hopefully, we will be able to start here very soon, so we'll be able to get iterations in front of you, discussions, things will come up.

Plus, there are some great topics this year that we're able to talk through, like information blocking and others which office he will have components in next year's report. So, to the degree of it, I think there will be a lot more engagements, but I look forward to any other ideas that you may have.

Carolyn Petersen - Individual - Chair

Steven?

Steven Lane - Sutter Health - Member

One thing that has come up repeatedly in our Interoperability Standards Priorities Taskforce is the challenge we face because there are multiple standards that are being used to support interoperability, specifically the parallel use of CCDA and FHIR, which is, of course, at a point of rapid evolution and use. I don't see this called out as a focus area in the report. But I wonder if it is worth mentioning the need – we've used the word harmonize. Clem has another preferred word. I am trying to remember what it is. I don't know whether it's rationalize or normalize or standardize.

But the idea that we have to deal with the fact that we're living in multiple universes at the same time and as we're trying to move the ball forward, we need to be cognizant of the fact that you have got communities, applications, users that are using one and/or both of those standards and really trying to make a shift to a newer set of technologies. So, I think it's perhaps worth calling out in the annual report is a future focus area.

Carolyn Petersen - Individual - Chair

Thank you, Steven. We've been taking notes of the goal of making any needed edits today so that if we need to, we can bring the revised draft back to this group later in the day, again, with the goal of being responsive and complete. Thank you.

Aaron Miri - University of Texas at Austin - Member

One of the other comments I will say to that also is there's a number of discussions, Steven, that came up that obviously could be pertinent information blocking and other items that maybe would make next year's report as well. So, perhaps it would be something of a footnote of, "This is important," with further explanation going into next year. So, just a head's up on that.

Carolyn Petersen - Individual - Chair

Christina?

Christiana Caraballo - Audacious Inquiry - Member

Thank you guys both for all the hard work on this. As a member of the workgroup, I know how much went into it behind the scenes. One thing I would say as a lesson learned and something that would improve the next round is – I know this is the first time so again, great job – I felt like we did a lot of things based on topics and discussions and PowerPoints. We definitely discussed topics and took notes and brainstormed quite a bit and we started this process in the summer.

I think it would be really helpful to have some type of transparent document where we are seeing kind of draft outlines with a little more detail throughout the process. I know some of our other taskforces have done very well with Google documents. I don't know if that's appropriate for this, but some type of draft that we can react to and see it a little more holistically would be really helpful.

Aaron Miri - University of Texas at Austin - Member

That's a great suggestion. That's a great one. Arien?

Arien Malec - Change Healthcare - Member

Red dot. Good. We ran into the denial of service attack. So, first of all, really appreciate the hard work. I read multiple drafts and there's nothing that I disagree with. It might be appropriate for -- I would suggest changes for this report – but it might be appropriate for future reports to draw out the policy recommendations that Congress in particular may need to pay attention to and also to kind of give a state of the state with respect to health information technology, interoperability, and patient access.

One overriding meta-comment that I may be a little too repetitive about is a perspective that the US healthcare system can make substantial progress but it's a very large boat that requires coordinated steering in a particular direction, not a nimble speedboat. I think yesterday's news report on the state of user experience in health information technology underlines that in some cases, we've tried to go too far too fast and in other cases, we haven't gone fast enough in particular areas.

I know that Congress gets frustrated. It's probably the appropriate way to think about Congress's attitude toward the progress and health information technology. It might be useful sometimes to reflect back the degree of progress we have made, where we are stuck, and in some cases, what the root cause of being stuck is. Have we tried to do too much in too short of time? Have we tried to do too much into many different directions? Or are there additional policy considerations that need legislative approach as opposed to a regulatory approach? Thank you.

Aaron Miri - University of Texas at Austin - Member

Arien, I think that's a great suggestion. We can definitely take that into consideration. I would say that in this report, we did try to show some lineage of success and progress and things that have happened, even with the standards committee and policy committees that preceded us. So, you'll see a lot of those references, particularly in the appendix of the document. I think it's a great point to try to summarize at a high level. I think the foreword was a good job too to be able to

articulate some of those components, but we could look at next year's report. Absolutely.

Carolyn Petersen - Individual - Chair

I think we intended to go down the road of a state of the state kind of approach in the landscape analysis. But clearly it seems there is an interest in more and we can look at that next year, for sure. Ken?

Ken Kawamoto - University of Utah Health - Member

Perfect. Thanks for the report. I did provide some suggestions on February 20th to follow-up on the last HITAC meeting on the area of privacy and security. I know it was not I noticed it wasn't in there. So, I'll repeat what I recommended. I just wanted to see if it was considered.

So, my recommendation was to add on to the end of the section paragraph on lack of user awareness and education about privacy and security protections. Formal guidance should also be provided on compliance with relevant privacy and security regulations, such as HIPAA, of current uses of FHIR APIs such as FHIR applications or CDS services, sending of full patient demographic details in all cases, the use of broadly scoped data access tokens.

So, perhaps this is something that has not been considered enough this year to be able to be put in here, but I think for my user perspective it's a big issue because we do worry as healthcare systems if we're HIPAA-compliant if we use the standards. It would be great to get a federal guidance that yes, it's fine. Don't worry about it. You are completely HIPAA-compliant, or this is what you need to do.

Carolyn Petersen - Individual - Chair

Right. We held those for next year, but we do have these on record and we will be looking to incorporate those into fiscal year '19 report. Thank you.

Aaron Miri - University of Texas at Austin - Member

Once again, thank you again, everybody, for your feedback. The comments we got via email were extensive from several members. So, thank you for that. It was a lot of reading. So, the degree of it, thank you all for that and we look forward to push this forward for a vote.

Carolyn Petersen - Individual - Chair

So, the question we have today is you've seen the completed documents and our revised draft and disposition of all your comments. Are we ready to say yes to the draft? Or do we need more cookies?

Aaron Miri - University of Texas at Austin - Member

I move to -- what are we actually doing? As a committee we are endorsing this document to transmit to Congress. I move that we endorse this document to Congress.

Robert Wah - Individual - Chair

I will second that. You want me to run this as Chair?

Carolyn Petersen - Individual - Chair

We have a motion to accept the draft as it is and send it on to Congress and a second. Can we call for a vote? All those in favor of submitting this draft as-is please acknowledge by saying aye. All those not in favor of endorsing and moving it forward please so state by saying in a saying nay. All those who wish to abstain from endorsing this report and moving it forward, please note so.

All right. It looks like we have an approved final report that will be ready to go forward. Thank you so much.

Aaron Miri - University of Texas at Austin - Member

Thank you all.

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

Thank you, HITAC, for your approval and work with us on this product and again, our deep thanks to ONC team, headed by Michelle Murray, for all of their support and work and helping us bring something that we could bring to you and change to reflect your concerns and priorities. Thank you again.

Aaron Miri - University of Texas at Austin - Member

Thank you.

Robert Wah - Individual - Chair

Thanks Carolyn and Aaron. And thank you all for your review and comments on this report. It's a very important report. We are clearly ahead of time based on our schedule. I would just say that we also have a public comment period scheduled for 12:00 noon that we will try to be meeting that commitment to the public to make sure that, as I said before, when we tell the public what time we will have a public comment time, we work very hard to make sure we stay on that schedule because people make plans around that planned time that we give them.

The next order of business is to discuss the Interoperability Standards Priority Taskforce. And the two co-chairs are Ken and Steven. Maybe if you can move down toward the hot seat down there, I guess we'll call it. While we're doing that, we'll just, again, say that what we had planned this morning was to have the Interoperability Standards Priority Taskforce discussion followed by the Information Blocking Taskforce update.

Again, this day is primarily for the taskforces to report out their current state of progress and to take comments for that. We have two this morning and three this afternoon. So, with that, we will turn it over to can and Steven. Ken and Steven.

ISP TF Speakers

Steven Lane - Sutter Health - Member

Thank you so much. We appreciate the chance to come back before the full HITAC to report on the work of our taskforce. We are going to go over our final recommendations regarding orders and results as well as closed-loop referrals and care coordination. Then we will give you a preview of the future work we are going to be doing.

Just as a reminder, we have presented to the HITAC twice in the past, once in October with a summary of our then draft recommendations regarding orders and results. We then presented again in December with a summary of draft recommendations regarding referrals and care coordination. So, it has been three months since we were here. In that time, we have had three additional meetings, one in January and two in February, during which time we reviewed and finalized our draft recommendations in those two areas.

So, we're going to go through those today really at a higher level trying to focus in on the changes that have been made from the time we presented the draft recommendations until their finalization. We then reviewed areas for future focus for the committee. We are about halfway through our work now and we considered five different potential future areas of focus, including evidence-based disease management, social determinants of health, prior authorization, price transparency, and medication and pharmacy data.

We spent some time balloting with the group to determine what we felt would be the most fruitful use of the group's time and we decided on medication and pharmacy data as the next area of focus. So, we did spend one of our meetings focusing in on that and will have some preliminary findings from that to share.

The other areas that we balloted – we decided that the social determinants of health was really getting a lot of attention from a number of groups and was moving forward. So, the committee decided that was not going to be an initial focus of ours. But the other three areas of evidence-based disease management, prior authorization, and price transparency we felt really shared commonalities and we are hoping to look at all of those as a group and Ken will be describing what our approach to that will be later on.

So, going ahead, I'm going to take a quick review. I doubt we're going to take the full 45 minutes today, but we're going to go through the final recommendations regarding orders and results. Much of this has been here before, but just as an overview, we came up with quite a number of recommendations that we bucketed into two levels of priorities, priority one and priority two.

The first focus areas, as you can see here on consistent encoding of labs and other test result data, the fact that results needed to be sent to clinicians in codified format, that orderable tests needed to be standardized between systems and that that needed to be based on mapping to standard technologies, and a significant focus on the fact that results need to be available to patients and their proxies in order to view and receive those results and make full use of those. So, those were all considered the top priority areas in this domain.

We then focused on the need to standardize ways to differentiate the type of result. This is actually a new recommendation that came out of our receipt of comments in the taskforce meetings as well as an acknowledgment that the currency CDA standard does not – I don't believe

the FHIR standard either, prescribe a process whereby components of results could be grouped.

Some of this is getting pretty well down into the weeds of how the orders and results data is going to be transmitted between systems. But these were felt to be appropriate for taskforce recommendations. There were a number of additional recommendations that came forward in this second priority domain, some of these you have heard of before – the need for standard interoperable methodology to identify what has been ordered and the status of an order, the need for code sets which provide the optimal granularity to describe the data that is being exchanged.

What we have is we have sometimes a one-to-many and sometimes a many-to-one challenge where the code sets that exist do not allow for specific mapping or automated mapping between systems and there is a need to try to right-size that, whether that is true advances to the standard code sets, expanding in some areas, perhaps contracting in others or information modeling that will allow this to be done more completely and in an automated way. This has been seen as a real challenge in real use in our attempts to share this data across systems.

There is clearly a need to integrate external decision support tools in the ordering process, integrating prior authorizations, as we have already heard discussed and we will be discussing here more. There was an increasing focus on the benefits of provenance metadata. This has been called out in the USCDI Version 1. But our group spent some time considering provenance, as you will hear later. This is also being considered in the USCDI workgroup.

But within that general area, there is an identification of the need to send unique reference IDs when results are shared between systems, which allow those results to be iterated if there is a preliminary version, a final version, corrected version, etc., the need for reference IDs to be of the to connect those up and also an acknowledgement that as data increasingly moves in and out of the healthcare system into patient-controlled systems that may be outside of the protection of HIPAA, that there is concern that there is a way to identify if any of that data has been modified or tampered with and the thought was that was perhaps part of a larger definition of provenance.

These two slides provided a summary. We have a whole series of slides that go through each of these priorities in more detail, but I'm not going to go into tremendous steps knowing that this is in the packet that people have. Also, for many of these priorities, we did recommend specific policy levers that we thought would be appropriate to encourage their use. Those will be included in our final report to the HITAC and to the ONC, but we don't include those in the slides today.

So, we're going to go through – and again, each one of these slides goes through the individual priorities. Again, I'm not going to read each one of them to you. Most of these you have seen before. Sufficed to say here that this issue of coding of test results, whether they are laboratory, pathology, cardiology, radiology is incredibly important for this data to be able to move seamlessly and automatically between the systems to share between providers, payers and patients and other stakeholders. Next slide.

This speaks to the same point, sending that codified data to clinicians. Next slide. The importance of being able to map these standard terminologies for orderable tests – this is a little bit different

than the results themselves. This is the test that are ordered, the idea here being that once an order has been placed for an individual that they should, as we have been discussing, have the ability to shop around and take that order where they would like in order for it to be performed. And unless or until we have standardization of the orderable, that will not be possible. Next slide.

This speaks to the challenge of making these results available to patients and their proxies. And again, we do have some specific guidance in that area with regard to how that could be achieved through policy. Next slide. These are some of the newer additions, the idea of differentiating results by type so that systems can more seamlessly separate, for example, lab results from radiology results, from pathology, and even within the lab separating hematology from chemistries, etc.

In the absence of standards to support this, the receiving systems have a hard time to figuring out where to send or where to file received results. So, this was called out really but one of the major vendors as a challenge that should be incorporated and addressed within both CCDA and FHIR-based data exchange. The same with the issue of sending components. The idea for example, that a chemistry panel might include a sodium, potassium, a creatinine, etc. and if those components are sent individually as opposed to grouped together, the receiving system has a much harder time determining how to receive, file, and then display those results. Next slide.

Interoperable methodologies – here again, this has been a real challenge and we wanted to make sure to include orderables and having a process for identifying those. Some work has been done on this by the folks at LOINC, but I think that needs to be extended and that's what the taskforce felt. There are number of standards that are already in use, but they need to be harmonized and supported.

Also, as I mentioned, the existing code sets do leave something to be desired and I think continued work needs to be done if we are going to be able to automatically map and exchange discreet data between systems. Next slide. We have discussed these points here in the past, the importance of incorporating decision support, especially leveraging the CDS Hooks standard as well as prior authorization, which we will go into more detail later. Next slide.

I discussed briefly the challenges of provenance. Next slide. And then here again, the idea that I mentioned briefly about reference IDs so that results can be tracked over time as they may change. And in the next slide, this notion that -- one more down, I think that was a duplicate. Well, the slide before that was meant to address this issue of tampering and the need for digital signatures, some way for a recipient to know that the results received are true to the original resulting agency and have not been changed along the way.

There's certainly been a lot of talk in the industry about blockchain. This might be one of those areas where that could be put to use with the idea of being able to assure that the results stay consistent as they move through the ecosystem. Next slide.

So, that was a quick run through where we have been with orders and results including some of the changes that were made. We've also done a deep dive on closed-loop referrals and care coordination and finalized our recommendations in this area.

Again, I will start with a high-level summary, where we focus on the need for closed-loop communications to support this use case, the importance of standardizing the clinical data that is collected prior to a referral or other transition of care and the need to send that data with the patient to streamline the referral process, the importance of clinician-to-clinician messaging about patients.

There are a number of tools that are available for use in this area, but this has not been well-adopted and is not really in use today in large part, especially as patients traverse the healthcare system through different organizations that may be using different vendor systems.

The importance of having communications to support referral management and care coordination and the governance of this whole process – so, we'll go into a bit more detail here again. We split our recommendations into a top priority and secondary priority, where we include the importance of integrating and incorporating received data into the recipient EHR or other HIT system.

The challenge of patient to clinician messaging – today mostly done with in EHR-tethered patient portals, but with the emergence of PHRs, of potential for direct messaging, or potentially using FHIR-based messaging tools to support patient-clinician messaging, there is a need for advancement of standards in this area.

There was acknowledgment of the potential value for a multi-stakeholder care plan that can be shared across institutions. Some work has been done on this, but again, there's an opportunity to advance standards in this area and then real-time text messaging, of course, is becoming a greater part of how we communicate within the healthcare system, primarily today within the acute care setting, perhaps between physicians, nurses and other members of the care team, but increasingly we see providers and patients and other stakeholders using this and again there is a lack of standards to support this area.

So, again, just going through in a bit more detail, some of this we brought to you in our prior presentation and has not changed a lot. This first one really speaks to the importance of closed loop referrals, being able to send a patient from one provider to another and then have that referral be managed sufficiently efficiently and the data coming back to the referring provider.

A lot of work has been done working on the 360X standard, which is based on direct and other accepted health IT standards and our taskforce felt that this was important work that needed to be brought into the real world. So far, this has been done in connect-a-thons, but has yet to go live and we think it warrants the continuing support of ONC and others to get it live and then also looking at the possibility for supporting these workflows using the newer technology of FHIR, where that might be applicable. Next slide.

This issue of collecting standardized data is a very big nut to crack. Our taskforce did a lot of work on this, which we have presented here previously. We reached out to the American Medical Association's Integrated Health Model Initiative Group with a very specific proposal that they might take this on. We've had a bit of back and forth, but they have come back to us very recently

and agreed that they would be happy to serve as a convener for this.

We have identified a number of other stakeholders that we thought could support this, but again, the basic idea is to say if a pediatrician is referring a patient to a pediatric cardiologist for a consult about a new heart murmur, what is the specific information that would be appropriate to send along? This also could apply with other transitions of care, for example, from acute care to post-acute care, in an out of home care services, etc.

But the idea of a significant body of standards that would support this clinical communication and these transitions of care our group felt would be very valuable and I think would benefit from the support of ONC.

Here again, looking for opportunities to leverage the new FHIR resources and technology to support these care transitions as well as looking at smart FHIR technology to be able to do some of this work with in more of an app-based infrastructure. Next slide.

We talked to clinician-to-clinician messaging and the challenges of getting that implemented. A lot of work has been done here to identify what are the opportunities and needs for the EHR and other vendors to really get this up and running. Once again, as per my earlier comments, we have the parallel CCDA and FHIR-based technology that could be supportive of these workflows.

Provider directories, many have identified this as a critical need within our industry. If you're going to be messaging and referring between providers, there need to be standards for these directories so that you can find the appropriate provider to provide the service that is needed. And all of this really requires governance, which was discussed in some detail and will, again, be included in our recommendations back to the ONC. Next slide.

We talked a bit about incorporating the data into the EHR and how critical that is, really into all health IT systems. Patient-to-clinician messaging I mentioned earlier is now being managed through a number of different technology solutions and really these need to be integrated into the established workflows.

Today, most clinicians are accustomed to managing communications through a patient portal, but as patients appropriately look to take greater control and to be able to coordinate all of their communications through a single toolset that might allow them to communicate with providers at different organizations and across their care team, we really need to look at how to integrate these together so patients have the convenience they need while providers still have workflows that they can manage. Next slide.

We talked about the care plan, the real-time text messaging – both of these were mentioned here during our prior report. Next slide. And then we have a number of other recommendations that will be coming forward. None of these has changed since the last presentation. Next slide.

So, again, after finalizing our recommendations around orders and results and closed loop referrals and care coordination, we turned our attention to the next domain of interest, which

the taskforce determined would be medication and pharmacy data. We've spent some time collecting input on where the opportunities exist here.

I must say there was some controversy about whether or not this was the best place to focus yet because, of course, many groups and individuals have put a lot of work into making this as good as it is today. We have e-prescribing. We have e-PCS. We have electronic prior authorization in place. In the marketplace with a number of vendors working on all of those. But there are still some persistent challenges and Ken will walk us through the feedback we have collected to date.

Ken Kawamoto - University of Utah Health - Member

Thank, Steven. So, this is still a preview. We're in the middle of still discussing these. We've identified a number of issues and we listed them here. We welcome any feedback from folks who aren't on the taskforce as well.

So, in this domain, again, we have what we have consider top-tier priority one issues that need to be addressed and then also secondary ones. So, in terms of the priority ones, one of the items we identified as an issue is that the medication administration dispensation information is not universally available. So, this is things like outpatient pharmacy fill data. It does include things also like PDMD data.

So, NCPDP is clearly addressing this. One of the areas where we identified a gap to was in the FHIR standards. So, the US Core FHIR profiles include when you prescribe a medication or patient reported medications, but it does not include when a patient has medication dispensed. As we know, patients oftentimes don't take the medications that are prescribed. I believe for chronic conditions, it's about 50% of the time people don't take their medications that are prescribed. So, this is important information. So, this is an area where we're planning to make some recommendations.

Another one is in the area of medication reconciliation. This is good in the sense that now we have a lot of data from various institutions we are reconciling. It is painstaking for providers in that now they have all this data that oftentimes overlaps that they need to reconcile and sometimes need to reconcile over and over again. So, we have recommendations that we're drafting here to make this less painful and burdensome from a provider perspectives in terms of reconciling all the data on medications from various facilities.

A third priority recommendation area we have identified is for the transmittal of free-text SIGs. So, for looking at medication data, obviously structured data such as number of times a patient is taking a medication a day, the dosage, route, etc. is useful. At the same time, there's a substantial amount of prescriptions that are written by free-text and there was some discussion around whether we should require structured SIGs. There was, I think, a general consensus that would be too burdensome.

So, what we are left is with this free-text SIGs. But if you look at the current standards, such as the US Core FHIR profiles, they don't actually require free-text SIGs if they're available to be transmitted. So, this was an area we identified as an issue that would make it difficult to make use of these if there's no structured data and no free-text SIG to go off of.

The fourth priority that we identified was access to prescription drug monitoring program, PDMD data. So, there are two aspects of this. One may be simply that based on state regulations, etc., we cannot access this data. In terms of being able to incorporate it into recognized systems such as EHR's.

The other part is that it can be cost-prohibitive, where even if the access is available the amount of license fees, the usage fees that have to be paid can be substantial, especially when only using it for the only purposes but when trying to access it for the purposes of pulling in the data. It can be a significant cost increase when requesting the source data.

Fifth priority, priority 1E, is the difficulty of knowing the net price of prescribed medications. This starts getting into the other topics that we plan to tackle but this one is around cost and price transparency. So, this is the notion that for patients and for prescribers, when prescribing medication, oftentimes it's a black box. As to how much it will end up costing the patient, this is challenging because it includes like how much of a deductible has a user paid.

I've personally had experiences where you pick up a medication. You're shocked at how much the out-of-pocket cost is. I'm sure my provider did not know what it would have been. This is an area we identified as an important need. And the last one also has cross-over to the other topics. This is around prior auth. So, again, it can be quite burdensome for some medications to get prior authorization to be able to prescribe the medications when indicated. So, this is an area we also identified as needing to be addressed.

In terms of secondary priorities, we identified one being that the National Library of Medicine hasn't RxNorm application programming interface but doesn't have codes for discontinued drugs. So, what this means is when a medication goes off-market and you say, "Hey, what are the opioid medications?" or, "What of the hypertension medications?" that you basically don't get results for drugs that may have been off the market, say, for about a year.

What this means is if you're saying, for example, "Has the patient ever taken a drug of this type?" you can't make use of this resource or otherwise make false assumptions. This is an issue that the National Library of Medicine understands and just needs to get prioritized and resourced, but we think this is important, given how important that resource is.

Another second or priority was that free-text SIGs are prevalent, but difficult to interpret or use when structured information is needed. For example, at our health system, we found that for opioid prescriptions, in a year period, I think it was about 15% to 20% of our prescriptions were free-texted.

When we tried to make use of that information to do things like morphine milligram equivalent calculations, that was difficult and most of the products such as vendor-provided products to take account of free-text SIGs. So, this was an issue. Some recommendations include building some resources around being able to do natural language processing on these kinds of SIGs.

And a final secondary recommendation, the ability to forward an e-prescriptions to alternate pharmacy. This may be something that's covered in the upcoming NCPDP recommendations, but this was identified as a need. Next slide, please. Go ahead.

Steven Lane - Sutter Health - Member

If I can chime in – one thing I don't think we captured in the slide which the group discussed is the idea that even though discrete SIGs are not captured universally that when that data is captured discreetly, that it should be transmitted discreetly and received discreetly so that it can be put to use.

Ken Kawamoto - University of Utah Health - Member

Thanks, Steven. I believe this is our last slide. This is a preview of featured domains. As Steven mentioned, the taskforce has been identifying areas that we thought were important. One of them, as he mentioned, was social determinates of health, which, although we identified was important, given the amount of work going on, we will probably not get to that this year.

The other three that members pretty much put as a tie in terms of importance were evidence-based disease management, price transparency, and prior authorization. So we're looking to go to these after the medication-related topic. One insight that Steve Posnack had was that these are essentially different use cases with very similar technology needs.

That is that for all these, we need to collect appropriate information, we need to send that information to, say, a service that analyzes it relative to the set of rules and requirements and return the recommendations to the requester, which then has to be incorporated into a workflow.

So, putting it in technical terms, for example, all these could potentially leverage the CDS Hook standard that is emerging in HL7 and starting to get some vendor adoption. Our current tentative plan is to see if we can roll these use cases together and see if we can consider them together as an overall use case and priority in providing point of care information to providers and patients and other stakeholders.

Steven Lane - Sutter Health - Member

So, that, I think, is the end of the formal presentation. We are happy to entertain any questions or receive comments. Clear as glass?

Ken Kawamoto - University of Utah Health - Member

I think Sheryl has a question.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

Thank you. Sheryl Turney, I participated on this group and I wanted to say thank you for your leadership in terms of the discussions. I personally learned a lot in addition to trying to participate. A couple of things though now that we are at this point because some of the topics we have discussed like the data provenance and also some of the topics with provider directories are going to come up in the rules that we are currently commenting on right now.

Is the anticipation in this group that we're going to take those comments that we are currently making and bring them back to our priority group to add to the discussion that we have already had or are we going to restart those discussions when we get back together in a group. I think some of the topics, especially the data provenance assistant the and USCDI would be completely appropriate to bring back to this forum.

Steven Lane - Sutter Health - Member

I will comment first, Sheryl. You make a really good point, which is that our discussions of the rules and the comment there are clearly going to come back and influence the work of the ISP taskforce. Also, I think we have been very well aware from the beginning of our taskforce work of the strong connection of ISPTF with USCDI into as our taskforce is looking at the standards and USCDI is looking at the content that will be transmitted.

So, as you know and others may not, Terry O'Malley, who is one of the cochairs of USCDI, has been really working closely with us on the ISP taskforce and we are really trying to stay as well-aligned similarly now with the re-instantiation of USCDI. I've been working closely with Christina and Terry in trying to keep those efforts as well-aligned as we can. Do you want to add to that?

Ken Kawamoto - University of Utah Health - Member

I think obviously we want synergies. The key is how to avoid unnecessarily duplicate of work. We are all engaged in a lot of efforts around this HITAC.

Brett Oliver - Baptist Health - Member

During your discussions, we're talking about a lot of new technologies. Was there any talk about existing technologies that are not being utilized because of cost considerations, specifically discontinuation notifications to pharmacies that at least where I'm from, 99% have turned off? That's a major patient safety issue. Any discussion regarding existing technology that's not being utilized?

Steven Lane - Sutter Health - Member

I think you make a really good point, Brett. There are vendors who are working on med discontinuation communications, medication change communications that have been incompletely implemented, I think, by both the pharmacy vendors and the EHR vendors.

I don't think those came up in our initial comments, but I think it would be nice for us to add those to the list of opportunities for us to advance the standards or advance the requirement for use of standards because, for one, I would love to have those baked into my EHR. That would be great. I have a lot of very manual workarounds that I need to tell a pharmacist that a medication has been changed or discontinued and it be great if that happened automatically.

Ken Kawamoto - University of Utah Health - Member

Just to add to that, I think that's the recurring theme of we have what we might consider legacy standards and from next-generation standards and this came up in the referrals discussion about do we go off direct-based messaging or do we try to move to things like FHIR-based messaging?

It is a hard question, I think. I don't think there is an easy answer to it but I think it is a very relevant point that we have to decide on because obviously, the legacy standards tend to be more mature, at the same time, the industry is starting to move to some non-use standards tax.

Christiana Caraballo - Audacious Inquiry - Member

So, thank you for that presentation. The one thing I would like to bring up is taking off social determinants of health, especially for the reason, Steven, you said you were taking it off of the list because the industry is moving forward with it and I think that's the exact reason why we need it on a list. We have a lot of federal agencies and groups that are looking at incorporating social determinants of health, but they are doing it in their own little buckets. I think it's really important for standards to support the different initiatives.

We have got under the CMMI the Accountable Health Communities Model is looking at social determinants of health. ARC just announced a challenge within the past week or two about incorporating or developing tools to incorporate social determinants of health and specifically referenced the need for standards-based tools.

And then we have ONC has started to look at social determinants of health under like the social, psychological, and behavioral health data classes, but we're still not coming together in creating implementation guide for organizations to collectively look at social determinants of health and have a way to start in a standardized way so that as we continue to incorporate social determinants of health into the broader health community, we are doing it the same way and it becomes more scalable.

Steven Lane - Sutter Health - Member

I couldn't agree more with your comments, Christina. The challenge that we face with taskforce is it has a limited period of time to work and we determined that we would leave it up to the taskforce members to determine where they felt they were most enthusiastic about visiting their energies.

So, as I say, we put this up. We brought the experts. We had a deep discussion. We balloted and it was a lower priority than the others. It's certainly my hope that the work of this committee, like the work of the USCDI, will go forward. Of course, the ISA is going forward. And I think that there is a great opportunity for the input of the HITAC and other interested members of the public to contribute. So, I agree. I think social determinants are key, but we're not going to get to it probably this year in the taskforce.

Ken Kawamoto - University of Utah Health - Member

Maybe just to add to that, if we are able to go faster because we are able to do that, for example, by merging some topics or if we have an extended timeframe, we could potentially get to it. At the same time, I think social determinants of health is a classic example that can work very well to USCDI because it's really about the data classes, etc. So, it very well may be without been considered, really, by the ISP taskforce it could move forward to the USCDI.

Steven Lane - Sutter Health - Member

I think Arien is next.

Arien Malec - Change Healthcare - Member

Thank you. Just with respect to the point on discontinuation, medication discontinuation – we did discuss in the orders and results work section the broader ecosystem considerations. So, one of the issues that we get into within interoperability is that there may be a standard that is perfectly good for doing X, Y, and Z, but it's not adopted uniformly by the ecosystem. This is the case where we have pharmacies and EHR vendors that both need to implement the same standard and same semantics.

So, as we get into the work, we might want to consider some of the ecosystem effects that are associated with medication information transmittal, same kinds of things apply for things like SIG and others where pharmacy actors tend not to do much with SIGs. Sorry, TBM actors not tend to do much with SIGs relative to med history, whereas pharmacy actors do carry SIGs.

So, drawing a broader ecosystem consideration can sometimes be the appropriate of addressing that stuff. People sometimes believe that if information isn't flowing, it's because we don't have standards. Sometimes we have a good standard that's not appropriately adopted. Thanks.

Andrew Truscott - Accenture - Member

All right. Thank you. Great work on this committee. Excellent. One feedback of them I would have for consideration for future reports and what not is diving into an element of social determinants of health was his patient-reported outcomes. PROs are something that's vitally important to University of Texas Health as well as Travis County in Texas and as we expand our utilization of PROs with the community, there is a gap in the type of PROs and standards around them.

Some PROs have structure and some do not. We've managed to wing it in some cases for what we think it might work, but it would be greatly beneficial to have standards around that so can be more universally adopted and tremendous research and feedback and positive quality affect showing utilization of PROs and a course of care can lead to better outcomes. Thank you.

Steven Lane - Sutter Health - Member

Thanks. Andrew.

Andrew Truscott - Accenture - Member

Thanks ever so much for leading us to this veritable minefield of opportunity on this taskforce. I just want to pick up on Christine's comments as well. I agree. I'm not sure it was necessarily considered a low priority as much is not quite as pressing and needful as the others focused upon, but I would suggest that this is probably a candidate to be picked up for future work as we are able to make that recommendation anyway for future work to be undertaken.

Just one point – that lack of use of a standard does not mean the standard does not exist. It just means it has not been adopted. So, I think maybe in our preamble, we reflect that just because someone is not doing something doesn't mean that there's an absence of the means to do it.

Steven Lane - Sutter Health - Member
Carolyn.

Carolyn Petersen - Individual - Chair
Thanks. I want to join in with others and commending you on the excellent depth and breadth of this work. I want to follow on to Aaron's comment about PROs and the importance of working towards inclusion of that. I agree and I also think that this may be a gateway that can help us think about how to start bringing in patient-generated health data.

As we know, at this point, a lot of that comes out of very disparate sources and things that are not traditional kinds of data gathering instruments and devices that are native to healthcare, but going forward, that will be something important in the future. So, I strongly encourage the group to look into that further. Thank you.

Denni McColm - Citizens Memorial Healthcare - Member
Hi, I'm Denni McColm. I might have missed this, but now, what's next? These are recommendations that will go forward to – we want ONC to do something about it or what? What do we do with these next? Great work, by the way.

Steven Lane - Sutter Health - Member
Yeah. We didn't include the slide that reiterates the charge of our taskforce, but it was spelled out in Cures. I don't know if Denise has the language handy and maybe could read it off for us. But basically, our charge is to look at priority uses of health information technology to identify the associated standards that support those uses and then to make a report. That's the extent of our charge.

So, we will be making a report that will be the work probably of the taskforce in Q3 to return to the ONC, basically spelling out our findings and recommendations and then it's going to be up to ONC to move that forward. Most of our recommendations in terms of actions and potential policy changes really speak to the ONC and to CMS, where we think there are opportunities for rulemaking, etc. to support the advancement of these recommendations. But that's definitely going to be out of the hands of the taskforce.

Ken Kawamoto - University of Utah Health - Member
Tina was next and then Steve.

Tina Esposito - Advocate Healthcare - Member
I'm wondering if there's an opportunity to be a little bit more deliberate in – we can completely acknowledge that there's only so much work that the taskforces are able to do, but to feed into what Carolyn and subgroup around the annual report is on in terms of identifying potential opportunities for the HITAC in upcoming years, social determinants of health, patient-reported outcomes – so, to be very deliberate in terms of what was just left on the table because we didn't have enough time to do it. I just think that would be a nice way to continue level of continuity and setting the direction for the taskforce as well.

Steven Lane - Sutter Health - Member
That is a helpful suggestion and we can definitely do that in our report writing.

Ken Kawamoto - University of Utah Health - Member
Steve was next and then Christina.

Christiana Caraballo - Audacious Inquiry - Member
Just echoing one more time on the patient engagement piece – we've all kind of said it – patient-reported outcomes, patient-generated health data, social determinants of health – when you think about that under a bigger umbrella, it's all patient engagement. So, I think that could become our use case and you have got multiple things under that. It's how do you engage me to get information about me?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
All right. Thanks. Steve Posnack. I wanted to thank you all as well for the continued efforts as well as the recommendations that you produced thus far. Perhaps to piggyback – for some of the other issues that may not get their full attention, as was mentioned, the statutory requirement includes the summary report and findings. So, some of the other areas that may not be fully addressed by the taskforce during this time at the turn of the crank here could be well represented as some of the findings that don't get precise recommendations.

With respect to the sleight of recommendations that you have identified or the priorities you have identified being the priorities taskforce, all of them are listed as a priority, which is great. It's great to have them all documented. In some cases I can see them being implemented in parallel, either in part by ONC or coordination with another agency or by a respective private sector partner in the field.

As you all consider your work going forward, it may be helpful as part of the final writeup to consider what may be parallel process in certain other areas – the NLM recommendation is something we can chat with them about. Similarly, with the US FHIR Core Profiles, it's something we can implement through HL7.

So, there are a number of different opportunities where I can see us tackling a few of these at the same time, but if there are others that seem to you all to have a dependency or more linear progression, the one that would make the most impact upfront would be helpful to at least have an asterisk next to it. Thanks.

Ken Kawamoto - University of Utah Health - Member
Anybody else? Okay. Dr. Rucker?

Donald Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
Yeah. I think we can help you with what Steve just pointed out. It's a wonderful list and very valuable to have that list, but I think we do want to, as I think you've done, we want to make sure

in the final public that we map each of those things as best as we can to who is going to do it or how it's going to be done because that's very helpful and that can sort of help us with the boundary cases to what Steve had mentioned earlier with IAG and FHIR, for example, but there are actually a whole bunch of boundary cases here that, as we sort through those things, that will move things along.

Some of them are, I think harder, because I think things like social determinants of health, I think are really – the core – where is the landscape even start? What is the overall approach from that. There are probably a bunch of academic papers, I'm guessing from different disciplines of researchers that looked at this. I don't know if this group has that information, but I think that one is really just like what part of the landscape do we even start to look at it on social determinants of health. So, we look forward to working with you on that. But this has been great.

Ken Kawamoto - University of Utah Health - Member

Thank you. I think we definitely do need to prioritize further. And we did not report today, but in our work would include specific actors and recommendations for those specific actors as well. So, they are in there. Cynthia?

Cynthia Fisher - WaterRev - Member

Thank you. I think the taskforce and subgroup for itemizing and putting the priorities in order. And I guess as we also sit here with the patient and caregivers in mind and getting access to their care into their information and to their outcomes, if you think about it, as we go about this – and I support some of the comments here that are really patient-oriented.

As we look at moving toward the Uberization of healthcare, ultimately as we present the standards and we present the priorities, I think we want to be able to -- we can so readily see where we can get our Uber driver and why not also to see the pathway of where we can get access to care, how much that care will provide us, what is the care record of the provider?

So, we can look at the price. We can look at the availability and ultimately, think about how great it will be when patients will play into the value metric equation as they do go and report outcomes, but also report on the metrics of experiential care.

Then I think ultimately too, we want to look at the two-way feedback into the patient physician records and notes and that the patient has a voice electronically to correct erroneous reporting and also provide their own patient health information two-way as well. I think it's really important that we can do it in so many other industries and as we sit here to do the best we can to allow that pipeline or that pathway to allow that mobile access for the patient as we move forward.

Ken Kawamoto - University of Utah Health - Member

Any other comments?

Steven Lane - Sutter Health - Member

Thank you all again for the opportunity to present. I anticipate we will be back in a few more months and do it again.

Robert Wah - Individual - Chair

Ken, Steven, thank you very much. We are a few minutes ahead of time. We have had a discussion about having a break. As Chairs, we know we owe you all a little break, but we are also mindful of the fact that information blocking has been a very hot topic. I will put this out there and if you disagree you can all challenge it, I guess.

I think we ought to just take self-breaks as we need to because I really am nervous that we would not have enough time for blocking. We've gone from having too much time to worrying about not having to enough time. It's just the life of being co-chairs up here. We're just going back and forth. So, I think we will proceed with information blocking now. If you need to take a break, feel free to get up and take one.

We're very mindful of our commitment to the public that we're going to take public commemnts at noon as scheduled. Dawn can only stay a certain amount of time and I want to make sure we're responsible for his time as well.

So, with that, if I could ask our co-chairs for information blocking to move down to the form. We'll get the slides loaded for that and we'll go ahead and proceed to information blocking. I wanted to give you a road map of where we are and why we're doing it. So, even though we have a couple extra minutes, I want to give that time to information blocking because I have concerns that we won't have enough time for that. So, with that, Michael and Andrew, take it away for Information Blocking Taskforce update.

IACC TF Speakers

Andrew Truscott - Accenture - Member

Here I was thinking I could take a break. Thank you, Doctor Co-Chair, Madame Co-Chair. It's great to be here this morning presenting the deliberations and progress made by the Information Blocking Taskforce. We are not just talking about information blocking. Go to the next slide. We are actually talking about a breadth of the regulations around information blocking, which touch upon several different aspects. Here, we have the taskforce members who are engaged, myself, and Andrew Truscott and Mike Adcock sitting to my right.

As you can see, we have a broad spectrum of individuals across the HITAC who are engaged in this taskforce. Anyone would think there was a significant degree of interest in information blocking, for some reason. It's a great group because we have a very diverse set of opinions. As is very true in many aspects of healthcare, we probably have more opinions than we do have people on the taskforce, which is also good. We have the exquisite task of picking through that smorgasbord.

I have to say, at this point, whoever is transcribing my comments, as is true in all the taskforce and work group meetings, every now and then, it does say [indiscernible]. So, it will be interesting to see how this will get transcribed.

As we work through the regulations, we can only thank the contributions which have been by ONC staff. The effort being put into the regulations is tantamount. It's very clear a lot of thought has been made. Thank you very much. And also, thank you very much for helping us navigate what the intent was, which is sometimes not as obvious in the drafting language as you might believe. I think it's a good dynamic. We're providing insight back on how some of that language has been perceived or could be perceived by the broad range of stakeholders who are engaged on this taskforce specifically.

I'd also like to think members of the public who are also showing an interest in the work being undertaken by the taskforce. We do see you appear on the calls even though you stay very mute. I can only encourage members of the public to actively comment as well. The HITAC is here to receive input from the public as we make our recommendations to the national coordinator and we take that position very seriously. Next slide, please.

Okay. So, this taskforce has got a wide range of activities it's undertaking. One is around the actual definitions, which are provided within the regulations. We are not specifically looking at the definition of information blocking, as that is defined in 21st Century Cures very clearly. That information blocking definition is being used as the core of what we're coming from inside this taskforce.

However, we are looking at the definitions and interpretations of some of the standard statutory terms which are in there. For example, who are the actors? The definition of a health information network versus that of a health information exchange, the ambiguity that exists both inside the vernacular of those terms in the broader health ecosystem as well as a multitude of different statutory references either in a capital exchange or lower case-E for exchange. We have had great dialogue on the taskforce about what actually the actual defined terms are versus common usage of those terms. And actually, quelle surprise, they are different.

We are looking at the exceptions to information blocking, where there could be a statutory legitimacy around information blocking and where the intended and unintended impacts of such exceptions, potential coercive forces on the market and potential intended -- I'm sorry, unintended implications of some of the drafts as it currently stands. Also, looking at the complaint process. So, actually how do information blocking decisions get complained about and escalated, both within ONC and OHE?

Looking at disincentives – so, where it's intended disincentive. This is a request for information. We are also looking at requests for information around a variety of other aspects, including price transparency. This taskforce is also making abundantly clear that where we're talking about transparency, we are not necessarily talking about reasonable costs as well. These are completely different aspects.

Also, looking at enforcement, how is this enforced through the health IT certification process. And we're looking to bring enhanced clarity to that process. This taskforce believes, I think, and members of this taskforce who are on the committee, please feel free to comment as we go through the Q and A, but we believe the enforcement of information blocking regulations is going to have a greater degree of workload upon ONC than has happened previously and we need to

make this as clear a road map and runway as possible. Next slide, please. I'll hand it over to my Co-Chair, Mr. Michael Adcock.

Michael Adcock - Individual - Member

Very good. Good morning, everyone. We broke our work down. There was a tremendous amount of work and we broke it into three primary work groups. Group one was relevant statutory terms and provisions. So, we were looking at definitions. You can see the topics we discussed there. We'll go into those in a little more detail. Because we had 12 members who volunteered for the taskforce, we were able to break each group into four people apiece, with Mark being on the calls with us and then Andy and I being on the majority of the calls together.

So, here are the members of work group one. Some of the progress and recommendations we have made – as Andy said, we talked a lot about the health information networks and exchanges, both capital E and N and lowercase E and N. We did feel that the definitions for and distinction between HIE and HIN should be clearer. We discussed whether the scope and proposed definitions aligned with the intent of the 21st Century Cures Act.

Also, we are working on recommendations for revisions to the reg text and the preamble to make sure we have definitions clear that are broad enough to cover the people they need to cover, but also, narrow enough that there is a difference between HIE and HIN.

Electronic health information definition – our proposed recommendation there was to add language that clarifies the information is inclusive of human or machine-readable form. We have seen things in the industry where information blocking could be overlooked because things can be considered data if they're only able to be read by machines. So, we want to make sure that we add that in the preamble for clarification.

Price information – we had a lot of discussion about price information. We had multiple views on addressing price transparency in this rule. One view was that price transparency is very important, but out of the scope for this rule, we must consider the unintended consequences of addressing that.

We also have the view that patients need price transparency now, and this rule is an appropriate lever for addressing the issue. We are reviewing ONC's request for information regarding pricing information and will provide more detail about the scope and parameters of price information that would be included. We also are considering the implications of including such information in a definition because there are lots of intended and unintended consequences.

The next item that we discussed were practices that may implicate the information blocking provision. We looked at scope and implications of examples of potential information blocking and are considering updates to the examples that are located in the preamble.

Next, we moved on to parties that may implicate information blocking provisions. We looked a lot at the ONC's use of the term actors for regulated entities under the information blocking provisions, had discussions of whether or not to add to that definition or to make sure the actors

were well defined within the examples of entities.

So, we discussed examples of entities that would or would not be considered an actor under the proposed definitions of healthcare provider, HIT developer, a certified health IT, health information network and health information exchange. We want to make sure that anyone could be held accountable will fall into at least one of those categories. We are looking at clarifying the language in the preamble.

So, what we're hoping to do, if it's okay with the co-chairs, is to take questions and comments in between each workgroup so that we can address the individual questions that were asked and proposals out there and comments just in case anyone had discussions, we'll need to be as brief as possible so we can get through all the workgroups. This is a very interesting topic for a lot of people, so we'll move right on to questions. Arien?

Arien Malec - Change Healthcare - Member

Yeah. Sorry. This is something I've spent a fair amount of time thinking about. So, I might have a lot of questions or comments. With respect to the definition of health information network and with respect to the intent of the Cures Act, one of the issues I've raised is that if you follow the definition of each electronic health information and the definitions proposed for health information network, it places under regulation and regulatory burden a number of actors that I think are outside the intent of Congress.

In particular, I've made the case that banking transactions could be considered a health information network transmitting electronic health information. There are other broad exchanges occurring across the country. And a perspective that we should tailor, at least at this time, the actions under information blocking regulations, particularly relative to price controls, contractual controls, and those other things to areas that are egregious or areas that have been implicated in practice to impede the flow of information.

So, where information is already flowing, where it's not, the intent, and potential for unintended consequences. I feel the group should focus the definition of particularly health information network and health information exchange in ways that address those needs.

Andrew Truscott - Accenture - Member

Thanks, Arien. I hear what you're saying and I think as you are probably privy to, we have had many conversations through the work groups, which incidentally, for those of you unaware, it's four and five hours a day the work group meetings have been going on the last two and a half weeks to get to this stage. It's the addressing about whether if you treat HIN as a noun and HIE as a verb, which is generally the market usage with notable exceptions where you have organizations who call themselves an HIE as well.

We are trying to pick our way through that with the intent of Congress in putting the definitions down and bringing them forward. Thank you. If you have recommendations or proposals around the drafting, we are all ears as we work through this. We are on time in getting our recommendations to HITAC done. So, now is a good juncture to put that in. Thank you, Arien. Cynthia?

Cynthia Fisher - WaterRev - Member

Thank you, Andy. Following up on the comment about networks and exchanges, both HINs and HIEs, I think as we look at the definitions of network or health information network and exchanges and health information exchange, you know, it is important. I understand your concerns, Arien. However, I do believe that it is important that it should remain broad and based on the function of the entity that it's engaged in with respect to the proposed rule.

One of the things as we sit here, we need to consider that the entire healthcare industry is shifting in ways that we can't anticipate for the future. We are seeing now substantial vertical integration. The healthcare industry stakeholders are merging with increasing frequency. We have new lines of data exchange taking place, new lines of business.

As they consolidate and form these partnerships, policymakers need to consider the functional broad definitions of HINs and HIEs to ensure that the data holders cannot shift their liability and legal obligations with respect to information blocking. So, the functional definition gives regulators the flexibility to enforce information blocking as a healthcare industry and its stakeholders will continue to merge over time. And then finally, perhaps in the preamble, we can consider today as we see examples of these types of entities that participate in the function of networks and exchanges.

Andrew Truscott - Accenture - Member

Thanks, Cynthia. We are absolutely focused on making sure the recommendations are ones that embrace the fact that the healthcare ecosystem is changing. It is moving. There is a future. These regulations will be intact for a considerable period of time. Thank you. John?

John Kansky - Indiana Health Information Exchange - Member

Thank you. This comment isn't in response to what Arien or Cynthia said, but I think it's well-timed. I took the unusual step for me, because I'm not known for brevity and clarity, of writing this out. I hope I don't get in trouble with PETA for this analogy, but we'll see. Policy is inherently a blunt instrument and surgically solving problems in complex industries is really hard. I think everybody would agree with that.

I believe the intent of this regulation is to whack the bad moles from information blocking. But if the definition of moles and the definition of mole whacker – I didn't know what to call that thing – are broad, large swaths of the forest are going to get whacked and forest animals will be squashed.

The goal is to solve the information blocking problem or make it dramatically smaller. Clearly, we don't want the effort to understand and comply with the regulation to have a larger negative industry impact than information blocking itself. That's sort of a John Kansky overarching comment. I have specific examples, but can save them.

Andrew Truscott - Accenture - Member

Thanks, John. I think something which has become more prevalent as we're working through this

particular work group is we've had this comment several times now, which is, "This is going to touch everybody." I think that's something which we have all kind of thought was happening across HITAC.

But now we're actually realizing as we have gone through the regulations in detail, that actually the impact of these regulations will be felt across every single actor, and it's something that's going to benefit patients absolutely directly, but also because every other actor inside caring for a patient is going to have to comply with some level of these regulations in many different ways. John, thank you for that. Sasha?

Sasha Termaat - Epic - Member

It's hard to follow the mole analogy. I had two definitional thoughts for this workgroup to be considering. One came out of the work from another workgroup, where we talked about some of the implications of the broad definition of electronic health information and the other workgroup talking about the provisions for exporting electronic health information, the breadth of the definition, and its extension into realms beyond the legal medical record, data for research.

As Les pointed out one of our discussions, data that extends beyond that within certified products certainly had other implications for that provision that we discussed there but seems relevant to this conversation also.

My second definitional question for the group, and possibly it was discussed – while many of the definitions, as Arien pointed out, seem to have been broadly interpreted, the definition of health IT developer given in Cures actually seems to be quite narrowly interpreted as only health IT developers of certified health IT products.

While I understand the rationale provided with the link through the certification program, it seems that if other provisions are going to be broadly interpreted over all the actors in a health information network space, the health IT developer provision might also merit a broader definition than only those who who provide certified IT products.

Andrew Truscott - Accenture - Member

Thanks, Sasha. Let's take those in reverse order. So, that second one, that's something we noted, that some of the language appears to be implying certified health IT. We've had confirmation that's not the intention. So, we're going through tweaking that out now. So, with a health IT developer, it's not just a health IT developer with certified health IT. There are particular ways, aspects of the regulations, which are pertinent just to certified health IT, obviously, but the actual broader information blocking regs apply to all health IT developers.

I'm looking forward very much to tomorrow's presentation by CMS touching upon HIPAA around some of this definition space around the EHI. One of the overarching principles Mike and adopted as we sat together with Mark from the get-go is simplification of regulation to make this understandable and as accessible so that any reasonable health IT person can say, "This is what this means." EHI would be a prime example of that. We're going to simplify that out.

I should also note that there's a whole discussion going on around the preeminence of regulatory text versus preamble. I'm sure every other taskforce has also had that conversation. On this taskforce, we are definitely taking the line – and I'm channeling my inner Malec at this point – that if it's not in the regulatory text, then it's kind of a useful comment.

But we are saying look, the preamble gives the amplification to the regulatory text. It actually says this is what the intent was and this is what the regulatory text should be saying. That's the approach we have been taking. Was that helpful, Sasha? Okay. There were a plethora of signs thrown up. So, I'm going to go to Dr. Miri next.

Aaron Miri - University of Texas at Austin - Member

Hello. First of all, thank you very much for the presentation. I do have a comment about the preamble particularly. I realized that from an intent perspective, the goal is to make sure the information flows as appropriate, that there is no bad actors, per se, and everybody in the ecosystem is playing fairly.

One of the things we can do a better job of, I believe, in the preamble calling out specifically how patients interact with the data in ways certified developers may not be providing the best mechanism for those patients to receive their data. I'm going to give you a very specific example.

Today, I use a certified HIT vendor for one of my products who refuses to provide multilanguage support and therefore only allows for English-speaking patients to receive their data. This obviously puts a large percentage of my patient population at a disadvantage, given that I'm in Texas. They have given a certified letter to all the CIOs of their product saying, "Sorry, we're not going to do it. We know it's a problem," which you can imagine what my behavior is towards to that.

So, to the degree of it, there's got to be some construct in the preamble called out, where patients are on the wayside going, "Wait a minute, are there standards of participation for me as a patient to receive my information?" It's an interesting concept. To that degree of it, I feel the preamble could go a little further in to talking about patient interaction and the way patients benefit or could be disincentivized from using an HI-certified HIT product based upon what I consider to be information blocking.

Andrew Truscott - Accenture - Member

Thank you. That's good input. We'll take that on board. Cynthia?

Cynthia Fisher - WaterRev - Member

Thank you, Andrew. I went back and looked at the Cures Act. We had a lot of debate in our information blocking session. As we looked at the definition of EHI, I go back to what Sasha said about looking at the broadness of it. I was scratching my head on how right now, it appears to be limited to identifiable information. There's nothing that we can find in the legislation that suggests that EHI should be limited to the individual with identifiable information.

When Congress used the term health information, they did not use the term individually

identifiable health information and not also protected health information. If Congress wanted a limit to identifiable health information, they would have used these other terms. I do think as we move forward, we should look at the health information as defined. Right now, as we see it defined, we look at its definition and it all goes back to HIPAA in 1996. So, I just point that out as we consider moving forward with EHI.

Andrew Truscott - Accenture - Member

Thanks, Cynthia. I think that's one of the threads that we've been talking about through thr workgroup already is making that clear. That's partly why we're looking forward to the presentation tomorrow. Arien?

Arien Malec - Change Healthcare - Member

I'm sorry for another crack at the apple. Now I'm regretting that I volunteered for the seven exceptions work group suspect is definitions work group. It may well be that the key to addressing John Kansky's metaphor is through the definitions. In particular, I think there's something very valuable about the notion of the facts.

The Supreme Court has adjudicated that data as facts are not subject to copyright. HIPAA provides information that the facts of the record must flow. The combination of that with the combination of gatekeepers of information or potential gatekeepers of information, if we put the right definitional structure, then we may well have the right downstream policy rules that are in the regulatory texts, modulus some cleanup we need to do.

It's the broad funnel at the top leaking down into the broad information blocking and information blocking exceptions, then the significant penalties downstream with that that I think creates a lot of concern.

If we tailor the recommendations in ways that make information flow faster, better, cheaper, freer, but preserve the notion of an ecosystem, a broader ecosystem that enables information flowing, that addresses enrichment of information that it flows, we may find a regulatory framework where we're addressing the blockers of information without driving a regulatory frame work and price control framework for the U.S. healthcare system.

This might be fruitful in getting the definition of EHI right, getting the definition of network right and exchange right and also getting the information blocking right. It could have substantial benefits to tailoring the benefits to be more of a scalpel and less of a sledgehammer or C4.

Andrew Truscott - Accenture - Member

Thanks, Arien. I think that's helpful observations. Can I ask as we go through and bring back to full taskforce that you actually make sure we're touching on that?

Arien Malec - Change Healthcare - Member

Absolutely. Already thinking it through.

Andrew Truscott - Accenture - Member

I didn't think of that, longer than 160 characters.

Arien Malec - Change Healthcare - Member
That might be trouble.

Andrew Truscott - Accenture - Member
Leslie? I'll just call you up, whichever wants to go first is fine. Hit the button with the little speaker.

Leslie Lenert - Medical University of South Carolina - Member
I wanted to just say that one of the most interesting parts of the law or proposed regulation is this idea of population level transfers or group level transfers. To delve into this specifically, the need to preserve the competitiveness in the EHR market by allowing people to essentially migrate at a minimum cost from one vendor to another is really an important aspect of information blocking that needs to have the standards worked out.

There are the clinical standards. I do agree that 90% of the use cases, that limiting to the medical content of the record is important, but if we're really going to eliminate this sort of vendor lock-in and restore competitiveness to the market for EHRs that will drive improvements in quality, there has to be a route to migrate from one EHR to another, including the billing information and the financial data that's required to do that successfully.

I think that there could be more attention in the regulations, specifically to the use case of how to restore the competitiveness of the market by reducing vendor lock-in to a specific EHR based on this statute that says you have to be able to export your entire populations and move them and those types of things.

Andrew Truscott - Accenture - Member
Thanks, Leslie. That's absolutely right. There is some regulation drafting around that. Part of what the work group is doing is taking real world use cases, such as the migration one you outlined and actually saying how would that apply? How would these regulations enable and remove some of the barriers around such migrations and allow that kind of frictionless movement. You're absolutely right and we are taking that into account. Thank you. Denise?

Denise Webb - Individual - Member
Thank you. I wanted to reinforce and maybe reiterate the points that Sasha made. I'm on the Conditions of Certification and Maintenance Taskforce. As we were discussing the EHI export certification requirements, which replaces the data export requirement of the 2015 edition, we found it confounding that the definition of EHI is so broad and covers so many actors, and not just the data that's collected or stored in certified technology, but across a number of technologies.

So that's a point that I think we have to discuss as a committee on how we're going to resolve some of the conflicts between the broad definitions and the requirement that there has to be an export function that exports all EHI regardless of whether it was stored and collected by a certified technology.

Andrew Truscott - Accenture - Member

And as you know, we have been discussing that. Denise, would it make sense if we actually had yet another meeting because we don't have enough meetings, if we had a joint session between the two taskforces just on that subject matter just to cover that off so we have a harmonized and consistent approach? Yeah? Lauren, can we get that one scheduled, please?

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

We can certainly do that.

Andrew Truscott - Accenture - Member

No more questions? Steven?

Steven Lane - Sutter Health - Member

Just a comment to follow on Les about the transportability of the data – I think that my reading of the rule is focused on this notion that the provider can switch EHRs and take all the data from their practice and move it to another, whether they're changing practices or changing vendors, which I think is very important. But also, we have to be clear that the patient needs to be able to switch EHRs in essence.

The rule is clear that the patient needs to be able to download all their data. But the idea that then can be re-ingested into another system at one or more additional providers where they are seeking care, either for a consultation or for a full transfer of their primary care I think that's really important and we have to be sure that is spelled out.

I also want to acknowledge that this is going to be a very big lift for the vendors, to be able to both produce and ingest this sort of data. We have to be careful what we ask for because from what I've heard from some of the vendors, it could take them years, not just the two years we are giving them, but even more years to be able to build out that technology and capability. We have to be cognizant of how challenging that might be.

Andrew Truscott - Accenture - Member

That's absolutely right. It ties back into the work yourself and Dr. Kawamoto have been doing on your taskforce as well as the work of the USCDI taskforce as well. It's all very well not allowing information to be blocked, but it has to have utility once it's been received. Les?

Leslie Lenert - Medical University of South Carolina - Member

Just to re-emphasize, the link is that the provenance of the data has to go with the data, especially if you're going to rely on patients to be your conveyance mechanism. We have to have a unique identifier for the data itself and where it was produced to be tracked with this, lest we corrupt the system by data that had been modified inappropriately and/or repeatedly entered because the same element has come from different sources throughout the system.

Andrew Truscott - Accenture - Member

Yes. Okay. We'll move on to workgroup two. We are a third of the way through the taskforce. One of the big overarching things you also have is ensuring the intent of Congress with the draft of 21st Century Cures is reflected in the regulations and recommendations upon those regulations.

And we're also mindful that since 21st Century Cures was enacted back in 2016, the health market has not been standing still and there have been shifts and changes and we are moving forward. We are trying to balance those two. Work group two has been focused upon the exceptions around information blocking. I'm going to rocket through these pretty quickly because I'm sure people around the table will have viewpoints on many of these issues.

Here you have the key topics around the exceptions – preventing harm, promoting both privacy and security, recovering those costs which could be reasonably incurred, the licensing upon RAND terms, the responding to requests which are actually infeasible – there's a great bit around infeasibility versus impossibility – the maintenance and improvement of health IT performance, and then there's another around additional exceptions, areas where we believe actually there are additional exceptions to information blocking that could be recommended, the complaint process around them, and another RFI around the various disincentives that healthcare providers might have because of this.

So, Valerie, Anil, Arien, and Steven have been providing invaluable input. You have my heartfelt thanks for this. This is a very, very difficult area. We have had great joy and mirth as we've gone through the regulations around understanding of the difference between an and and an or, the way that ands get compounded with other ands and some ors and the fact that you can actually have drafting that has both double, triple, and quadruple negatives inside it.

And it's always interesting when one of the co-chairs goes off on a tangent because he missed the fact that it was actually a quadruple negative this time as opposed to a triple negative, which plays back to our simplification. We are trying our best to simplify these down, make them understandable to all constituents. Next slide, please.

Okay. The first one around preventing harm. The progress and recommendations we're making so far is around preventing harm with inaccurate data. So, the understanding that actually in our experience across this workgroup, pretty much everybody's healthcare record has some degree of inaccuracy within it, but that shouldn't prevent it being shared. So, clarifying how inaccurate data would actually not necessarily be a complete exception and how that could be taken through.

Misidentification of a patient's electronic health information – so, looking to limit the cases where the individual holding the data knows that that is not the valid patient as opposed to it couldn't be or it might not be. There's also a proposal around the definition of organizational policies. So, it's not very well to say we have a policy that says we might cause harm, therefore we're not going to share that information, preventing those kinds of overreading of regulation.

There's also a proposal for clarification of how this should be documented. So, when this exception is relied upon to prevent information blocking – so, to cause a blocking of information

– how that needs to be documented out and how that needs to be written down so that it's well-understood as to the purpose and the decision that was made to enact this exception. Next slide, please.

Okay. So, promoting the privacy and security of EHI. There's concern around the overhead that these requirements might cause. We don't want to increase undue burden. So, we're trying to form that balance around the burden of the exception. We have a proposal that the policy should be lawful, recognizing that there are different states legislation in this regard that a policy needs to comply with the laws of the state in which it's looking to be enacted as well as federal and local law.

There's a discussion going on around how we should document and record both consent or dissent, because consent has different statuses. It has to be expressed, but it be a consent to share or dissent to share. Then looking at the sub-exceptions – it ties into some of Sasha's comments earlier – where a health IT developer of certified health IT is not covered by HIPAA. So, we have to talk about a definition of what's meaningful disclosure.

Those are some of the conversations going on around security, looking to clarify the documentation which comes out of this. There's a common theme here about if you're going to cause an exception, then you have to document why that exception was there in a meaningful and reasonable way. Then looking about, say okay, if the actual requester if the data subject themselves and they're consenting to this, then there is no exception that can actually be raised. It wouldn't be reasonable to do that blocking if the patient is competent and has made the decision. Next slide, please.

I see people looking at these slides with some degree of, "That's what you're talking about." These are important because they have impacts not only upon the exceptions, but also on the actual process of information blocking and therefore what is reasonable. So, reasonable costs could be incurred.

We are clarifying out what our recommendation would be to the National Coordinator of what's objective and verifiable. There are some of these terms are used inside the regulations, looking at how those are being expressed inside the preamble and just being able to define and say, okay, this is not something we can't objectively define as opposed to being an overly subjective text.

We are also looking into finding a proposal about how reasonable profits are allowed. That's the intent of the regulation, but also not placing an undue burden upon either ONC or OIG to try and define what those profit levels would be and have the unintended consequence of a market coercion.

We are looking at how this actually can be applied in real life and enumerating out the costs incurred, you could inadvertently place an undue burden in having to do that process. Again, with the clarification of language around what's non-standard and intangible, trying to make these more in aligned to other regulations as well as common or garden usage. Then we are looking at how this ties in with RAND licensing as well. We'll come on to talking about RAND, reasonable and nondiscriminatory, we'll be coming back to that in a couple exceptions' time. Next slide,

please.

Okay. Looking at the requests which are unfeasible – we're trying to promote innovation in the healthcare ecosystem. We're trying to enable start-ups to rapidly enter and promote better patient outcomes. Therefore, we don't want to inadvertently disincentive, but also overly permit start-ups. So, it's a careful balance to place, again, around where you have a start-up entering that they could potentially use this exception. So, we want to balance that one out.

We're also looking at the language, again, around the definition of reasonable alternatives and about what a timely response really is. So, I'm sure there are many people around the table who have an opinion on that. We are soliciting all opinions, both directly around the meeting room today, but also please send Mike and e-mail or both of us, touching upon that as well. We are all ears because frankly, some of this stuff, we're not sure if we're going to get this netted out completely inside the workgroup timeframe. We also don't want to leave ONC in a precarious position of saying, "We think you should change that or refine that," and that's not as helpful as you want to be to the process. Next slide, please.

So, here we go with RAND terms. This has caused a considerable volume across the workgroup and discourse, not only looking at the actual meaning and what we're trying to achieve here in the underlying preamble, but also the perceptions across the workgroup and the broader taskforce about where we want to go with this licensing. I'm not going to wade through the detail here, but there is considerable volume of discussion about the difference between a service and a product and how licensing of a service which consumes products could be versus an absolute product itself.

These are preliminary proposals which we're working through around some straightforward things around timeframe. We have asked ONC for clarity around the use of the world loyalty and whether that's inclusive or meaning what we're trying to achieve here and also around the definition of standards essential technologies. This is particularly relevant with other practices which already extends across the healthcare ecosystem around other standards essential technologies and how they are licensed between various healthcare parties. Mark is looking at me nodding sagely. This is one of those discussions we're going to try to put to bed over the next five or ten days. Next slide.

Okay. The maintenance and improvement of health IT performance. This actually was fairly straightforward exception that we worked through. It's always delightful when an exception stimulates not too much conversation apart from a sage nodding of heads around the table and this is kind of where we think it will go as well.

The big delta here is around TEFCA. We are awaiting the next draft of TEFCA and that is going to have material and manifold impacts upon not only this but also other exceptions and also the concept around safe harbor, etc. So, we are eagerly looking for that and it will be interesting to hear from ONC around how the rule setting will tie in with the TEFCA availability and consideration too and how this taskforce, the TEFCA taskforce, and the board of HITAC can help and contribute to that.

We haven't got to complaint process and we haven't yet gotten to the disincentives of healthcare providers RFI. Where it's an RFI, we are providing more narrative and verbose and loquacious feedback to ONC. We are trying where we can to actually do a definition of a proposed regulatory text for all the other aspects because we feel that's actually going to be more helpful to ONC than our somewhat excessive verbiage, which might inadvertently be coming out. Next slide, please. Questions? Look at that. Straightaway. Aaron?

Aaron Miri - University of Texas at Austin - Member

Thank you. I appreciate this. This is a very meaty subject, so, I appreciate the conversation on these topics. I have three comments. Each of them sort of tie together. So, I'm going to go through all three and then we can talk further, if necessary.

Under preventing harm, has there been a suggestion around organizations who may not want to share data with another organization because they feel that the requesting organization is either untrustworthy or has a cybersecurity concern and therefore, "I don't want to share with you. I don't trust where the data is going to be in your house, so, too bad. I don't want that liability." That's number one.

Number two, under the promoting privacy, has there been consideration of adding specific language around FERPA? As you can imagine, University of Texas, we're a major medical school, also with my health practice, I have to of comply with both FERPA and HIPAA and a number of other regulations. FERPA is a major consideration point when dealing with patient information also, as shot records are going to be part of a student's record. So, all of that can tie and get messy after looking into it.

And number three, under promoting security around the need for information sharing – in August 2018 the FBI gathered about 100 leaders across Texas to warn of foreign nation state actors trying to intercept and gather threat data and data EPHI, research data, IP, all sorts of things to the degree that there's got to be a mechanism for an organization to say, "Okay, legitimately, Aaron, there's an issue with X, Y, and Z. Be aware of it so that you don't inadvertently share data out with an organization, be it a developer or not without the construct of conversation with federal agencies." Those three comments.

Andrew Truscott - Accenture - Member

Thanks, Aaron. For your first and third points, I acknowledge them. That's useful. Thank you. For the second, we have already escalated into ONC and asked for feedback on how the interplay works with other regulations and other legislation in place. As we have been sending exceptions around other legislation as well, we have taken that one on. John?

John Kansky - Indiana Health Information Exchange - Member

In response to recovering costs reasonably incurred, I'm trying to offer another example of a non-mole forest animal that I think is supposed to not get whacked. I assume the intent is to leave intact reasonable HIE pricing models and most HIEs have pricing models that are subscription-based and tiered based on size of organization, ability to pay, which my initial reading, I was concerned that was going to be okay because the assumption of pricing seems to be on a transaction by transaction, based on the cost only.

And then in terms of uniformly applied, several HIEs, including IHIE don't apply pricing uniformly, depending on what that term means, depending on, for example, the amount of data in a given market that the HIE can provide, etc. So, just expressing an example of maybe the unintended consequences.

Andrew Truscott - Accenture - Member

Thanks, John. I'll just comment on the tiering. That's a discussion that is ongoing in the workgroup right now. We don't want an unintended consequence to be where there is that tiering model that smaller organizations suddenly find their fees are going up because actually now the tiers have been collapsed. That would be an unintended consequence, certainly from our discussions across the originators of the regulatory text.

So yes, we are taking that on board and seeking to provide clarity and a recommendation to ONC on how that should be addressed. Certainly, it's our understanding on the taskforce that that would be unintended. Thank you. Arien?

Arien Malec - Change Healthcare - Member

First of all, John, my interpretation of the text is that those kinds of pricing would be, in fact, disallowed, at least under the regulatory text as currently written. I'd also point out that the regulatory text, even though the commentary allows for reasonable profit, the regulatory text does not contain provisions for reasonable profit.

And I just have at this point, maybe for Elise, a question about reasonableness relative to pricing. As far as I know, there's no standard for reasonableness. I'm not sure how if we change the reg text in the cost recovery mechanism and add a notion for reasonable profit, we haven't gotten to comment on the reasonableness test, whether that's a logical outgrowth or not.

Then finally, I want to underline this notion of BAA terms. There may be an intent. I don't know that Elise or Don can't comment wholly on the intent, but there may be an intent to nullify BAA terms, particularly BAA terms that provide additional restrictions from covered entities for data use that may impede information exchange. But because complying with BAA or other contracts is not an exception as written, and it's not clearly preempted as written, it could place actors in a position of being forced to comply with one law or contract law at the same time, which I think would cause some significant issues.

So, maybe one, just a procedural issue is if we comment that we need to add a reasonableness test on the cost recovery relatively pricing and to profit, what's the logical outgrowth with respect to commenting on reasonableness text and the other may be any commentary that you might have to have on BAAs versus information blocking exceptions.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

I can start and then turn it over to Mike Lipinski who's on the phone joining us. So, in terms of the reasonable test, it's a comment that would be helpful for us to understand where if there's a

lack of clarity or there could be a helpful description of what we mean by particular terms such as that, that would be helpful to know and that's something that we can take into consideration as we're putting together the final rule. Let me turn it to Mike for the second half of your question.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Division Director of Federal Policy and Regulatory Affairs

Hi, this is Mike Lipinski. Can you all hear me?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

Yes, we can hear you, Mike.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Division Director of Federal Policy and Regulatory Affairs

All right. Sometimes we talk to no one. So, I mean, the bottom line is we welcome comments on any situations where you think stakeholders aren't adequately covered by a proposed exception. I would say it's contextual. So, we know that business associates, which could be a covered actor, a health information network or developer, certified health IT. Our business associates for covered entities, some of which are not specifically covered in the information blocking provisions, depending unless they're functioning in a certain way.

We also lay out a lot of information as to get to the knowledge standard of know or should have known that their actions would likely to have interfere. We talk in the preamble about if you had contracts that intentionally interfered with the access exchange in use.

So, I mean, that's as much as I can say. We don't specifically address the business associate situation except for when they are allowed to deny an individual's access to the EHI, which is specific to HIPAA and the specific section we lay out in the regulatory tax, which is 45 CFR 164 524, A1, 2, and 3.

So, I'm not sure if that's ultimately helpful but I think it does point out that it's a somewhat complex situation depending who the actor is, acting as the business associate, and what's actually in this contract. But we do address contracts and how they are used to essentially information block.

Aaron Miri - University of Texas at Austin - Member

So, first of all, appreciate the dunk on regular notations. This is not a theoretical issue. This is an issue of clearinghouses that are covered entities under HIPAA that are also deemed to be covered under BAAs. This issue of which rules are dispositive is a non-theoretical issue and one that would be helpful to clarify. So, I think we'll put recommendations to that effect and recommendations to that effect. Thank you.

Andrew Truscott - Accenture - Member

Dr. Rucker?

Donald Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator

Yeah. So, I think first of all, folks, especially in situations like this, you provide detailed comment. I don't believe there's a limit on the comments, so, absolutely people should provide detailed comments. I do want to put the broader perspective here, which is the reason this is a law is because the public is extremely unhappy with what's going on in healthcare and transparency. If there are BAA things that need to be rewritten, it's a later law.

So, I think sort of the broader public surround here has to pretty clearly come in. I think when people do the comments – and this is just to the public listening today as well as folks on HITAC – I think what would be most helpful is really to understand that broader surround and see what the overall intent of the law is in making your comments and getting the American public back in control of their data. I think Leslie Lenert made some comments and Denise did too about how to get the data out so folks can control it. So, I think those will be very important to sort out that whole issue.

In terms of the process, we are happy to entertain any comments on reasonableness. If this was a free market administration, it would be leading profit. So, I wouldn't worry that there's an implication on not having profit. However, we have gotten multiple complaints from various stake holders that various licensing agreements have essentially precluded a lot of public good activities, without getting into the specifics of it.

So, I think the reasonableness test was put in, that there's a general proportionality on what is being charged that sort of makes sense to the public. I think often the test of that is actually, "How does this look in the newspaper? Is this something reasonable or is this not?" I would throw that out as sort of the part of the thinking here.

Andrew Truscott - Accenture - Member

Thank you. I think I speak on behalf of the taskforce and those share our sentiments, which have come through in all our discussions and certain deliberations so far. We're talking in the next work group about the some of those contractual-type barriers and how we're looking to address those.

I think something which hasn't yet made it to the slides which certainly has been a discussion point is around the same way that we're looking to revisit contractual prohibitions to also look at BAAs. They're constituted as part of a contract as well, but also may exist in isolation to themselves, and where BAA is preventing information sharing, it is unreasonable to do so. Thank you. We've got Les next.

Robert Wah - Individual - Chair

Just really quick, as I keep reiterating, I feel like we have a commitment to the public comment period, which is coming up very quickly. I think maybe we'll take these two comments that you have right now and without a response from you all, just take the comments and then maybe we'll allow the public comment period to start at 12:00 noon. If we have any time after that, then we'll go back to this. But I really want to honor the commitment to the public that we're going to

let them comment at noon.

Andrew Truscott - Accenture - Member

Thank you, Dr. Chair. One thing we have noticed on this taskforce is the public comment periods come up remarkably quickly.

Leslie Lenert - Medical University of South Carolina - Member

Quick comment – I think your regulation should specify that the exemptions should not be used to deny requests from government agencies, public health, and perhaps anything related to investigation of EHR safety, that information blocking statutes should probably not be – it should explicitly state that those aren't relevant to those types of queries.

Andrew Truscott - Accenture - Member

Thanks, Les. Are we going to Sasha? Quickly.

Sasha Termaat - Epic - Member

Thanks, Andy. I wanted to express my support for the workgroup's attempt to simplify. I know that one of the things that ONC outlined as a goal was that the provisions be clear, predictable, and administrable, which I think makes sense, but there's a lot of subjective language in the way these definitions are proposed, and the exceptions are opposed that I think don't meet up with that goal of being clear and predictable for all of the actors. I think it's important we aim for a level of objectivity that gives the clearness and predictability that's desired.

Andrew Truscott - Accenture - Member

We're striving to do that and also recognizing that the enforcement won't necessarily be coming from ONC, that OIG is also involved and giving clarity is upon us.

Public Comment Period

Robert Wah - Individual - Chair

So, again, I don't mean to be the guy who just wants the trains to run on time. I do want an open and free discussion here. But I feel an obligation to honor our commitment to the public. So, if we could maybe vacate your chairs there and we'll allow the public that's in the room to sit there and comment as well as open the lines. Those of you following online, we have displayed the public comment dial-in line for taking comments. Once this public comment period finishes, we can go back and wrap this up and then get to our picture and our lunch. How does that sound? Okay? Lauren, you want to orchestrate the public comments?

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

Starting with any individuals in the room, if you could come to the presenter table and state your name. As a reminder, we have a three-minute time limit for comments. Thank you.

John Travis - Cerner

My colleagues often want me to remain on mute. John Travis with Cerner. A couple comments that I have on some of the exception conditions, the one that dealings with infeasibility, I think there needs to be clarity between it and the next one on offering licensing, especially to judge infeasibility in terms of the time scale, the manner of the request, the former availability of the data requested, and how a RAND effort in good faith may demark what is infeasible based on the manner and behavior of the requesting party. This is one we are greatly concerned offers a lot of mischief that frankly can be bad faith.

And then on the interoperability elements being offered on RAND terms, I think ONC needs to consider a couple tiers in the ten-day proposal for offering licenses or offering some kind of legal right for access. First is to distinguish if what is being requested actually exists. I know the taskforce looked at that as something that's a very chance-y response timeline, but especially in cases where what's being requested has no particular capability that actually exists, that's not a reasonable timeline at all.

And then, I think, you need to allow for distinguishing commercially available offerings from those that represent solutions or data sources that have been deprecated by the vendor. So, it may be that – and we have this at Cerner. We have clients with very old versions of our technologies, in some cases that dates back decades. There may be other solutions and what our basis of certified EHR technology, in particular, and it's very difficult to make that information available on any par with what is currently a commercially available solution. So, just a couple of things there.

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

Thank you for your comments. Anyone else in the room who would like to provide a comment? If not, we will go to the phone. Operator, can we please open the public line?

Operator

Yes, thank you. If you would like to make a public comment, press star-one and a confirmation tone will indicate you're in the queue. You may press star-two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your hand set before pressing the star keys.

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

Do we have any callers in the queue at this time?

Operator

No callers at this time.

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

Okay. Maybe we'll give them another 30 seconds to dial in. While we're allowing them time, I'll just remind everyone before you break for lunch, we are going to proceed next door to the diplomat room for a quick group photo then we'll break for lunch. Operator, any callers in the

queue?

Operator
No callers at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
So, I think that would conclude the public comment period for now. As a reminder, we'll have a second public comment period towards the end of the day. So, I think we have a few more minutes to wrap up the information blocking session.

IACC TF Speakers

Robert Wah - Individual - Chair
Back to our two co-chairs of the taskforce. Thank you for accommodating the break.

Andrew Truscott - Accenture - Member
I'll hand it over to my esteemed cochair.

Michael Adcock - Individual - Member
Very misused word. Group three, we'll go through it quickly. It discusses conditions and maintenance of certification. You can see the members on the taskforce. I can say that this was a very, very productive workgroup. We got to raise a lot of information and have several recommendations that I'll go through quickly. Next slide, please.

Under communications, we have multiple proposed recommendations. We have definitions that we want to clarify, administrative functions of HIT could be non-user-facing based on the assessment if those communications are not matching the purpose described in 21st Century Cures and also affect a limited set of users. We want to provide for some type of administrative functions.

We also under this section should be amended to a list which third-party content might appear on the screen. Trying to enumerate elements per screen is not a feasible recommendation there, so we're looking to amend that proposed recommendation.

Unintended consequences of fair use – we had a lot of discussion around fair use and others usages should be explored by ONC. The concerns were about risks to vendors, IP that the taskforce wishes to be sensitive to. Again, we want to be sure we're looking at innovation. We do not wish to impinge upon innovation.

Also, ONC should draw a distinction around purpose of use in relation to fair use of screen shots. We had a lot of discussion around screen shots, looking at the intention that the disclosure is responsible for ensuring the appropriateness of the purpose. In a lot of clinical settings, we use screen shots to share information and setup, so we want to make sure that the disclosure is

responsible for that.

ONC should revise estimate in regulatory impact analysis. If you look at the effort for noticing contracting is underestimated at 40 hours for our clerk. More roles are involved than just clerks, including work involved on the part of the recipient. So, there's a lot more than just that. So, we need to look at that regulatory impact analysis. Next slide, please.

Recommendations to amend B2I and B2IIs proposed in the underlines – we wanted to add renew to the health IT developer must not establish, renew or enforce any contract or agreement that contravenes paragraph A. We added the relevant client with the relevant client on a plan to the next section and then added a third. The plan required by paragraph II of this section must be completed within five years of the effective date of this rule. I wanted to make sure the timeframe was correct.

The next recommendation was that ONC should add a category of communications titled Unprotected Communications to their framework. Communications in this category would not be extended, that these protections, including communications such as false communications, communications protected by attorney-client privilege, etc. Unprotected communications should not receive unqualified protection or necessitate permitted restrictions. So, that was the proposed recommendation there. Next slide, please.

Enforcement – we propose ONC should use e-mail and certified mail for notices initiating direct review, potential nonconformity, nonconformity suspension-proposed termination, and termination. So, it was in there that email be used. We added certified mail to that to make sure that people are informed since this is a serious issue.

The next is the band section. We proposed indefinite communication of past records. We want to make sure the ban is communicated at the start and end date if the ban is lifted. We thought that seemed appropriate so that as a consumer or as a purchaser of any of these services, we'd be able to go to the chapel and look at this and see someone had been banned but that ban had been lifted due to conformity or coming back into conformity.

The next recommendation – we don't recommend establishing a minimum time period over which a ban must last, even if a health IT developer is a repeat offender. If a developer is willing to go in and make the changes and make them quickly, we didn't feel that there was a reason to establish a minimum time the ban must last.

Addressing self-developers – we want to call out exception for self-developed systems so that communications by health IT users aren't restricted by virtue of being employees of the same company doing the development. So, I want to make sure that the health IT users aren't restricted. Next slide, please.

Again, that was a very busy work group. I went through that quickly with respect to time, but there was a lot of great discussion and recommendations pulled out. We had lots of workgroups but there was a lot of great discussion. We'll open up for questions, comments. Raj?

Raj Ratwani - MedStar Health - Member

Thank you, that was really good. I have a general comment. So, if you look at communication with safety and feasibility information, I think the intent is to open up the ability to communicate that information and have more transparency. As we look at doing that, there are three important pieces. The first is you have to be conduct the usability and safety tests of EHR products of certified health IT.

The second is you need to allow people to participate in the studies should you set up a study. The third is being able to communicate that information. As I read the proposal right now, it seems like the last two are addressed. So, it's addressing the ability to share things like screenshots. It's addressing the ability for people to potentially participate through addressing intimidation.

But I'm concerned about the first part, which is there may be vendors that are intentionally blocking the ability for people to create usability tests or safety tests of products. If that's the case, then there's really nothing to communicate. The other part is just irrelevant because you can't conduct those kinds of studies. So, have you thought through that or anything that would make sense to put in to address that particular issue?

Andrew Truscott - Accenture - Member

We were having a debate about who was going to answer. Yes, we want to eliminate that level of mistake around understanding the intent. If you have specific thoughts, just funnel them over. You're more than welcome to come along and observe the meetings. That's fine too.

We also have to recognize that they're – to channel my inner Orwell, not all health IT developers were created equal and there are different levels of players, both in terms of sophistication of organization, how long an organization existed, etc., and the same goes with providers. The regulations touch everyone equally in terms of enforcement. However, they might actually have different levels of impact in the different organizations. So, we just need to be mindful of that as well as we're going through this. But I agree with you completely around the clarity. Thanks, Raj.

Robert Wah - Individual - Chair

Seeing no other comments. Again, thank you to the two co-chairs of the taskforce for getting us through this. Again, when we put this schedule together, they were sort of estimates and you guys we're very good about staying pretty close to everything. So, thank you for that as well.

Like I said, I'm not trying to stifle discussion by my comments, but we do have a number of commitments, one of which is also to our photograph taken about now. So, thanks again for your work to both the co-chairs of the taskforce and the entire committee. With that, I'm going to turn it over to Lauren to give us logistics of our 12:15 photo time and then we'll proceed from there.

I think right now we're scheduled to come back from lunch at 1:30. If you could please all make that happen promptly, that will keep us on schedule for the afternoon. We currently have a tentative break in the afternoon schedule that is subject to being used or not used depending

how the time flows. Thank you again and we'll see you at the photo shoot.

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

Thanks, Robert. So, just out the door to your left, the Diplomat Room. If we can ask the members of the Annual Report Workgroup to gather first and then we'll do the rest of the committees. Thanks, everyone.

HITAC Speakers

Robert Wah - Individual - Chair

Welcome back from lunch everyone. Nice. Welcome back, everyone and again, thanks to everyone for the great discussion this morning and again, for your patience and understanding about the schedule issues. We want to welcome our Deputy National Connector, Dr. White, to the discussion. Don, good to have you back as well.

Again, we have a full afternoon. We do have a scheduled break at three, that is going to be flexible as I said before. We are going to start this afternoon with the Conditions of Certification taskforce update. If we could have Raj and Denise move towards the hot seat down there, that would be great.

Again, as I've mentioned a few times, we have a commitment to the public to have a public comment period at 4:00. So, you may see some rearranging of the schedule to accommodate that commitment. With that, I think we are ready to go. I will turn it over to our co-chairs of our taskforce on Conditions of Certification, Raj and Denise.

CMC TF Speakers

Denise Webb - Individual - Member

Good afternoon. So, for the next few minutes were going to be talking about the conditions and maintenance of certification. I'm going to go over our taskforce membership, what our charge was and Raj and I will break up the discussion on the recommendations. We have recommendations in three of the four areas we're charged with and then we will have time for questions and feedback.

Here's our roster of our members. It was principally a group made up of members from HITAC, but we also had one guest representative that was invited to the taskforce, John Travis from Cerner.

So, our overarching charge was to take a look at what was proposed in the rule concerning conditions of certification and maintenance requirements for the remaining requirements. The first three were discussed by the Information Blocking Taskforce and we covered API, real-world testing and attestations conditions and maintenance of certification requirements.

We also reviewed the updates being proposed to the 2015 Edition Health IT certification criteria

and modifications to the program, then finally, deregulatory actions related to certification criteria and program requirements. As I said previously, we have recommendations on all of these except for modifications to the program.

I will begin with discussing an overarching recommendation that we had and this relates to providing some clarity on the rationale for maintaining a 2015 Edition. We got into a discussion about this as we were looking at the records retention requirements for the ONC ACBs as well as the health IT developers. So, these record retention requirements are applicable to various sections in the proposed rule.

We questioned why the rule would propose to modify the 2015 Edition so extensively rather than create a new edition. These broad-sweeping changes that will result from this rule may cause some confusion for the users of CHPL and also there's some consequences from the records retention standpoint whereby if the edition is continually modified rather than being retired and replaced by new edition, that would extend the retention of records for an inordinate amount of time. So, we are recommending that ONC introduce a new edition of certification rather than the proposed changes to the 2015 Edition.

I will next hand this over to Raj and he's going to cover real-world testing.

Raj Ratwani - MedStar Health - Member

Great. Thanks, everybody. So, have the wonderful post-lunch slot, So, we will do what we can to try and prevent post-lunch slump. I will try and go to some of this quickly, some are basic things that I'm sure folks have read through or will read through and the ones that deserve a little bit more attention, we'll try and spend more attention on those.

So, jumping right in under real word testing, our recommendation number two is that ONC should consider reconsider the due date for real-world testing plans, providing more flexibility. In particular, I think the way the schedule is laid out, it ends up falling right around the holiday time for vendors. So, re-looking at that, I think, would be a positive thing.

Within the context, also, we strongly support the idea of a pilot year. We think that's really good thing to do and that could potentially also shape the future recommendation, which is to have a testing template for vendors. We'll touch upon that a little bit later on.

Recommendation three is to have a little bit more clarity around the care settings and venue for where testing should occur. Specifically, talking about which settings and what's a sufficient number of settings. The language is pretty gentle right now and we're looking for more specificity there.

Recommendation number four is to provide guidelines or a template for a test plan. So, currently, if you look at something like safety enhance designed, NIST has a great template that's provided which can guide vendors and we think something like that could be really strong in this area as well perhaps after the initial pilot year.

Recommendation number five is that ONC should provide clarity around how successful real-world testing is met. So, that could be, number one, continued compliance with certification criteria, number two exchange in intended use settings, and number three, receipt and use of electronic health information and certified EHR.

Recommendation six is that ONC should clarify and define term scenario in use case and also workflow. At times, those seemed to be used interchangeably. It talks about scenario-based testing and use case-based testing and depending on the field you are coming from, those have different definitions and different connotations.

Recommendation seven, we recommend vendors be given discretion to incorporate permissible testing approaches. That might be, for example, automated testing, regression testing and there's other options there as well.

Recommendation eight, I think this one might warrant further discussion if time allows, is that the ONC should provide clarification around testing the exchange of information or about the use of the information. We believe those touched very different components. So, the exchange of information is really about the passing of information from one system to another, whereas the use of information would only apply to a subset of the particular functions, but really has to do with a lot of human factors and usability components.

So, that's once information is exchanged, would a provider or other user be able to actually understand that information and apply that information in a clinical setting. So, if the intent and the way use of information is used in the NPRM, it seems like that's the case, then that would potentially open up a different flavor of testing, more akin to the safety enhance designed testing. That also relates to the clarification of provider involvement, which would drive some of the timelines it cost and so we touched on those later as well.

Recommendation number nine is the ONC should clarify the expected involvement of providers and third parties to support the real-world nature of testing. The taskforce suggests providers using the certified technology should be involved with in real-world testing with the health IT developers, but the final rule needs good guidance on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases.

Related is if there provider involvement, ONC should adjust provider estimates of the cost impact analysis in the proposed rule so the cost estimates don't necessarily account for what would be required from providers.

Recommendation 10 is the ONC should allow for flexibility for vendors with regard to real-world testing where there’s no difference in testing approach, result, or capability. Specifically – and I'm not going to go to the definition of each one of these – but things like common capability, unchanged capability, common requirement, production experience, and to clarify the applicability of requirements for various practice and care settings, and also for attestation allowing for attestation to have retesting.

Recommendation 11 has to do with the term measurement that's used. So, ONC should include

a description of measurement and provide clarity about the rule of measurement and specify for what kinds and for what purposes are proof points. We think that the pilot year can be a good time to understand what measures are being used and then particular metrics that seem to be insightful and useful could be carried forward in that template that we are recommending for subsequent years.

Recommendation 12 is that the ONC should elaborate and provide more clarity on the standards version advancement process when a version of standards is available under this process but does not have testing tools available yet to determine conformance.

Recommendation 13 is ONC should clarify the role and expectations of third parties over which the health IT developers have no control or authority over. There is a fair amount of discussion in the taskforce about this particular component and where real word testing should rest when it comes to looking at third parties. Recommendation 14 is ONC should review and revise regulatory back time estimates. Wee touched upon this earlier depending on the level of provider involvement and other resources that we required.

And recommendation 15 – and this is under attestations now – ONC should include a specific deadline at the middle of the year and at the end of the year, beginning of year to try to avoid holidays and other issues there.

I'm going to turn it over to Denise to go into APIs which is I note a considerably bigger topic.

Denise Webb - Individual - Member

We have several recommendations concerning the APIs. The first recommendation, recommendation 16 – in the proposed rule there are three distinct rules discussed, the API technology supplier, the API data provider, and the API user. While there's quite a bit of discussion on the relationship between the technology supplier and the data provider with the API user, that same amount of discussion does not exist between what the relationship is or should be between the technology supplier and the API user.

So, we are recommending that there be an explicit statement of that relationship and what is acceptable and clarify what activities are expected or permitted to occur between the API technology suppliers and API users.

Recommendation 17 – ONC requested in the proposed rule for four options to be considered for the FHIR release that was to be proposed in the final rule. The proposed rule proposes FHIR DSTU2, release two, and we are recommending that ONC should adopt solely FHIR release four, which is option four in the proposed rule, 4170.315 G10.

The reason the taskforce is recommending this is that release four is the first normative version. It also supports enhanced capabilities such as bulk data. We had a quite a bit of discussion concerning the multiple patient population health use case. It would prevent dividing the focus of the industry with multiple standards. We do think that the committee will probably want to have further discussion on that.

Recommendation 18 – we are recommending ONC should move forward with implementation specifications and implementation guides to ensure that everybody is working from the same set of specifications. This would enhance interoperability and reduce implementation complexity and cost. We do see value in health IT developers harmonizing to a specific version and release.

Recommendation 19 concerns of the SMART Guide. We are recommending ONC address legitimate and expected activity for the SMART Guide to protect patient data with respect to providing persistent tokens to applications and their ability to keep the token confidential or to be able to keep the secret.

The taskforce recommends further clarification be provided in the final rule. Someone will need to ascertain that API users provided a persistent tokens are creating products that security token appropriately. But it's not really clear in the present proposed rule who plays that rule and we think that there needs to be clarity on who it is and how the determination is made.

Recommendation 20 – the taskforce has concerns over ONC not proposing a standard for a request for multiple patients' data or this bulk data request and we do recommend that there be a standard specified in the final rule which is available in FHIR release four.

There are concerns that each developer could implement this differently and invest time in nonstandard ways and likely have to spend the money and time transitioning to a standard way. This taskforce also recognizes that there is an immediate need to support this use case and this type of request.

Recommendation 21 – we were puzzled by the requirements to update the API documentation within six months after the final rule is published. When there are 24 months being provided to actually have the API deployed and in production with users. So, we are recommending ONC clarify what happens at six months and what happens at 24 months concerning API documentation.

Recommendation 22 – ONC should further clarify in the rule the requirements and expectations around app registration as far as that condition of certification. This is based on the number of issues we discussed as a taskforce concerning app registration. So, the areas that we are looking for clarification in the rule are around what the practice of registration consists of or does not consist of and who's responsible for keeping a list of registered apps, what verifying the identity of an API user consists of or does not consist of, and again the party that would be responsible for performing them.

And if this is an optional activity, specifying that those who decide not to perform it would be excused from possible cases or consequences where API users misrepresent themselves. Vetting was mentioned related to registration. So, we're looking for clarification on what vetting an app in contrast to verifying the identity of the user consists of or does not consist of and, again, who is the party responsible for vetting and who is prohibited from vetting.

And then this is also optional and not performed – again, looking for some specification around clearly excusing the API data provider from any possible consequences attributable to poorly designed or malicious apps. Then finally, identifying any tasks such as an API data provider white listing a particular app for the first time when API data provider endorsing particular apps – any of these tasks that would fall outside of registration, identity verification, and vetting – so, looking for specificity around the tasks and identity of the parties that then cannot perform them and what happens if they aren't performed.

The next section concerns updates to the 2015 Edition certification criteria. Out of these additions and changes the one that we had the most discussion on related to electronic health information export or EHI export. We did discuss earlier on the information blocking taskforce presentation some of the concerns about the broad definition of the EHI and our taskforce is recommending that the rule provide clarity around the scope of the EHI export and we are recommending it be limited to EHI-collected and retained by certified EHR technology and only apply to the EHI that is part of the legal medical record.

Narrowing it to the legal medical record was an important consideration when it came to research data and protecting that data from disclosure to the patient when the research study was underway. Obviously, we did acknowledge that the EHI definition was much broader than what we are proposing here and recognize that there would have to be other alternatives for exporting data outside of certified technology.

Recommendation 24 – ONC should clarify that the export process must accommodate a manual review by the API data provider to comply with state and local laws prior to being released. We had quite a bit of discussion related to laws that prohibit release of certain EHI to a patient, such as some psychiatric notes was an example and that the export process would need to accommodate compliance.

Recommendation 25 – ONC should divide audit log data for transitioning systems use case. We are not proposing that for the patient data export use case due to privacy of information related to help system staff that may be contained in the audit log data.

Recommendation 26 – ONC should not require specific time frame restrictions or flexibility for data export. The rule asks for comment on this whether there should be some parameters available to stay export just the last two years, for example. There was quite a bit of complexity and experience to help IT developers complying with the timeframe flexibility and timeframe in the view download in transmit certification criteria.

Recommendation 27 relates to the electronic prescribing certification criteria. We recommend that ONC make the eRx transactions that are not applicable to all settings or that need piloting the optional. If all transactions are required, this could jeopardize the timeline which is – I believe it's in January 2020 to have this available and in production use.

We specifically recommend revisions that are seen on the slide here. The first part that we are recommending here has to do with the changes to limit this to products relevant to their domain and system design and that have been piloted and ready for widespread use. Then you will see

below the areas that we are recommending be optional.

Here's the rest of the criteria. You will note here we added the recommendation on II and III that this would be only available if the segment is supported by the standard for that transaction.

Recommendation 28 concerns the clinical quality measures certification criteria. We are recommending as an important technical correction for the quality reporting use cases that ONC update the quality measurement proposal for the second table here in this chart. The first table is what is proposed in the rule, current NPRM, and instead we think it needs to look like the second table here because obviously, the inpatient implementation guide would not apply to the ambulatory setting. So, we think there's some confusion here that could be cleared up.

Recommendation 29 – the CMC taskforce agrees quality reporting use of FHIR is a good aspirational direction and we certainly think this is the direction we should go but we don't believe it's ready today.

The last two recommendations concerning the 2015 Edition certification criteria are around privacy and security. These two recommendations are linked because the first one suggests that ONC should only apply the privacy and security attestations to new certifications and new products once the rule is finalized and not to products that are already in production.

We were concerned about the potential vulnerability that this might create or unintended consequences of publicly noticing whether existing products or operating with these criteria or not if there are malicious actors that have this information and what they might do with that. In recommendation 31, we recommend ONC add a text box, not just a yes/no attestation to describe their yes/no attestation and this would help with clarity for use cases.

Raj Ratwani - MedStar Health - Member

I think there are only two more, I promise. Deregulatory actions, removal of randomized surveillance requirements, the taskforce recommends that the 2% minimum requirement should be removed and that the ONC should not remove the prohibition on the consecutive selection of one Health IT model.

And final recommendation, number 33 removal of certain 2015 Edition criteria – the ONC should adopt general principle of not duplicating data capture criteria within the certification criteria for data classes included in the USCDI and based on the principle, the taskforce also recommended looking at other criteria, for example, demographics. With that we made it. Questions or comments?

Arien Malec - Change Healthcare - Member

Thank you. Obviously, nice job. Good recommendations and pretty significant recommendations. There's a lot of work that went into it. A couple of notes – number one, with respect to real-world testing, one of the things I've been advocating for the ongoing is the delegation of certification and real-world testing to designate intermediaries. One of the best ways of doing real-world testing is actually exchanging information. So, for example, e-prescribing, if you actually are the

prescribing that's a reasonable basis for real-world testing that you actually are e-prescribing.

Likewise, with respect to many of the other certification requirements, the best real-world testing is demonstrating that you do it in production. For a wide range of actors. I know most of the issues and concerns about real-world testing have been secondary to potential certifications for versions of technology to deployed in the field and demonstrating in the field that you are doing in exchange would be useful. Did you have a comment on that one?

Steve Ready - Norton Healthcare - Member

This is Steve. Exactly what Arien proposed in terms of the production use of systems is accommodated as far as the proposal conceptually that if help IT developers to whom we have proposed be obligated to come up with their plan for real-world testing chose to include in their plan that they are part of CommonWell or Carequality or Surescripts Testing to meet the certification criteria that had been identified within the scope of real-world testing, if that wasn't clear in the preamble, that is a accommodated in part of the post.

Arien Malec - Change Healthcare - Member

Maybe I should've read all of the red text rather than 171 in its entirety, multiple times. So, with respect to bulk data, I just want to clarify that way the FHIR is structured is that something being included in FHIR R4 does not mean that it is ready for use.

With respect to bulk data, the Argonaut Project has taken on bulk data export as a project to demonstrate real-world viability of the existing bulk data standards. ONC previously has put in place good regulatory flexibility that allows for EHR developers to work through a process like Argonaut or others to get the standard right before certifying to the particulars of the standards that exist at that time.

I have the same comment with respect to QRD in FHIR. If we think the right evolution is FHIR, but we name in regulation QRDA, then what we've done is disincentivize actors from transitioning to pure FHIR-based exchange for clinical quality reporting. So, if the intent of the recommendations is to keep QRDA as the certified requirement, we're not providing appropriate regulatory flexibility for people to switch and practice to FHIR-based quality reporting.

The last one with respect to vetting and validation of apps – just a couple of principles I think we should keep in mind is that the reason to vet or validate with respect to patient access is to make it clear which apps are trusted and un-trusted, but not to limit the use of the app of the patient's choice to access the data of their choice.

That's consistent with OCR guidance as well as with the CMS app criteria. I think the same thing would likely apply on the provider side that we want to make sure that there may be a staple of applications that are trusted but that shouldn't impact the ability of well-meaning actors who have their own vetting process or the patient from using the capabilities of their choice. Thanks.

Steve Ready - Norton Healthcare - Member

This is Steve again. This is going to be on one of my fine-tuning aspects. So, on the vetting, just to

clarify what exactly has been proposed at this stage is we don't explicitly require vetting to be conducted so it's permissive. If a health IT developer, in this case in the API language, API technology supplier would like to institute a vetting process, we provided the guidelines and guardrails by which the process could be followed in a way that would not constitute information blocking or other anti-competitive behaviors that would prevent third party apps from ultimately getting access to APIs.

The vetting, though, to be very clear is about the authenticity of the app developer, not casting judgment on the app itself, whether or not it would compete with the help IT developer services, whether or not they don't like the type of app that is being proposed. It doesn't matter in terms of how the proposals went, it's acutely on the legitimacy or the authenticity – sorry to use the proper words from our rule – the authenticity of the actual application developers themselves.

That could be a one-time thing that the application developer is entrusted by that developer and then any app that the app developer subsequently produces would potentially go to some other type of streamlined process. That would be one thing that – there are other things I have on my list, but I want to make sure the committee members have a chance to discuss and make sure that was clear.

Robert Wah - Individual - Chair

I'm happy to call on people. I will go this way. Andrew?

Andrew Truscott - Accenture - Member

The retention period, we've been discussing that, obviously. We referenced 17402 on assurances. It might make sense if those are lined up. So, we should probably get the taskforces to talk at the same time we talk about the other stuff we were just talking about earlier.

The FHIR R2 versus R4 discussion is an interesting one. I wouldn't be surprised if Ken has something to say on that as well. To my mind, us putting aside the regulation, any particular versioning could potentially – it doesn't really future-proof us that well because over time, the releases of FHIR aren't going to change and they'll be developed. Perhaps we should consider actually putting the onus upon HL7 and saying HL7, whichever one you say is a valid one right now, that's the one we want to have.

So, that allows the actual standards to develop an organization to maintain diplomacy over the standards which they create. So, it's something, I think, for consideration. So, that was on recommendation 17.

Recommendation 26 around export – drop the timeframe around that. Invariability, what seems to happen is where something is very hard and there's no obligation to do it, it generally doesn't get done. So, maybe consideration – maybe an elongation on the time scales, but still there's something in there.

Denise Webb - Individual - Member

The timeframe we were referring to there is ONC had asked for comment on whether there

should be flexibility in the features of the export function, not the timeframe of when you get the work done to provide the export function.

Andrew Truscott - Accenture - Member
It might be worth updating that recommendation.

Denise Webb - Individual - Member
If that wasn't clear, we can do that.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Just a note on the comment regarding FHIR 2 versus FHIR 4 – for discussion with committee, just want to know there is a proposal in the rule around standards versioning update process which would allow where a floor is established that developers could move upward from that and be held accountable once they decide to move up a version to performing at that version.

So, I don't know if it directly answers the concern you raised, but let's say the decision was to start at FHIR 2 if developers decided to move up to FHIR 4, for example, then they would be held accountable to performing at that level, per those requirements.

Andrew Truscott - Accenture - Member
There's a presumption in that statement that R4 is better than R2 and we know that's not actually a linear progression. So, rather than us trying to determine that and litigate it inside HITAC, we should actually ask the SDO as they are the closest people to it. That's what I'm thinking.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Right. Absolutely. I think that's subject to conversation to the committee I just wanted to let folks know about the proposal that's in there currently and see how that might juxtapose with what you're suggesting as well.

Denise Webb - Individual - Member
We had quite an extensive discussion about each of the four options for the first one was Release 2, the second one was Release 2 and 3, I think. Then there was Release 2 and 4 and Release 4.

I think where he landed as a taskforce is that we were most concerned about what we're proposing for those smaller or less resourced developer companies that might be more challenged as well as their customers to move to Release 4. But we also talked about how by the time this rule is finalized and the two years goes by, we are going to be probably way beyond release two. So, don't we really want to push everybody towards four, which, as Arien pointed out, we're just now testing through Argonaut the bulk data that's not at a normative stage right now, but a lot can happen by the time we get to the point of having to deploy this.

Andrew Truscott - Accenture - Member

To achieve the outcomes of what we are looking for with regulation doesn't necessarily mean deprecating R2 and also, frankly, what are we going to do about R6 and R9 and R 11?

Denise Webb - Individual - Member

That's where we have the standards advancement process which I think accommodates that.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

I think for the committee, let us know what you think about the different FHIR versions or any version, for that matter. I was more mentioning that there may be some consideration for the committee regarding the standard versioning updating process and the consideration of FHIR and which one the committee thinks that they would want to recommend back to ONC.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

We reached microphone limit. There's one other bit of context that we've covered in the past, but it's a good reminder for the committee overall is there are regulations about regulations. So, we have to comply with the Office of the Federal Register's regulations related to how we write them and one of the processes we have to comply with is called incorporation by reference, which is like the building safety code. You don't have to take that and put it in the whole regulation, you refer to the building safety code from 1986 or whatever it is and that's the incorporation by reference process.

That makes whatever that book is from 1986 the law as if it were in the actual letter of the law. Similarly, what happens for us from a certain perspective – as much as we would love to just reference or point to other organizations to have them identify what would be the best standard for the current context, in order to set requirements for the Health IT developers out there, we need to choose a particular version in the rule and incorporate that by reference to set this baseline. Otherwise we can't – that's a process we're bouncing. That's where we're looking to use the standards version advancement process to help move forward in not let us get stuck where we currently are.

Andrew Truscott - Accenture - Member

Okay. So, for clarity, you have to say a specific standard.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Yeah. That's a combination of the Federal Register's rule as well as the Administrative Procedure Act. The dynamic here is if we were to not specify a particular version and then the industry would go forward, there would be a delegation to whatever standard organization there would be to change whatever that version is to whatever they wanted it to be they would create this weird compliance dynamic between the regulator community and the regulators in terms of what the actual requirements would be.

We've had to address this a number of different ways. The version advancement process is the

most recent one we try to use with our new Cures authority.

Andrew Truscott - Accenture - Member
I think it's challenging to keep our applicability regulation fresh.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
Absolutely.

Andrew Truscott - Accenture - Member
This might be an inadvertently causing potentially eventually some staleness. Arien's got to be on this.

Arien Malec - Change Healthcare - Member
That's why our ONC colleagues in the federal government get paid the big bucks. So, this topic has been something that we have been discussing as a group for a long time, how to create flexibility to move up while creating a floor and also not make or be and in practice.

Just with respect to R4 and this particular issue, I actually think we aren't on relatively good ground here. Number one, R4 is the only release for which forward compatibility, at least for the standard elements is guaranteed by HL7. Then number two, as a point of fact – and again, this is not a statement from the Argonaut Project – but at HIMSS, we held a meeting/gathering of Argonaut stakeholders and informally polled them on this topic and that there was a strong consensus in the room to, "Please let us go to R4 and have one standard to apply to."

I think each of the Argonaut members – I don't know if Argonaut themselves will comment, but I'm sure that each of the Argonaut members will comment individually. But I suspect at the end of the day, we will get a clear consensus in this area.

Robert Wah - Individual - Chair
I just want to break for a minute because our National Coordinator needs to depart. So, I wanted to give him the floor for just a couple minutes.

Donald Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
Thank you. Sorry, I have to go. I think this has been a great discussion. I appreciate the thoughtfulness and the amount of detail in the recommendations. That makes it a lot easier, I think, for all of us to work together to get this stuff nailed to what is both a public good and something that is reasonably workable for all concerned and look forward to hearing the rest of this and we will go through every one of these recommendations and take them into account as we get this thing out the proverbial door.

Obviously, again, we'll encourage you and certainly the folks that you work with in each of your communities to engage in comment. Obviously, the reality is some of these things we only have

a couple minutes. Item number 19 or 18 or whatever on a slide deck may have a lot more nuance in it than we can get to fitting three things per page on a slide.

So, we absolutely invite people to go into further detail and if they are clarifying questions, we can answer on that because there's been a lot of thought that's gone into many of these specific line items already. I think we can bring this to a very good spot.

Obviously, the version thing is just a perfect example of the funny intersection of technology, administrative procedure, act law that never frankly even thought about computers and getting this also in the context of just the public expectation of what's going to show up on their smartphone. Can you take your data? Can you deal with it?

So, anyway, thank you very much and I look forward to further participation here, but I do have to run this minute. Thank you.

Robert Wah - Individual - Chair

I think I heard he likes the 33, bring more. Ken, I think you had your sign up.

Ken Kawamoto - University of Utah Health - Member

Thanks. Great work and sorry wasn't able to participate. I was in Disney World for the last two weeks. Just a few comments, although I'm sure this would have been more fun. I did put some of these in the Google Doc proposal, but since there wasn't time to discuss, I will bring them up here.

With regard to the FHIR version, I do think giving ONC the flexibility to choose the latest stable probably makes sense because there are sometimes chances for errata. There are versions of FHIR like Release 3, for example they found an errata and have a 3.0.1 instead of a 3.0.0, giving them that flexibility, I think makes sense.

With the real world provider evaluation, if there are provider aspects to it, I think it's important to make sure there's no unfounded mandates, actual clinical evaluations tend to take a lot of resources. So, that's is something we want to be careful about.

With regard to provenance as part of what's going to be certified, I think it's proposed to do name, organization, and date. A suggestion is to also add role so that it is not just John Smith from Practice X who provides this information yesterday, but is John Smith who is a physician or medical assistant or what have you. I think that would be useful to know.

Then in terms of the overall security and privacy of the proposed approaches, I think it's implied by ONC basically saying, "We recommend use FHIR. We're going to use FHIR. We're going to SMART, etc." that it is, in fact, regulatorily compliant. I think would be good to have explicit guidance providing data in this way is HIPAA-compliant. I brought this up many times.

But I think there is still some question about, for example, if a third-party app only needs to know a patient's height and weight to tell you what their body mass index is, is it HIPAA-compliant for

a healthcare provider to send them the patient's name, address, cellphone number, home address, work email address, and also give them access that they could use to pull the patient's HIV test results because that is the way the current standards are written. And I think it very well may be reasonable. I think would be good to get official guidance that, in fact, is reasonable as long as you have a business associate agreement in place, etc.

Then the final one is the reference to Argonaut. I think Argonaut has done a lot of great work, but it is a closed group that is not open to public feedback. I think they've done a great job of taking Argonaut work and bringing it into HL7, which is an open membership body in the form of US Core implementation guides. As a practical matter, things tend to fly through the HL7 process once Argonaut comes in saying we've implemented it.

But you can still catch some things as referenced by some of the recent balloting on the Argonaut work that went to US Core, where, for example, we can identify things like we are missing the search parameter which would make it really likely to pull past medications, that kind of thing. I would feel pretty strongly that ONC should not reference Argonaut as a requirement and really work towards taking what flows out of Argonaut that gets us put into a public body like HL7 before it gets referenced.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

I will try to be brief. I'm happy to make myself available to help you fine-tune some specifics that are in here in the interest of time, but did want to thank you all for the voluminous amount of recommendations in response to our voluminous amount of regulatory proposals.

As Dr. Rucker mentioned, the more eyes that we have on these, the better we'll be able to make a final product. With respect to the 2015 Edition itself, you all are also grappling with the same contexts and concerns that we had as well and equally keeping in mind that this year in terms of broader industry context, it's the first year the 2015 Edition is required for compliance by CMS.

So, in coming out with yet a new edition at the same time this current edition was required for the first time for providers was another communication consideration that we had to keep in mind together as well in addition to I think what we would view as minimal new additions to to the edition and a lot of removals from the current edition from a de-regulatory perspective.

All that said, you all are certainly are welcome to, as you have, provide the comments that you have, I'm sure we will receive other clarifying comments about how do we make the Cures modifications to the 2015 Edition or some other named component of our rule clearer for industry in terms of the compliance-related changes that would occur. That is one thing.

On the six-month aspect of the API-related recommendations, the other point to keep in mind is we have three API certification criteria today. A lot of the condition of certification conditions would apply directly to them upon the final rule. So, we needed a timeframe by which to apply the full suite of the condition of certification to the three existing certification criteria that are available today, including the maintenance of certification requirements like and endpoint publication and the like.

So, that's what that six months is about. It's about applying to the current API certification criteria that are out there. That would apply to products that are deployed in public today. We already covered the vetting. The one fine-tune to know on for Recommendation 24, I think that was in overextension of the API data provider.

That's only in the context of the API certification criterion is that terminology used. It is not used in the context of the EHI export certification criterion, which would B10 if I'm keeping track here. So, those are the other fine-tuning.

The last one, which we can take offline as well is the e-prescribing – all of the transactions that we referenced in our rule are required by CMS for Part D prescribing. So, there's a direct attention by us to realign back to the new script standards that CMS has referenced for Part D, all those transactions are effectively required not designated as optional or alternative for CMS Part D prescribing.

So, the industry's request for us to realign back to CMS now I just want to highlight that as well. There's not only do we have the layers of our own regulations to contend with to provide coherent alignment, there are also the other federal partners we have that issue regulations and standards in this space in some cases. Again, there's more that I'm happy to provide offline with the taskforce as well, but in real time just for everyone's benefit as well.

Part of the reason why take so long to do this stuff is all of these extra checks with you to make sure that we are aligned before we go out with our proposals. Thank you again.

Denise Webb - Individual - Member

Steve, we might, on the recommendation related to the six months versus what happens in 24 months with the APIs, if that information you just provided already exists in the preamble, it would be good to point out where that is, otherwise we will put our recommendation forth so you all can provide that clarification.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Yeah. I can send it to you.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Thank you. I think Arien was next.

Arien Malec - Change Healthcare - Member

A quick comment just to clarify my use of the term Argonaut Project and HL7 – I think in general, Argonaut Project has agreed to work with HL7 and have HL7 go with formal balloting process, which creates significant value. My only point is that standard is a standard insofar as it is aligned with an organization like a standards development organization that makes sure that we are on the right side of IPR and other kinds of rules and that is used in practice and tested in practice.

It’s the tested in practice piece that's important. Sometimes we have the inclination to take something off the shelf that's been it's gone through a process but never gone through an implementation process and that's the part I'm referring to. So, thanks.

Denise Webb - Individual - Member

Sasha?

Sasha Termaat - Epic - Member

I just wanted to further dive into the e-prescribing comment that Steve made in that I think there is an intention on CMS’s part that when the transactions are used, they follow the new script standards that's proposed, but I don't think there was an intention on CMS’s part that any product that participated in e-prescribing at all would have to support all transaction types.

I think there's a natural distinction between some types of products, pharmacy products versus EHR products that you’re prescribing and that pharmacy-to-pharmacy transactions don't make sense for all products so it goes to certification. That that was the attempt we were trying to clarify in the certification criterion.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

That helps and that will be really helpful commentary to add to the recommendation and also illustrates the complexity of regulating in this environment when you have two different agencies that are regulating the same standard but for different purposes, one from a certification perspective and another that may include pharmacy-related actors as a covered – I do want to use any other term that we have – a covered organization for the purposes of Part D prescribing that we don't necessarily engage with.

Denise Webb - Individual - Member

One other thing I was going to mention, Ken, on your comments, the one on provenance – I think that's applicable to the USCDI Group Taskforce because I don't believe we covered that in the taskforce. I’m just trying to get the other taskforce to pay attention.

Robert Wah - Individual - Chair

Other comments for this taskforce? Seeing none – I would think our two co-chairs, Raj and Denise. Thank you for bringing the 33 recommendations to us and thank you for your taskforce’s work and all the members on your taskforce as well. If I could then ask Christina to take the co-chair seat on the next taskforce. While they go down there, I would point out that while we were out lunch another batch of cookies, I mean materials came out. So, if you haven't been following that, there is another batch that came out that you might want to just check for tomorrow. I think we will move to this next taskforce on the Core Data for Interoperability Taskforce. Christina, you want to take it from here? Make sure you put your microphone on.

USCDI TF Speakers

Christiana Caraballo - Audacious Inquiry - Member

Sorry. Steven is joining me because Terry is not here and we come into the hot seat with the buddy system. Steven – our taskforces align a lot. So, he's joining me today.

So, going into our first slide, I know everybody's excited to talk about USCDI. On our agenda today, we are going to go toward taskforce members and we are going to discuss phase 1 and phase 2 of our charge. A little different than some other taskforces – we are going to continue afterward next in-person meeting and we have a phase 2 of our charge, so we will discuss what that looks like too, go to some of our draft recommendations and open it for questions. So, next slide.

Here's a snapshot of our membership. Terry O'Malley is also co-chair of this taskforce but couldn't join us today. And here are the rest of our members.

So, phase 1 of our charge is going to be to review specific data elements within the USCDI version 1, specifically looking at new data elements under the first bucket, we're going to be looking at including address and phone number under patient demographics, then we are going to look at provenance. We will be discussing our first round of recommendations today on those and then and in our later phases, we will be looking at clinical notes, pediatric vital signs and then anything that's missing. So, next slide.

Here is a visual depiction of the data classes that we are looking at. Something to keep in mind is that all the data elements that are highlighted or those in blue are actually from the common clinical data sets, so, they are just pulling over from what already exists and we are not really looking at those right now as part of our phase 1. We are looking at what's new. So, those are the highlighted are the ones in purple, which are the focus of our recommendations.

A couple things to think about as we go through this process is that as we are considering the data elements, we're doing it in buckets. So, we are looking at what exists now in current certifications, what do EHR currently certified support data elements in existence now whether there required or just part of certification as kind of like the base for the USCDI, what can we do today?

One thing I want to remind everyone is at the USCDI is the floor, not the ceiling, so it's the basics that everybody needs to do. Then our bucket two as we go through this process is to look at what we want next. When we think of what we want next that can be what we want next within a data class that already exists or creating a new data class.

So, one thing that our taskforce has done along the way is kind of identified that second bucket and started listing things that we want to look at in the future which will be part of our phase 2. Just to reiterate, today we are going to focus on what's happening today. So, next slide.

The first one we are going to look at is patient demographics. Under patient demographics, there is the proposal to include address and phone number. Our taskforce discuss these and under the address, we are recommending that a standardized format and content of address be used and

we are also drawing attention to the need for individuals experiencing homelessness and refugees.

Under the phone number, we are recommending the use of the mobile phone. A couple things that we pointed to were AHIMA's Patient Identification Glossary, the United States Postal Service for address standardization, and the current requirements in the certification.

When we are looking at patient demographics, we as a taskforce thought what is the purpose, what's the use case behind patient demographics, and we see this as a huge opportunity that the industry has also identified as a way to tackle patient matching. So, there have been a couple reports including a recent one by Pew that identified demographics as an instrumental way to address patient matching.

So, in our discussion, we also started to think of additional data elements for inclusion and they are neck pain, last four digits of your Social Security number, a personal ID, such as a driver's license or passport, an email address and alternative address, which could be work or school.

So, before moving on I actually wanted to stop and get the HITAC's thoughts on what we are looking at so far. Steven, did you have anything to add on that?

Arien Malec - Change Healthcare - Member

Definitely endorse the use of alternative methods for identification in the work that, for example, CommonWell has done and other HIEs have done with regard to patient identification. I think there is a hope that additional machine learning and AI techniques will get to perfect match on known demographic information.

I know that the reflection of IHIE as well as other organizations that have followed posits that there's a pretty substantial upper limit you can get to with core demographic information and other identifying information, other attributes are incredibly helpful to link records. Those attributes include, as noted strong identifiers like driver's license numbers. Mobile phone is a fantastic one because it does tend to be persistent.

None of these things, as well as when available, the medical record number of the sending system – that's also incredibly helpful matching identifier – none of these are primary identifiers in the sense that if you match them you should automatically match the patient. There needs to be secondary follow-up to make sure that information is matched, but I highly endorse the notion of including these secondary attributes as complements to matching logic in the USCDI because it will greatly facilitate downstream patient matching and linking.

Aaron Miri - University of Texas at Austin - Member

Great job. I think these are excellent recommendations and I think are critically important. One component I do want to bring up just to consider and think about is I think there certain elements as related to SSN or some personal ID that might dissuade folks seeking care. Case in point, in Texas and some of our very rural counties which we serve, we serve a large number of care in rural counties, there's a number of folks who present that do not speak English that do not have

identification on them and if you ask identification or those attributes, it scares them off and they don't seek care and they come back with more complex comorbidities.

Our goal as a provider is to obviously offer care in the communities. Real-world story – our social workers going into the community to meet with these folks individually have to go several times to assert themselves that we are here to help you, we're not here for any other reason. So, to the degree that we can use standardization and documentation and AI as Arien mentioned would be critical. That's it.

Steven Lane - Sutter Health - Member

One piece of feedback on that – I think either a number of things that we've discussed in our other taskforce where we talk about if the data is present, it should be made interoperable and transmitted, but I think you make a good point that there are times when the difference between acquiring the data and facilitating the transmission.

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

If we could have everyone on the phone your lines, please. Thank you.

Andrew Truscott - Accenture - Member

How do I follow that? To echo his Aaron's comments, this is about consistency of identification.

Steven Lane - Sutter Health - Member

That is certainly one of the key use cases.

Andrew Truscott - Accenture - Member

As opposed to demonstration of entitlement to care and what you're talking about, you're talking about the refugees, homelessness, etc. I think that needs to be made pretty clear. But on those last elements you are proposing for discussion, are we suggesting there should also be or could there also be a level of validation? So, simply because you provided something doesn't mean this right or wrong or indifferent.

So, rather than we collect information for the sake of collection – actually, we should do something with it. Say if we're collecting a driving license, then actually doing a validity check with the driving license is correct and corresponds to that individual would kind of seem to make sense. Otherwise we have a false level of security, at least perceptive security, and you have an illusion of accuracy to a degree of precision, which would be an unintended consequence. I'm looking at Aaron right now.

Steven Lane - Sutter Health - Member

One thought I had and feel free to jump to is the USCDI is about the data content. What you are talking about with regard to verification is much more about the process of collecting that data and verifying it and I don't know that in USCDI we discussed the process so much as the content.

Andrew Truscott - Accenture - Member

You are right. I'm considering that we shouldn't consider these without connecting the two together because USCDI will put a deliberately strong view here, Mr. Posnack, that if we screw up USCDI by filling it full of meaningless data, we diminish fundamentally the importance of USCDI. So, considering the process by which data finds its way into a data set and the utility of the date it means we increase the manifest value of USCDI far greater than people saying it may or may not be wrong.

Christiana Caraballo - Audacious Inquiry - Member

I think you make excellent points. I think something to remember is that when we're thinking of use cases, we're not trying to solve the use case in our taskforce. We're saying what data do we need to collect and gather that's available in order to solve things like patient matching and other use cases we've identified. I just wanted to make that clear.

But your other question was with the additional data elements, I think we are proposing that we wanted to start discussing the ones that were recommended under the current draft, address and phone number, within the USCDI don't actually have – they're still blank for what actual standards support them. So, we're trying to offer guidance around those two that are being proposed then identify any additional ones. So, I think the feedback on Social Security number and other things are extremely valuable.

Tina Esposito - Advocate Healthcare - Member

The only thing I would add and Andrew, I think you're right – I had the pleasure of being part of the subgroup and I think we had a conversation – in some respects this also relates back to provenance – so it's not exactly aligned but it's very similar. So, I would say we did have a little bit of a conversation about ensuring that this is how do you know how accurate this is. So, I think more to come on a secondary side as we talk about provenance.

Andrew Truscott - Accenture - Member

We're not the first people to try and do this. So, we should learn from the experience in other jurisdictions as well as within this country. We have a great deal of experience in trying to make this happen. So, we should build upon the shoulders of giants.

Steven Lane - Sutter Health - Member

Any specific soldiers shoulders you are thinking of? Any specific shoulders you are recommending we stand on?

Andrew Truscott - Accenture - Member

I wouldn't like to necessarily to point fingers, but frankly Australia, Canada, close to home, UK, my homeland, there are other countries who have gone through this same process. We should leverage that. I think, to be fair, a lot of the thinking that's gone behind this you've done already. I'll just keep mine on. You can't talk. It's great.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Don't tell my wife because she would love the setup. It's good segue in terms of two phase 2 for this taskforce as well, in that the work ahead of them will be to look toward the value overall and magnitude of how data makes its way into the USCDI itself, having that be a predictable, transparent process that the public can engage in.

And equally even the discussion we had this morning, relative to different data types for determinants and the like, every group has a different set of data that's really important to them and arguably is really important to healthcare and it's going to be an enormous task to try to sort through what makes it into USCDI first or over time that gives the most value to industry as a whole.

Christiana Caraballo - Audacious Inquiry - Member

Any other comments or thoughts on the patient demographics? Okay. We can move to the next slide. All right. So, the next one we are looking at – and this is still in the process, but the next one is the data provenance.

Currently, in the USCDI draft version 1, the new data elements are author, author's timestamp, and author's organization. Under these, we have a couple specific recommendations so far from our taskforce. The first under author is to specify a permitted author type by data type, for example, a lab director of labs, a surgeon for procedure note, just two examples.

And secondly, we are asking the question does this include setting, context, and location? So, for example, the vital signs being collected at home, in the pharmacy, in the clinic, or in the hospital.

The other thing we are looking at and considering is the chain of trust. This was actually a pretty lively discussion and right now, we are looking at minimum so a minimum. So, a minimum would be including the original author and immediate source if different from the author. So, that would say who is the original author and who did I receive the information from?

Additional data elements for proposed for discussion include unique identifier – this came up a couple times – and some of the things that were pointed to included the original ID of data, a supplemental ID, Medicare code, and a national provider identifier. Can we go back to the last slide? Is there any discussion or comments on provenance so far? Sasha?

Sasha Termaat - Epic - Member

So, I think this is really helpful context. I know in conversations with other experts in health IT development, when we started to talk about provenance, it felt like we almost need an entire implementation guide for each of the data classes where this level of provenance is suggested so it can be implemented effectively.

I know that it was hard when we started to talk to through examples to really put into our heads if a patient walks into a clinic and tells a medical assistant to write in the EHR that they are allergic to latex, who's the author or responsible entity of the patient's latex allergy, the patient who reported it, the medical assistant who entered into the EHR, the provider who finds the visit that the medical assistant documenting in, the person who originally diagnosed the patient with a

latex allergy whose name and other identifying information may not be known at the time this happened?

That was just one relatively simplistic example that didn't even address modifications to a particular data element which would need to be tracked with respect to this provenance. I think my sense and the sense of others as we started to dig into this is that this is going to be very complex to figure out with variances across each of the types of data that we would discuss how you might approach it.

I think it might be most prudent to focus on one or two of the areas where we want to figure out Provenance in detail with the level of specificity that's necessary for implementation and focus on those for the first inclusion and then expand the provenance data elements to the other data elements over time as we are able to build on that expertise.

Steven Lane - Sutter Health - Member

Sasha, I think those are really great comments and very much in line with what we discussed within the taskforce. This is why we are getting at this idea of perhaps coming up with a grid. I like the notion of an implementation guide, where for each data type, what would be an appropriate author?

Your example of that latex allergy is a perfect one and one could argue for a long time, but I think reasonable people can come up with reasonable guidelines. And the other point that was made is that there is the original author and also the source. When you were talking about the provenance of data, those, again, sort of floated to the top as the elements people were most interested in, but there's that notion of the entire chain of trust, where has it been, who has touched it. That can get to a level of absurdity with some of these things, but at least the beginning and last point in the note before it got to made a lot of sense.

Aaron, I think you were up next.

Aaron Miri - University of Texas at Austin - Member

Great slide. I think personally, especially from the University of Texas perspective, in our research components, chain of trust is critical. Obviously with any IRB study, you have all the evidence base for a cohort that's selected.

I think to the degree, though, of what Sasha said, I want to echo that – I think it would be useful for us to have a specific either implementation guide or use case we're trying to solve. I always tell folks try to solve a problem through a straw and then expand it. So, perhaps in how we get better API adoption, you have this first level of data elements stratification provenance to help solve adoption of API, something like that that helps drive forward the ecosystem and then we can figure out and work backwards with how the rest of it is.

In concept, I think it works but we could be careful because it could be a tricky slope. How do we deal with PGHD? How do you deal with patient-generated health dated? How do you deal with manufacturers and products that are not necessarily certified HIT products but do deliver health

data? How do we deal with all that if they are not following the same chain of trust?

Leslie Lenert - Medical University of South Carolina - Member

I think that you have to pick this up into two components. One component is that it would be very useful to prevent duplication of data elements in the record as we pass data around. If I have the data on my phone and I upload it, we don't want that data coming up as a different data point. That is one aspect of the provenance of this.

The other aspect that is more complicated that's been referenced here is this notion of can we entrain an assessment of whether the data are fit for purpose in the data element itself? I would suggest that that's a little bit like Whack-a-Mole, since we've been doing that or maybe Don Quixote-ish or whatever you want to say. It may be difficult to truly do an assessment of fitness for purpose along with the data elements itself.

It might be better to reference the data element where it came from – if the identifier allowed you to reference back to where the element came from through some kind of a hash table or some strategy like that, that may be all that you need and rather than like an HL7 V3X message, take the entire history of it so that you can assess fitness for purpose at the point of care when you are viewing the element. It's likely that that would – to me, that seems impractical.

Steven Lane - Sutter Health - Member

I'm sorry, are you suggesting that the assessment of fitness for purpose should and be maintained at the source as opposed to when this piece of provenance data is received?

Leslie Lenert - Medical University of South Carolina - Member

I'm suggesting that the first step is to say let's avoid duplication of elements in the record that the purpose of this provenance, the first thing is to prevent this having unnecessary elements to be reviewed and assessed in those types of things. So, if we can solve that problem, the second issue is much more complex. It's how do you automate the assessment or how do you manualize even the assessment of fitness of purpose of any data element?

That's what the provenance, as you expand all these elements of provenance, that's what you're trying to do, right? And that can get to be a very complicated task. So, I would probably urge you not to take that on and the first pass. But if you had to take it on, then perhaps it would be better to reference where that data were held rather than to where it originally came from rather than to look at the combined history of all the paths it passed through to get to where it is now.

Andrew Truscott - Accenture - Member

I, for one, think this sounds fantastic. It's been so long coming if we were going to enable true interoperability then actually understanding the provenance of data is fundamental to making that happen. We've got syntax. We get into semantics problems as the next big bastion. So, this is great.

NPI, National Provider Identifier, absolutely. It's kind of a no-brainer to me. The author type, I think what you mean there is role and trying to implement some kind of national approach that

seems like a very, very steep path. Every local organization already has its own understanding of roles and permissions and entitlement for its people.

So, incorporating that doesn't seem like a particularly big issue, especially because EHR's have the all within them. Sasha made a very interesting point about the delegation of authority and we do have a large number of operators of health IT who are operating at the behest of others and they're operating at the behest of someone who's told them, "Go and write up these notes. These are my notes. Go and type them up."

So, to being able to recognize that, that is a bit of a lift as well for organizations and health IT developers because it impacts how they have an identity and access model intact within their software itself. That said, it's a lift that needs to be done and if we here don't say it needs to happen, then it probably won't.

So, if we are serious about making this happen, we probably need to put that in place and say, "Here is your timeline, comply." All the other things which we talked about today so far and there are some heavy lifts and lower lifts, this is a big lift. It kind of needs to happen.

Arien Malec - Change Healthcare - Member

As somebody who's done data reconciliation, record reconciliation from interoperable data, I just want to endorse Leslie's point that if only I know where it came from and I have persistent identifiers for it, then I've solved a whole bunch of really hard problems like trying to figure out the same thing I saw before or is this a new fact?

There's a huge amount of duplicative work or duplicate checking work that goes into maintaining data sets, for example, displaying back to the patient or displaying back to the provider or if we're doing clinical quality measurement, that can be avoided if only we had some level of persistency and identifiers.

I think the other key consideration is, relative to patient-generated data, to be able to distinguish the immediate source of the data, it's sort of a lost cause if we are trying to source all the co-mingling of data across all of the different permutations that it goes into. But if only I know that this thing came from the patient and this thing came from the provider organization and I suspect we are going to get down to provider organization more easily than we are going to get down to specific actors within a provider organization, I think we've done ourselves a huge service. And then once we understand where we are once we've gotten there, then we can go the next step, as Les notes.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

All right, Steve Posnack. So, I think maybe to piggyback off what Arien was saying, some of what we are discussing seems like déjà vu to a lot of people that have previously been a part of the advisory committee discussions before. In the context of the USCDI, the intent that we put forward and portrayed was something I'll use in a cliché way is that minimally viable provenance in such that there's a lot of computational power that can be applied to the data that gets collected today in terms of all the rules and information that can be captured around it.

At the moment, when data is exchanged today in some cases not even meeting the paper equivalent of provenance that is occurring from a paper-to-paper fax transaction or something along those lines. So, even to get back to the state of where we could be from electronic perspective to provide some assurance of authenticity, trustworthiness to the data being exchanged, that was the first start that we had recognizing that it would be a heavy lift for a lot of organizations that may not be representing this provenance data along with information that's exchanged.

So, to the degree that we have an opportunity with the technology and computational power that's available to us to make a quantum leap beyond where we are not today, for lack of a better word, we have to resist a little bit of that tendency to get in the way of progress, incremental progress, because we could make this very complex very quickly.

And I'm not sure based on the prior exposure that I've had at many of these committees and the like that we are even meeting the basic provenance needs of healthcare providers the fields when they get data from various different sources for patients as well. To Arien's point, being able to just recognize that I got this same information from a source the other day or equally this is the institution that sent me the data and the healthcare provider from whom it came. Those would be some of the other bits of context to keep in mind as you all hash through this.

Steven Lane - Sutter Health - Member

I think what you are saying, Steve, is keep it simple at the start so that we have something that will move forward and try to keep the complication and all this nuance to future work.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

To do my best Truscott, yes. Once the experience with how some of the provenance data has helped and made a difference, to Arien and Les' points, then we can get a bigger coalition that recognizes the value of that data for other purposes beyond just some initial uses.

Steven Lane - Sutter Health - Member

Sheryl and then Cynthia.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

So, I wanted to pile on to as what was being said, but also to just frame it from a different use case perspective, because as you know, I represent Anthe, which is a payer. That data is now data we need to be concerned about relative to data provenance as well.

So, if I take a use case similar to what Sasha was saying, provider directories, we are involved in a couple of efforts now that include blockchain for being able to identify who's updating those provider directors. So, I know I mentioned this in the session, but we need to be able to make this recommendation broad enough to support those types of activities and not limit us so that we won't be able to utilize those particular types of technical advances.

But also, many companies and some of the state agencies that we're dealing with are now ingesting data from LexisNexis or someone like that, which is collecting data from many sources. So, today, we might receive the data through direct or a third party and one of the challenges we already have on the table is really knowing where they source this data from.

They collect it from many, many devices. Many of those cases might be a Fitbit or it could be something self-identified in MyFitness or whatever, but understanding the data provenance of all of that social type of data and activity data from personal devices is going to be important because it determines what's the best use of that data and how much priority are you going to give that when trying to make decisions that involve the patient. I want to recommend that we look at some sort of instructional guide or something of that nature because this is a very, very complex subject when it comes down to looking even beyond the clinical environment.

Cynthia Fisher - WaterRev - Member

Yes, I go back to what Steve and Andrew touched base on was really the importance of addressing the USDI element and the identification such that we look at the banking industry, we would never tolerate the delay of game if we couldn't see the finances and have immediate access to them. If you think about how the hand off and the provenances are exchanged in banking and finance and the API usability and the friendliness to the consumer, even where the innovators like Venmo can step right into addressing new ways and new outlets that are user-approved for handoff on how they share that data.

I just guess I would ask the committee that we really look seriously at deploying timely feasibly of making this happen rather than delaying game through complexity because of the urgency of need of care. You can look at the patient examples of just the incredible challenge to get access and every day, we hear of another case where a brain scan is done and it takes eight days and they still haven't gotten access and the surgeon says they can't. The patient doesn't have access for critical life management decisions that come into play. This is a very important area that we do need and have it on our shoulders to address timely.

Steven Lane - Sutter Health - Member

Thank you. Any other comments? I'll just observe. When we first looked at this, it just said author, author's timestamp, author's organization. I know my personal reaction was that's just not enough. There's so much more to do here. I think this kind of feedback is so important. Let's start there. Let's work through all the specifics that go with those before we start piling on a lot of additional detail.

Christiana Caraballo - Audacious Inquiry - Member

I think we can move to the next slide. So, here is just a snapshot of our work plan. Next, we're going to go into the clinical notes and then the pediatric vital signs and have finalized recommendations for HITAC for the meeting on the 13th of May. So, next slide is our phase two charge.

So, as I mentioned earlier, this taskforce will continue into a phase two, which will to review and provide feedback on the USCDI data element draft promotion model, specifically looking at the promotion model lifecycle for data submission, data element submission information, and data element promotion criteria.

Steven Lane - Sutter Health - Member

So, I actually had a question for the ONC staff. The phase two that we envisioned sounds like it's a bit of a review of what we did back in, I guess we'll call it phase zero of the USCDI taskforce, where we talked about the promotion model and how things would be brought in and worked through the phases.

It doesn't seem to include everything else, all the other content that was proposed in USCDI version one that came out now over a year ago, the multi-year listing of what elements should be included and then that whole big pile, which includes social determinants of health, which were not even yet on the calendar. Can you say how you envisioned bringing that work back into the USCDI process?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

So, we have given Terry and Christina a briefing on phase two, at least to give them a head's up in terms of how the context will go. We have since taken the recommendations from the committee and prepared a process, version 0.9 that we are going to give to the taskforce once you complete this. You will get your dessert, so to speak, to work on in reaction.

And I know that a year ago, the taskforce was asked to work on the USCDI in the context that we would put it in the rule. Maybe that was inferred by a lot of people, but its relevance to the framework common agreement, its relevance to the rule now, it's also referenced as a standard so that we can update it over time pursuant to the standards version advancement process. So, that would be a part of the consideration of the process discussions that would need to take place.

We have a proposal for how to deal with the levels of data and the maturity of the data, either classes or elements, by which the public and HITAC would have the opportunity to provide their input and recommendations. But our hope going forward in the future is that we can democratize the process of identifying what data is out there and then have a clear set of characteristics and thresholds by which the data can be mature over time and ultimately able to be promoted to the USCDI itself after it's been demonstrated that it's captured in systems, it's usable, it has relevant standards attributed to it, as such.

That will be something that will lay out for the taskforce to react t to and provide us the best recommendations as if we were going to implement it now. For the regulatory cycle, as it goes forward, USCDI version one will be finalized with the final rule in so far as it is inclusive of any recommendations that we receive and clarifications and tweaks that need to be made. Then after that would be when this process that we are going to seek feedback on would help kick in.

Steven Lane - Sutter Health - Member

Will there be a need to move beyond USCDI version one or does the standards version advancement process, once that's finalized in the final rule, will that be sufficiently expansive allow USCDI to move forward without additional rules?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Our hope would be for any standards included in the standards version advancement process, let's say an annual cycle would occur, anything that would be worthy of updating and including and being referenced and approved by the national coordinator, pursuant to the standards version advancement process and resisting the urge to use all of the acronyms we throw around in the office, that once the national coordinator would approve them, they would, in effect, raise the ceiling and be available to the community, help IT developers, and everyone at large to go to the new version of whatever the National Coordinator has been approved.

At some point, let's say we are four USCDI versions into the future. At some point, there would be a need to reregulate to create a new floor. But we don't want the process to impede leaders from leading and would rather use the regulatory floor that we are able to set with certification, be a way to move the laggards up as necessary over time.

Steven Lane - Sutter Health - Member

I don't mean to belabor the point. That is really helpful, that differentiation between the raising the ceiling through the standards version advancement process versus raising the floor through new regulations. But that suggests that USCDI version one, as published in 2018, which had a series of annual steps, we're probably not going to see new regulation to raise that floor annually at this point. Is that fair or do you anticipate we will be seeing annual raising of the floor was initially proposed?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

That's not our -- that's not what we proposed, but it is certainly something that people can comment on if they so choose to recommend that to us.

Robert Wah - Individual - Chair

I'm going to ask you to wrap up, Steven and Christina. I just found out we have a hard timeframe for the next co-chair. So, I'm going to have to get you to wrap it up. Thank you, again, for stepping in, Steven and Christina, thank you for being co-chair of this and Terry as well in his absence.

The next group is scheduled to start at 3:15, we have time for a very quick break. I don't believe it is physically possible for a group this large to take a five-minute break, but I'm going to allow that to go and we're going to get the next group started as close as I can to 3:15 because Chris Lehmann has to dial in with a short time frame and he is limited on how long he can be on the phone. So, let's take a quick break and be back at 3:15 to start the last taskforce with Carolyn being co-chair of that. Thank you for your indulgence.

HITCC TF Speakers

Robert Wah - Individual - Chair

All right. As Carolyn gets up to the microphone, let me just lay out where we are and where we're

going to be. We're about to start our last taskforce, the Care Continuum Taskforce. It's chaired by Carolyn and Christoph Lehmann. We're going to have our break at 4:00 p.m., again, to meet our commitment to the public comment period and if there is extra discussion pertaining to this taskforce, we'll do it after the public commentary period. That will leave us the option of extending the discussion.

So, with that, I see Carolyn making her way there. Okay. At this point, I will turn it over to Carolyn as the co-chair of the taskforce. I think we have Christopher on the phone.

Christoph Lehmann - Vanderbilt Universtiy Medical Center - SME
Good afternoon.

Carolyn Petersen - Individual - Chair
Good afternoon. So, I thank you for hanging in today as we gone through a lot of discussions about what the taskforces are doing related to the NPRM. I appreciate your attention during our last presentation of the day. Chris and I will be bringing you some discussion about what we've been doing on the Health IT for Care Continuum Taskforce.

Here is a brief overview of what we are covering today – our members in charge, some background, and a look at some of what we have decided with regard to some of the draft recommendations that we have had a chance to review so far, and then an opportunity to for discussion. As Robert mentioned, we will be doing a hard stop at 4:00 for public comment and whatever housekeeping that Lauren has for us. Could I have the next slide, please?

So, here's the group of individuals on this taskforce. Aaron and I are your HITAC members. We have four subject matter experts. Dr. Lehmann is co-chairing with me. Next slide, please?

Our overarching charge is to provide recommendations on ONC's approach, recommendations, and identified 2015 Edition certification criteria to support pediatric care in practice settings, some related criteria to support multiple care in practice settings, and request for information on how health IT can support the treatment and prevention of opioid use disorder.

Specifically, we are looking for recommendations on the following five items – it would be the 10 ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether to remove any of these recommendations, identify the 2015 Edition certification criteria for supporting the certification of health IT for pediatric care in practice settings, some pediatric technical worksheets, the 2015 Edition DS4P and consent management for API certification criteria, and finally how health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis. Next slide, please?

Taking another look at this in another way, in response to the requirements set forth in section 4001 of the Cures Act, ONC has 10 recommendations for voluntary certification of health IT for pediatric care that does not include a separate certification for pediatric care in practice settings.

ONC has identified current and proposed new 2015 criteria yeah that support pediatric care in practice settings. ONC has focused on nonregulatory initiatives that are nimble and responsible to stakeholders, including development of informational resources to support setting specific implementation that aligns with the ONC health IT certification program, lots of words.

Here on the next slide, we can look at a more graphical approach to this information and this approach. We have some pediatric stake holders who have identified clinical priorities and evaluated them with ONC previously. So, we have these ten recommendations that we are looking at in terms of if they are correct and appropriate given today's IT, and also if they are still needed.

And then we have in the lower left there, the list of current 2015 addition criteria. And on the right in the blue box, some proposed new criteria for the 2015 Edition. That would include the US Core Data Set for Interoperability that we just heard about, electronic prescribing, FHIR-based API, and data segmentation for privacy.

Next slide, please. As part of our work, we have been using a set of ten technical worksheets. These give us background information and they also guide us to look at four broad questions, which deal with things like relevant gaps, barriers, safety concerns, and effective use of IT, and so forth.

In particular, our taskforce is focusing on two questions, should any of the recommendations not be included? And should any of the functional criteria listed under the alignment with 2015 Edition certification criteria and the alignment with proposed new or updated certification criteria be removed as a related item to support any of these recommendations? Next slide, please?

So, we have had a couple of meetings so far. We are working through the ten recommendations first. We have reached a consensus that all functional criteria under the alignment with 2015 Edition certification criteria and the alignment with the proposed new or updated certification should be retained for the recommendations 1 through 6. And we have a tentative consensus for the same with regard to recommendations 7 through 10.

By tentative consensus we mean we have taken a very broad look at individuals and agreed, yeah, we think we will stick with these, but we will have more detailed discussions about those in meetings this Friday and perhaps next week. Our view at that point is still tentative. We will be discussing in the future the supplemental children's EHR format requirement. With that background, I will now hand the microphone to Chris to discuss the six recommendations that we have discussed and come to conclusions on. Next slide, please.

Christoph Lehmann - Vanderbilt Universtiy Medical Center - SME

Thank you very much, Carolyn. Good afternoon. As Carolyn outlined, I will talk through the recommendations that we already had a chance to look at. I just wanted to preface this with mentioning I was, until 10 minutes ago, on a call with Pew Trust that convened a lot of people that have stake in these pediatric recommendations.

Overall the consensus was that the recommendations are going in the right direction and that there is, however, some significant need to clarify and provide implementation guides. So, I thought that was a good message that I got from the group and they will all be working very hard and I encourage them to attend the public session of our taskforce.

With that, I'm going to go into the recommendations. Recommendation one is the use of biometrics, specifically growth curves and support growth charts for children. The description was that the system should include the ability to use pediatric a-specific norms for weight, height, length, head circumference, and BMI to calculate growth percentages and plot them over time using the CDC and World Health Organization growth curves as appropriate.

ONC has done some work and look where we have alignment with the 2015 certification criteria, that includes common clinical data sets, demographics, clinical decision support, APIs, and there's also some alignment, and you will see that on the first slide for all the recommendation with the new and updated criteria, such as the Core Data for Interoperability criteria. Next slide.

So, the group discussed this. There were some safety concerns. So, it's critical that the growth curves display the value on the correct data sets. We had some discussion about disease-specific data sets like Down's syndrome and those extensions were rejected because the data sets are not in the public domain.

As for additional implementation considerations, the experts suggested that this should be a decision support that is only a visual display that serves as an alert that allows the pediatrician who is trained to interpret these growth curves to see if a child is outside or below the 10th or above the 90th percentile or if a child is crossing percentiles over time and that the visual display is adequate as an alert.

Again, there was the effort to limit the growth curves to data that is in the public domain and evidence-based and have enough children to actually be relevant. That concludes the recommendation one. Next slide, please.

Next slide is recommendation two, focusing on something important to pediatrics. It is the computing of weight-based drug dosing. So, the recommendation was that the drug dose should be automatically computed based on the appropriate dose ranges using the patient's bodyweight or surface area. This should display the weight and the weight-based dosing strategy on the prescription. So, the alignment was for prescribing, Core Data for Interoperability. Next slide.

We had a significant discussion around this. As some of you may realize, when it comes to larger children who can take medication by mouth in the form of pills or tablets, this becomes actually quite challenging. You have to round to the nearest tablet or nearest half-tablet if they can be broken into two. It comes with significant challenges.

So, the group decided that for this round, they wanted to limit this to liquid medication with the caveat that future iterations of this recommendation might be extended into other medications. They agreed that this should be displayed in milliliters and calculated with rounding to not more digits than was humanly measurable in a syringe. So, those were the recommendations.

We talked a lot about the prescription standards and the fact that the latest standard allows the transmission of the weight. However, there is a lack of implementation on the pharmacy end which is concerning. However, anyway, the group agreed that the final dose should be transmitted with the metadata and that metadata includes the weight, the dosing strategy, and how the final dose was derived, including any rounding strategies if there were any. Outside of that, it should include the weight that allows the pharmacist then to duplicate the work of the dosing physician and make sure it's valid. Next slide, please.

Recommendation three is the ability to document guardians and caregivers. As families become more complex, the recommendation is to allow the EHR to provide the ability to record information about all guardians and caregivers. That includes biological parents, foster parents, adoptive parents, guardians, surrogates, custodians, siblings, and case workers with contact information for each. This aligns with a whole bunch of other issues, the care plan, transition of care, APIs, transition of care, demographics, data interoperability, data segmentation for privacy. Next slide, please.

So, the discussion around this was robust. This is a recommendation that was clearly a favorite and considered necessary and needed. The guardian and caregiver information was recommended to be documented in a structured way, including the role as a structure. That led to a discussion that there is really no standard that can be used currently to use in standardizing the role. There is need for work from a government body or a standard body to work on that going forward.

I'm sorry, I was interrupted with an incoming call. Anyway, the list should be able to have an infinite ability to add relevant contacts of the family. So, that should be a one to many relationship between the child and any potential caregivers and there should be the ability to manage those lists.

It means removing, archiving, adding, starting, end dates. That's kind of critical for consent issues. The person who is allowed to give consent might change over the time of the child. So, at one point, it's the biological parent. It might next be the foster parent and then the adoptive parent. It needs to be transparent to the pediatrician or the caregiver or provider for this child, who's currently able to provide consent.

This also led to a discussion that this was helpful also in the adult world. While this is critical for pediatrics, but especially in the geriatric population, this is a feature that might be a consideration for adult EHR going forward. Next slide, please.

Segmented access to information – so, this goes to the problem that we have that issues of reproductive health or sexually transmitted diseases or in this day and age, the desire of a young person to become vaccinated when the parents are not in favor of that. So, the issues around the need for privacy of health data is addressed with this recommendation. This started a very robust discussion with the group. First of all, there is alignment with data segmentation of privacy and transition of care, Core Data for Interoperability and APIs. Next slide.

Clearly, the discussion of the subject matter expert was to the point that this is great, but this is a recommendation that is difficult to solve and it that it is important to start with a critical first step. So, the issues that we discussed first were that this is supposed to prevent information that gets sent out to the dependent's family via the insurance, which is the biggest offender of this and that there is a lack of legal and clinical standards.

There was a discussion about all of the different state privacy rules and how challenging that is for EHR vendors who operate in more than one state. We discussed usability issues and the burden on the user. So, the recommendation was that we start with a critical first and an important step and that is to allow the EHR, the user to tag data that's considered private.

There should be some basic protection when the user adds data that is protected. It should not show up in CDAs, in portals, or an exit note given by another provider. So, there is some flexibility about what other things we may want to use this protection for, but these were the kind of the minimal set that the group discussed.

There is a critical need for a lot of further work. What does this mean for transmission of sharing data? If I have consented to you sharing that data with others and I've changed my minds on this, how do you catch this back? How can end users use the data received? And the level of granularity that might be involved with the tagging, not only the workflow issues with the pediatricians, but also just the amount of work that is involved.

So, in summary, while the group thought this was really critical in its important recommendation, but the solutions that are solid and robust are at least two or three iterations away. So, the first thing they wanted to see is the tagging and the ability to suppress that information in some documents and notes.

One more additional thought that was given to that is that the unavailable ability of information might actually disclose the fact that there is some information so there is another whole level of complexity that needs to be addressed in the future. Next slide.

Recommendation five, synchronized immunization history with registries – there was a lot of discussion about this, especially in the context of registries. So, the system used in messaging standards established meaningful use requirements to send data to immunization information systems and other health information exchanges. The systems use the standards established by meaningful use requirements to receive data from immunization information system or other HIEs. Alignments with transmission immunization, transmit to third-party, United States Core Data Set for Interoperability and APIs. Next slide.

So, as I suggested the discussion was robust. There was a lot of griping about immunization registries, especially from our vendor members, who pointed out how long it can take with a lack of adoption updates that are released from the CDC, how long it can take and it's not necessarily transparent to end users.

There was a lot of discussion about different registries. It might give you different forecast information. There really is a need for some research that drives the APIs for all of the

immunization registries with some tricky cases to see how much divergence there really is.

The vendors were able to provide us an anecdotal evidence, but it would be an important thing for the federal government to actually look at. That said, there was a suggestions that there is a need for future work for consolidating the state immunization forecasting model into a single resource.

Why do all of the immune registries have to reinvent the wheel when the CDC is updating their recommendations? That would reduce also the amount to updating a forecasting. There is a real problem with onboarding of practices for immunization registries. It can take months. And that is a real problem, as many EHR vendors use the state registration forecasting to provide that valuable information to vendors.

So, there is some need to look into this. I want to point out, this is one of my favorite complaints, that pediatrics is the red-headed step child meaningful use and of the things that are driven by states because we have 56 different requirements when it comes to meaningful use reporting, 56 different places to report it to, and 56 different ways of being audited.

We are constantly dealing with issues of incongruency of the different sources. Immunization forecasting is one of them. There is an important issue that was brought up that the source origins of the data that is received back to the immunization forecast is something that should be able to be verified. They need additional information to deal deeper if necessary. Next slide.

I think that's the last one I'm going to do in detail. It is the age and weight-specific single dose range checking. We talked about pediatric dosing that is weight-specific already. So, this aligns with the recommendation two. The system is asked to provide a medication dosing decision support that detects a drug dose falls out of the minimum/maximum range based on the patient's age, weight, and maximum recommended adult dose. A maximum recommended pediatric dose is known for a single dose of medication.

You notice there is the if known, only then it should provide a recommendation. The fact that there is no known dose, which for many drugs exists, should not trigger an alert. We found this to be completely useful in a study of immunization dose range checking at Hopkins. So, the alignment here is the clinical decision support, APIs, Core Data for Interoperability. Next slide, please.

Again, we had a similar discussion on recommendation two. In this case, the other thing we added in this is that the same work at Hopkins showed that minimum dose range recommendations are of very little value. We built it there at Hopkins for antibiotics only. It turns out even those can be used for other indications that are not antibiotic or antimicrobial in nature and create an enormous amount of noise in the system, which leads to alert fatigue and physicians ignoring alerts in the first place.

Additional implementation considerations included that this has a similar limitations on dose calculation as seen in recommendation two. The sources for the dose rate recommendations should not come from the vendors. They were very opposed to that. They want third parties and

resources to be used for this because they don't think that they can maintain and update this information. It should allow the provider to identify the information source and essentially allow the shown work for the clinician to validate this. There is a need to test the accuracy of this and this is the recommendation that will require a lot of QA and Q1 testing.

I think this concludes the recommendation. If you go to the next slide that we have discussed, remember, we had only two calls. It seems like we have done a lot of work and a lot of very focused discussions, but we only got through six of the ten recommendations of the state.

We also, as Carolyn pointed out, this taskforce, we became a little bit of a bucket for what other things do we need addressed and that is the opioid use disorder that impacts us as well since we have infants with neonatal abstinence syndrome. So, we do have some opinions on that and we'll address that in one of our later calls. And then the data segmentation for privacy was also added to this taskforce list.

So, at this point. I'm going to stop and turn it back over to Carolyn, who is in the room.

Carolyn Petersen - Individual - Chair

Thanks, Chris. This concludes the formal presentation contents that we have so we would like to facilitate a discussion and answer any questions anyone has. I will recognize the speakers and then Chris and I can decide who will respond. I think Arien is first.

Arien Malec - Change Healthcare - Member

Number one, just as a general recommendation, be careful what you ask for because you might get it with respect to certification criteria. There is a tendency to sometimes want to product manage the EHR through certification requirements. The results are generally not what you expect them to be.

With respect to pediatric dosing, the recommendation to limit to liquids only, just as a recommendation or as a perspective as somebody with a now adult son who has epilepsy and has been through a number of medications, there is a wide range of medications that require milligrams per kilogram dosing. The typical practice even in the area of hand-written scripts and then e-prescribing scripts is to handle it through SIG instructions simply because the calculations involved are pretty complex and require some degree of clinician supervision.

Then with respect to CDC and state registries, I participated on a CDC taskforce to look at the immunization registry standardization. I think we came up with a nice set of standards around immunization registry request response.

I suspect that in most cases, that work has not been deployed in practice because state immunization registries are typically underfunded. Then we have bizarre states like California that have like five different subregions that each implement their own standards. So, this is an area where I think the EHR vendors would love to standardize and where I think the compliance issues are on the state immunization registry side.

With respect to privacy data segmentation – and this will be a plea when you get to data

segmentation for privacy as a formal recommendation, but also with respect to the pediatric chart – just a reflection, as you noted, the state law varies considerably, that in some states, disclosure is required to parents and in others it is prohibited to parents.

In general, the issue that we have with disclosure requirements is we can express something in a standard, but we don't know how the semantics are supposed to work out in practice, which leaves stakeholders in a strange position. So, as we explore data segmentation for privacy, I think it would be useful to accompany data segmentation for privacy standards with policy guidance.

As an example, relative to SAMHSA data segmentation, if I receive something from a covered facility under SAMHSA, but then a patient comes in and tells me the same information, what information can and can't be shared? When can it be share? It is the policy considerations far more than the standards considerations that throw people in knots. I can see Sasha nodding vigorously as I am talking. So, just some considerations for the worker, thank you.

Carolyn Petersen - Individual - Chair
Great, thank you. Ken?

Ken Kawamoto - University of Utah Health - Member
Thanks. Just a general comment that I think applies to several of these – I think for a lot of these functionalities, it may make sense for the functionality to not be provided directly by the core EHR system, but by external resources. So, I'm thinking about the dosing guidelines, where there are medication knowledge vendors that provide these kinds of content. There could be other services, things like the growth chart, for example. It may make more sense instead of the EHR vendors to implement things like small for gestational card for gestational age kinds of things and the Down's syndrome charts, etc. on their own versus outsourcing it.

I will make a note on that one. There is a SMART on FHIR app that Boston Children's developed. But Intermountain healthcare in the Cerna platform made it production-worthy and we took it at University of Utah on an Epic platform and made it more robust. It includes all of these kinds of features but we are making it available free, open source. It's just we haven't tried particularly. We just disseminate it.

So, I think those lines of functionality versus getting into the specifics of how to implement, I think it would be good to have that notion of it doesn't necessarily have to be in the core product, the functionality just needs to be available to end users.

Carolyn Petersen - Individual - Chair
Great, thank you. Raj?

Raj Ratwani - MedStar Health - Member
Thank you for all of the great work here. One of the things I really appreciate about the recommendations is that several times, Chris you talked about the usability implications and where those touch safety. I'm wondering whether there is an opportunity to have a general recommendation to optimize usability and safety testing, in addition to having the usability touch

points on each requirement or each recommendation.

That may look something like having more rigorous usability test cases for pediatric certification, having participants that specifically come from PEs, which is not required right now, and also, evidence of usability and safety process, which is also not required right now. So, right now it's attestation and evidence would be more rigorous. If vendors are going through that process anyway to buy products of their user-centered design and usability process, that would serve as evidence.

Christoph Lehmann - Vanderbilt Universtiy Medical Center - SME

If I may briefly respond, Raj, you must have been listening to the call we had with Pew today because a lot of the things about general safety and usability testing as well as pediatric experts being involved in this was discussed in this group. I agree with you on that. The one thing I wanted to say about the Core functionality versus outside or web services or APIs or whatever, so far we have been very agnostic about this. I think we will continue to do so.

Arien Malec - Change Healthcare - Member

Real quick, I want to comment. I think a story synthesizes it all. One of the debates we had on the call around the medication component, several of the clinicians remarked about how because of the setup and the configuration of certain products today, a lot of times the dosage was wrong and they were relying on the actual pharmacist to self-correct. That should be your get out of jail. It shouldn't be the norm. In certain cases, it became the norm just certainly because of unusable. So, I think to your point, that has got to be corrected and looked at.

Carolyn Petersen - Individual - Chair

Thank you. Andy?

Andrew Truscott - Accenture - Member

Thanks. I think I may be echoing Arien a little bit, where there are existing things in place, we should leverage those. But there is a fine line to walk between certification and functional requirement definition. I think we may be inadvertently tripping the wrong side of that right now. So, be careful on that.

I think Mike and I commented in our opening salvos that when you get five people in the room, it is easy to get 25 sets of opinions and you're probably tiptoeing through that. That said, some of the concepts around familial groupings and custodianship and guardianship, etc., there are already state regulations around that and it goes beyond some of the different actors that you were outlining. It falls into people like CASA and those kinds of groups as well. So, just be aware of those.

A lot of that work has already been done by EMR developers and how to represent that in information models and in systems themselves. So, maybe we should leverage out the concepts of a legitimate relationship, etc.

Maybe this is a question to the top table – immunization information systems, etc., would they

come within the scope of the regulations anyways? So, the problem you are seeing with immunization information systems is not passing complete and accurate information, would that actually be resolved through their mandated compliance with the regulation? Anybody can answer. John? Please.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

So, I think it depends. Are you talking about the information blocking section? Where are you talking about?

Andrew Truscott - Accenture - Member

Okay. So, in one of the talking points, which was on your slides, there was over immunization information systems not passing full and complete information back.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

I see. Yes. So, I would say that is something that if you want to comment on, we can take a look at. The way the definitions are set up, they are set up as functional definitions. So, if you are performing a function, then we want to make sure the scope of the definition is correct to capture the right folks. So, if as you're looking at it as the information-blocking taskforce and you think it should or should not, you can let us know that and we'll take a look at that.

Andrew Truscott - Accenture - Member

Okay. I think you are saying because the immunization information system contains EHI under the currently drafted definition and it will be an obligation then that it has to maintain full and complete accurate information and therefore that should be accessible. Okay, sounds good to me.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

So, what I'm saying is I would look at the information blocking section, which is designed around the actors, the four actors that Congress that identified, then the definition of electronic health information and looking at those two together, whether the entity, whichever the entity is, would be covered and then obviously, whether there is an exception that would take them out of that coverage for that particular action.

Now, if the definition – I think this came up earlier in the conversation – if the definitions are too broad or too narrow to not capture or overly capture certain entities, that's what we need to know as well.

Andrew Truscott - Accenture - Member

I'll have a word with the co-chair of the taskforce to make sure that is as explicitly as possible.

Carolyn Petersen - Individual - Chair

Thank you. Are there any other questions or comments?

Robert Wah - Individual - Chair

Also, we know that Christoph has to leave pretty sharply at 4:00. If he has any further comments, maybe give him a chance to do that as well.

Carolyn Petersen - Individual - Chair

Go ahead, Chris. The floor is yours.

Christoph Lehmann - Vanderbilt University Medical Center - SME

Thank you. I just wanted to use the opportunity to thank you ONC for this opportunity. We know that pediatric certification is voluntary, but it could be a test case and an example for other specialty-specific certifications downstream. So, we are well-aware of the responsibility we have. I do appreciate all of the comments and feedback I received. I want to thank my co-chair and the ONC staff, who has been superb.

Robert Wah - Individual - Chair

Thanks for making time to join us today. Anything else?

Carolyn Petersen - Individual - Chair

I think we are finished.

Robert Wah - Individual - Chair

Wow, perfect. Okay. Lauren, do you want to take it over for public comment?

Public Comment Period

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

Home stretch, right? Okay. If we have anyone in the room that would like to provide public comments, please do so at this time. You can come to the presenter table. Please state your name. As a reminder, you have three minutes.

John Travis – Cerner

Let me make sure I do the mic right. John Travis with Cerner. Something we want to caution ONC about relative to the pediatric capabilities that are aligned to the voluntary criteria – I would point ONC to their press release where they refer to them as ONC Recommendations for Pediatric Health IT Voluntary Certification Criteria. They are not criteria, they are recommendations.

One of the things we observed is they don't precisely align to the criteria align to the criteria that align to them. There are functional gaps. We've already had conversations with people who are approaching, us asking about do we support the aligned criteria as if we support the aligned recommendations or seeing them as synonymous. They are different.

So, one of the things we'll comment on in our own comment but I'll make it here, it would be

good for what ONC has in the appendix to identify functional gaps or limitations for the aligned criteria and meeting those capabilities. People will use them. They will point to them. They will attempt to make use of them as contractual requirements or treat them as if they are certification criteria. So, that's already going on in the way that we're being asked about it. So, thank you.

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

Thank you for your comment. Anyone else in the room would like to provide comments to the committee? Okay. We will go to the phone. Operator, can you open the line for comment?

Operator

If you would like to make a public comment, please press star-one on your telephone keypad. The 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 speaker equipment, it may be necessarily to pick up your handset before pressing the star keys.

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

Thank you. Do we have any comments in the cue at this time?

Operator

Not at this time.

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

Okay. We will give it another minute or so. In the meantime, Robert or Carolyn, any other remarks while we wait for more comments to come?

Carolyn Petersen - Individual - Chair

I just want to thank the HITAC for all your kind attention and engagement in our discussions today. We went through a phenomenal amount of information in a number of PowerPoints really quickly and it is very gratifying to see people's engagement and efforts to really stay with it and keep us moving on all fronts. I know it can be a long day. I appreciate all of the work at this committee meeting as well as within the taskforces and on the calls. Thank you.

Robert Wah - Individual - Chair

I feel like we are tap dancing waiting for more people to call in, so I'll add to that. This has been a long day and we still have got another half-day tomorrow. So, thank you all for your indulgence and your participation.

Nearly everyone here has been on a taskforce, either as a chair or participant. Carolyn has been on more taskforces than the average HITAC member. It is, as we all know, a tremendous amount of work to serve on the taskforces, either as a participant or a chair.

But it is what we are here to do and it is great to see everybody rolling up their sleeves and taking part in this. Thank you for doing that. Obviously, we have a of thanks to the ONC staff, who keep us honest on these things as well as informed. We appreciate that as well. There is housekeeping stuff we will do this evening later, but I think it has been a great day, a little long on the sitting side and, again, we apologize for that.

Again, I recognize the batches have been coming fast and furious. We are trying to do what we can on our side to minimize that, but it is a lot of information that comes down in a very short time. So, we're forced to have this deluge of batches as we go along.

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

Thank you. Last check, operator, anyone on the phone?

Operator

Not at this time.

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

Okay. Thank you.

Robert Wah - Individual - Chair

I guess the last thing I will say as we wrap up is Carolyn and I are always looking for ways to improve this process. So, feel free to send us your comments, suggestions, criticisms, either by direct email, text, phone, smoke signals. We want to make this a good process for you all.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology

Robert, I want to thank you and Carolyn for your leadership, I really appreciate you. You have done a great job especially from 2018 to 2019 and onward, so thank you, guys.

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

Denise, did you have a comment?

Denise Webb - Individual - Member

Yes. I just have a request, which most of us will find helpful as we continue deliberating on the comments and recommendations that we will set forth in the final letters – if this is not too difficult of a task, if we could get each of the taskforce's could get the transcript for the portion of their discussion, that would be helpful to guide us on discussing some of the feedback from the entire committee that we received.

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

We can certainly do that. We typically post the transcripts within a few days of the meeting but we can parse out each taskforce discussion so you can have that accurate feedback. Any comments from the committee members?

All right. Just a quick note – most importantly dinner – if you sent me a note, you are confirmed for dinner this evening at 7:30 right here at the lobby level. Tomorrow, we start bright and early at 8:30. We have, as you've seen, a number of guests that we are excited to hear from around prior authorization.

And then I know we are already looking at another in-person meeting in April. That is very much intentional because as you see, we have a lot to get through with the draft recommendations we've looked at today and yet, more to come for some of the taskforces.

So, with that, I will remind everyone that you have all of the materials from today's presentation in one of your batches of cookies. If not, you can find it on the website and we are happy to give you anything else you may have missed. Otherwise, we are adjourned for today and see you in the morning. Thank you.