Health IT Advisory Committee

Transcript
October 16, 2019
Virtual Meeting

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Adcock Advisory Group	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	WaterRev, LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
Jim Jirjis	Clinical Services Group of Hospital Corporation of America (HCA)	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 Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member

Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member

Federal Representatives		
Name	**Organization**	**Role**
Terry Adirim	Department of Defense	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Kate Goodrich	Centers for Medicare and Medicaid Services (CMS)	Member
Jonathan Nebeker	Department of Veterans Affairs	Member
Ram Sriram	National Institute of Standards and Technology	Member

ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Cassandra Hadley	ONC	HITAC Support
Steve Posnack	ONC	Deputy National Coordinator
Seth Pazinski	ONC	Director, Strategic Planning & Coordination Division

Operator
All lines are bridged.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Thank you. Good morning, everyone. Welcome, again, to another HITAC meeting. A warm welcome to our committee members and members of the public. Thank you for joining us today. We have a very full agenda as follow up to our last meeting in September. So, I will officially open the meeting starting with roll call. Carolyn Petersen.

Carolyn Petersen - Individual - Chair
Good morning.

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

Robert Wah - Individual - Chair
Good morning, present.

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

Michael Adcock - Adcock Advisory Group - Member
Present.

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

Christina Caraballo - Audacious Inquiry - Member
Good morning.

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

Tina Esposito - Advocate Aurora Health - Member
Present.

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

Cynthia Fisher - WaterRev, LLC - 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
Good morning.

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

Anil Jain - IBM Watson Health - Member
Good morning.

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

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Good morning and welcome again. John Kansky. Not yet? Okay. 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
I do believe Les Lenert is going to be absent today. Arien Malec. Not yet. Denni McColm.

Denni McColm - Citizens Memorial Healthcare - Member

Present.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Clem McDonald. Not yet. Aaron Miri.

<u>Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member</u>
Good morning.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Brett Oliver.

<u>Brett Oliver - Baptist Health - Member</u>
Good morning.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Terry O'Malley.

<u>Terrence O'Malley - Massachusetts General Hospital - Member</u>
Good morning.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Raj Ratwani.

<u>Raj Ratwani - MedStar Health - Member</u>
Good morning.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Steve Ready.

<u>Steve Ready - Norton Healthcare - Member</u>
Present.

<u>Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer</u>
Sasha TerMaat.

<u>Sasha TerMaat - Epic - Member</u>
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Andrew Truscott. Okay. 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
Our federal representative, Kate Goodrich. Terry Adirim. Ram Sriram.

Ram Sriram - National Institute of Standards and Technology - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Adi Gundlapalli. We may be hearing from them later. Jonathan Nebeker. Not yet. Also, from ONC, we have Steve Posnack, our Deputy National Coordinator, Elise Sweeney Anthony, our Executive Director, Office of Policy, Seth Pazinski, visiting director of ONC. And with that, I will turn it over to our Deputy National Coordinator, Steve Posnack, for a few welcome remarks. Steve.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator
All right. Thanks, Lauren. Good morning, everybody. Welcome to the trick or treat edition of the HITAC in October here. I very much appreciate your time. Dr. Rucker could not be with us today due to other commitments but you are always in good hands with our full staff. He extends his thanks for all of your efforts to date as always and especially as we close in on another set of final recommendations today.

I wanted to thank Ken, Steven, Terry, Christina for all of their diligent task force leadership over the past few months and I'm looking forward to the discussions today as I'm sure you are also. We have two member updates to provide for everybody. You already heard Dr. Jim Jirjis. I got your name correctly, sorry about that, here at HITAC who is replacing Patrick S.

And I'm going to ask Jim to briefly introduce himself first. And then, also we have Dr. Abi Gundlapalli, sorry about that, our new CDC federal representative. And I'll ask Jim to, if you don't mind, introduce yourself and then, Adi, you can follow right there after.

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member

Yeah, thank you. Jim Jirjis. I'm Chief Health Information Officer for HCA Healthcare. I've been so for about six years. Before that, I was at Vanderbilt. Most of my career has been in working with software developers around all of the exciting stuff that is on the agenda here. So, I'm delighted to be a part of it. If we get this right, the possibility of making huge change in healthcare is upon us. I'm delighted to be on the committee.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator

Thank you very much, Jim. And Adi. Is he on mic? I see he texted in. Oh, maybe next time unless he gets joined in via audio. Adi attended the September meeting and just wanted to give himself a chance to introduce himself to everybody. But we'll keep moving on and we'll fit Adi in any time you're ready as part of the agenda. Again, we're excited to have you both.

The other update from a membership perspective is that the application period for the GAO vacancies is now closed. You should anticipate to hear our decision on those by the end of the calendar year. And so, we'll keep everyone posted as that shapes up. Today's agenda, as everyone will cover, you'll hear from ONC about some of our key focus areas as we move into 2020 as part of the objectives and benchmarks presentation.

For the HITAC overall, the work from the ISP and USCDI Task Force is winding down in this cycle. As we're approaching the end of the year, we'll start to talk about 2020 HITAC planning all together in its entirety. And then, ONC has a number of other potential topic areas that we're interested in getting your input. We also welcome your thoughts today about the potential focus for continued work efforts, follow ups, and the like. And I will turn it over to my partner here, Elise, to make some brief opening remarks before we turn it over to Robert and Carolyn.

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

Good morning, everyone. I actually think Steve did a wonderful job of welcoming everyone to the trick or treat edition. I did want to express a note of appreciation for all of the work that's been done. As we start our – September was the first one but as we move into the next period of activity for the HITAC, I always just want to take a minute and just show our appreciation and thanks for all you do. It truly is an amazing opportunity but it is a volunteer opportunity.

And we know that there are day jobs that you guys have as well. So, whether it's waking up super early because you're on the west coast or reviewing the documents that are coming through as part of the vote for today, we really do appreciate all of the time that you take. As Steve said, we look forward to the conversation today around 2020 planning as well as sharing with you the objectives and the benchmarks that we plan to have and, of course, as you vote for today. So, many thanks and let's go ahead and get started.

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

Great. Robert and Carolyn, the floor is yours.

Carolyn Petersen - Individual - Chair
Great. Thank you. Good morning, everyone. It's great to see everyone out early in October for our tricks and treats. I think we have a really interesting and discussion promoting agenda ahead of us today with several items. I will share that the annual report committee is currently working on the feedback you gave us at the September meeting and look forward to presenting the next iteration with the landscape and GAP analysis in November. We decided at this meeting we would give our full time and attention to the ISP and USCDI votes as well as the HITAC 2020 planning and the objectives and benchmarks. And with that, I will hand the mic to Robert Wah.

Robert Wah - Individual - Chair
Thank you, Carolyn. And thanks to the ONC team as well. Good morning, everyone. And I also want to extend my welcome to everyone to the fall and October meeting. While Steve was talking about trick or treating, I think it's worth mentioning that the other big news in Washington besides the politics is there is actually going to be a World Series now in Washington, DC, which hasn't happened for a really long time either. So, we've got to bring the sports analogy into the conversation as well.

We are excited about the agenda today. We've got a couple of things to vote on and close out with our two task forces but also, we have made significant time available to talk about where we as the HITAC want to go next year in 2020. As you know, we've said many times that much of that is already sort of pre-planned by the legislation.

But we really want to make sure that we give an opportunity to have an open discussion about where we as committee members want to take the organization and the committee and our agenda in the next year. So, we'll have an opportunity to talk about that later today. I hope everyone got their batches in a timely fashion as usual and have had a chance to review and digest them. Also, I have to say that for the first time since being co-chair, I have an unexpected conflict today. So, I'm going to be on and off the line today and I'm going to rely on Carolyn as the co-chair to run most of the meeting.

So, my apologies but something has come up that has conflicted me from being fully participating in today's meeting. I'll probably be on the Adobe Connect monitoring it but, on the audio, I will probably be off most of the call and will try to join back near the end. With that, I'll turn it back over to Carolyn to take over. Thanks a lot.

Carolyn Petersen - Individual - Chair
Thanks, Robert.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Apologies. This is Lauren. I just want to do a quick audio check. Do we have Adi on the line on the audio?

Adi Gundlapalli - Centers for Disease Control and Prevention - Member
Yeah, hello. Can you hear me?

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Yes, we can hear you.

Adi Gundlapalli - Centers for Disease Control and Prevention - Member
Oh, thank you. And I apologize for the challenges with this. So, thank you, Steve, for the gracious introduction for Adi Gundlapalli from CDC. I just joined CDC about two months ago where I'm the Chief Public Health Informatics Officer for Center for Surveillance at the Genealogy and Laboratory Services. Prior to that, I've been at the University of Utah and the VA in Salt Lake City and have done clinical and research work involving surveillance and health services research. Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Thank you. Okay, Carolyn.

Carolyn Petersen - Individual - Chair
Okay. And thank you, Jim and Adi for your introductions. We're really looking forward to working with you on the committee. We will now move into the presentation from Elise and Seth on the ONC objectives and benchmarks.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
And before we do that, I think we just want to approve the minutes from the last meeting.

Carolyn Petersen - Individual - Chair
Good idea. Those minutes were distributed to the HITAC members earlier this week in one of the batches. Could I have a motion, please, to approve the minutes?

Male Speaker
So moved.

Carolyn Petersen - Individual - Chair
And is there a second?

[Crosstalk]

Carolyn Petersen - Individual - Chair
And will all of those in favor of approving the minutes, please signify by saying aye?

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair

All of those opposed to approving the minutes, please signify by saying nay. And are there any abstentions? And we have the approval for the meeting minutes from the September 17 meeting. And now, we will go into the presentation from Seth and Elise.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology-Executive Director, Office of Policy
Thank you, Carolyn. All right. So, today we're going to talk about the objectives and the benchmarks and just a little bit of kind of background. And I guess it's been about a year or so since we had this last conversation in preparation for the development of the last annual report. So, now here we are preparing and many thanks to the annual report workgroup for their work that's underway as we think through the next annual report and the pieces that would support that.

One of the key elements of that is as per Section 4003 in the Cures Act calls for ONC or the national coordinator in cooperation with the secretary to establish appropriate objectives and benchmarks that are used for advancing and measuring the advancement of the priority target area. So, in other words, as the Annual Report workgroup and the HITAC overall are looking at the priority target areas, ONC has identified the objectives and the benchmarks that we are using at ONC to demonstrate and show how those target areas are being advanced through our work.

So, in summary on this slide, I think one of the main things to note is that we're open to the feedback of the HITAC on the objectives and the benchmarks we've laid out. I'm going to talk a little bit about some of the components that Dr. Rucker has talked about in terms of what we are aiming to see and to move towards as part of our work at ONC. And then, we'll get a little bit more specific as we talk about the actual benchmarks that we're using for the '19/'20 fiscal year. Next slide, please.

 So, what are the priority target areas? And I know that our HITAC members know these by heart by now. But as Cures Act lays out, there are three specific target areas that are noted. And those priority target areas are interoperability, privacy and security, and patient access. In addition, there is also an opportunity for additional target areas to be identified and it is a process for which those can be included as part of the HITAC's work on a temporary basis. And we've laid that out on this slide as well.

As you can see, if you just look at these three, interoperability, privacy and security, and patient access, all of the work that has been done at ONC really focuses on these concepts making sure that patients have access to the information they need at the time that they need it as well as the providers that serve them.

And also thinking, of course, about interoperability and not just from the perspective of the standards that are needed to support the movement of information but also about the business practices that are necessary to enable that interoperability to happen effectively. And a lot of our proposed rules that we put out include many of those components. In fact, all three of these.

So, as we're talking about the updates to the objectives and the benchmarks for our fiscal years '19 and '20, I thought we would start by looking at what Dr. Rucker talks about wanting to see in the health IT landscape and how we can support the care continuum from the health IT perspective. So, Dr. Rucker

talks about patients having access to their health information on their smart phone so that they can shop for and control their healthcare.

So, they're part of the care continuum, part of the information that's moving, and that they have ready access to the information that they need and modern computing mechanisms. And one of the areas that we talk about, moving on to the next area, are API's, application programming interfaces. And as the HITAC has reviewed the rule and provided recommendations on some of the policies included there, we will all recall that application programming interfaces are a main component of how we're updating the certification program with the new conditions of certification as we've proposed.

So, as we look and we review the comments that the HITAC has provided as well as the comments from the public, we're looking at things like API's and how to ensure that they are an effective part of the landscape for health IT and how they can support new business models. So, whether it's app developers who want to work directly with the patient to help them with their information and movement of their information or use of their information or provider facing apps as well.

I think that landscape and the opportunities for how new business models can support the health IT landscape is a wonderful opportunity for care. And then, of course, data sharing rules of the road for industry. Some of that revolves around, as you can imagine, through the trust exchange framework and common agreement.

And what are some of the rules of the road? What are some of the practices that need to be in place to support that trust so that information can move effectively. But it also includes generally in terms of how we think about and support data sharing across the landscape. And that's the standardization using standards to ensure that information can be received in a way that it can be understood and used effectively.

So, those are some of the things that Dr. Rucker talks about. So, as we go to the next slide and we think about the two objectives that we're laying out for our fiscal year '19 '20, you can see here that they kind of underpin the landscape that we're seeking to see. So, ONC's activities are focused on two key areas in terms of objectives. One is to advance the development and use of health IT capabilities. And the second is to establish transparent expectations for data sharing.

And in many ways, these two components are critical to all of our work at ONC. But we think, in addition to the landscape overall across the stakeholder community whether you're in a provider organization or a patient organization or representing patients or a hospital system or a developer, these components are critical to supporting the ability of health IT to be effective across the care continuum landscape. But looking at that, here are our objectives.

And we're going to talk about the objectives or build them out in terms of the benchmarks that underpin those objectives. And let me turn it over to Seth Pazinski who leads our strategic planning and coordination division. And he's going to talk about the benchmarks in light of the objectives. Seth.

Seth Pazinski - Office of the National Coordinator for Health Information Technology- Director, Strategic Planning & Coordinating Division

Hi, everyone and thank you, Elise. So, the ONC benchmarks provide clear steps towards the implementation of the 21st Century Cures Act. These benchmarks, as Elise mentioned, update for fiscal years 2019 and 2020, the initial set of benchmarks that were presented to HITAC last year. The three areas that I'm going to talk about should be familiar to HITAC members. The HITAC has been engaged in all three of these topic areas over the course of the last year plus.

So, the three areas are the benchmarks related to the ONC Cures Rule, the Trusted Exchange Framework and Common Agreement or TEFCA, and advancing standards priorities. So, on this first slide, we're focused on publishing the ONC final rule. So, ONC, as you know, is currently considering public comments. And those include the HITAC recommendations on the proposed rule.

And ONC intends to publish the final rule covering key aspects of the Cures provisions like the Cures standards-based application programming interfaces for patients to access their medical records and the information blocking exceptions.

So, the second area from the benchmark perspective that we're focused on is publishing the Trusted Exchange Framework and Common Agreement. So, on the Trusted Exchange Framework, building off of prior iterations and HITAC feedback on those. ONC plans to publish the final Trusted Exchange Framework.

In addition, ONC is currently working with a Recognized Coordinating Entity to establish a work plan, which includes making the draft common agreement available for public comment. And the cooperative agreement awardee for the Recognized Coordinating Entity was announced as the Sequoia Project was the awardee that was announced last month in September.

So, the third and final area is about advancing standards priorities focused on coordinating health IT standards and certification to support interoperability. Much of the agenda for today's HITAC meeting is focused in this area. So, we're looking forward to receiving the final report from the Interoperability Standards Priorities Task Force on priority uses of health IT and related standards and the final recommendations on USCDI expansion model in addition to the HITAC work in this area on investing to advanced standards, particularly for FHIR Release 4 and for standards related to bulk data access.

So, again, the three areas from a benchmark perspective we're focused on is the ONC Cures Rule, TEFCA, and advancing standards priorities. I want to thank you for the time to present today but going back to Elise's comments, more importantly, for all of the voluntary efforts of the HITAC members over the course of almost two years now. So, when you look at the progress to date on the previous three slides that I've presented, you see all of the HITAC contributions across these three important areas. So, again, I want to say thank you and welcome any comments or questions.

Carolyn Petersen - Individual - Chair
Do we have any questions or comments from the HITAC members? I'm not seeing anything in the cue. Again, do any of the HITAC members have questions or comments for Elise and Seth? No? Okay. Thank you so much, Elise and Seth, for presenting to us this morning. Seeing that we have no questions or comments, I think we will move on to the next presentation that will be Steven Lane and Ken Kawamoto

presenting the Interoperability Standards Priorities Task Force final draft report and a vote on that. If we could have the next slides, and the floor is yours, Steve and Ken.

Steven Lane - Sutter Health - Member
Thank you so much. And we really appreciate the opportunity to return to the HITAC with our draft final recommendations and hope that we've got it right. We've had our draft report out to you for some time now for comment. We've received a number of comments, suggestions, edits from members of the HITAC as well as the great work of our task force.

And we come to you today in the hopes that we'll get approval for the report that will become the HITAC's report back the ONC and this chapter of our work will be complete. But just to remind people that the charge of the task force was to make recommendations on priority uses of health IT and the associated standards and implementation specifications that support these uses.

As Seth just reminded us, this is really one of the key focus areas for the HITAC over this past year to coordinate standards and certification to support interoperability. So, that's very much the focus that we've had on the task force. This is a reminder of who is on the task force today. We've had a little bit of shift over time but these folks have all been stalwart members representing the HITAC and a number of others coming from outside representing the public.

And we've had really terrific participation over the lifespan of our group. So, our draft report, which you've all had access to for some time, this is the outline. I'm not going to belabor it. We were hoping that we can go through this relatively quickly and accept any specific suggestions that people might still have. Again, we sent you all earlier the document that we've been maintaining on Google Docs with the opportunity to provide comments and suggested edits. I'm happy to say that none have come in over the past few days.

So, I trust that means that people are comfortable with what we have here. But we're just going to walk through it briefly as, again, you've seen this before at our last meeting. So, the report starts with an identification of cross domain recommendations. These have come out of our discussions and have really been identified as important areas really regardless of the type of data that we're talking about. And we've made specific suggestions in all of these areas.

Most of our focus in price transparency was in the area of medication data. But this has really come up in every area that we've discussed as well as patient access to data and the importance of lowering the barriers to patient access both in terms of the types of data and the time to access that data. The group did spend some time talking about the timing of patient access to data. Apparently, this was also a lively, competent discussion in our forerunner committees in the ONC.

So, this is clearly an area where there is a desire to advance that and making sure that patients get access to their data both easily and quickly. On the next slide, we lay out, again, as you've seen before, the highest priority what we're calling Tier 1 recommendations around orders and results. We really dug deeply into this area, learned a lot, met with a number of subject matter experts, and put together a thoughtful set of observations and recommendations in this area.

One item here at the very bottom, a need for vendors to send unique reference ideas, was escalated from a Tier 2 to a Tier 1 in our later discussions. But other than that, these are largely stable from the last time you've seen them. The next slide identifies our Tier 2 domains. Again, very important but we felt slightly lower in priority than the Tier 1 issues.

As I said, I'm going through this pretty quickly. If there are questions as we go through, HITAC members are welcome to chime in. Otherwise, we'll take questions at the end. The next slide goes onto our second domain that we considered with closed loop referrals and care coordination. A number of recommendations seen as the highest priority in this area.

And the following slide shows the Tier 2 recommendations that the task force has put together regarding referrals and care coordination. The next slide goes into our third domain, which was medication and pharmacy data. There was really lots to say here about the specific recommendations around standards. This is an area where a lot of progress is being made today with the advancement of standards.

But we saw a number of opportunities to move that along into other areas and to leverage the policy levers that ONC has in coordination with CMS. Those have been laid out in detail in our report. And the next slide has the Tier 2 recommendations around medication and pharmacy data that we've identified.

Really new areas such as adverse drug event detection where some wonderful work has been done by a number of organizations but there are great opportunities to move forward with standards to automate and make much more convenient the detection and reporting of adverse drug events in particular. At the end of our report, we go into detail regarding recommended next steps for this work.

We end with a summary and conclusion section in our report really highlighting the fact that while we spent a lot of time drilling into three domains and identifying priorities and recommendations, there were other areas that the task force identified as worthy of similar focus and investigation, specifically the evidence based care for common chronic conditions, the need to capture and share information around social determinative health and, as I said, cost and price transparency beyond the medication domain.

Another area that our task force really looked forward to working on was opportunities to improve interoperability between clinical health IT systems and the FDA. And we all heard at the recent ONC conference that the FDA has done a lot of upgrading of their infrastructure and technology and they're enthusiastic about working together to advance interoperability. And I think that's an area that our task force felt would be very valuable.

But really, our task force spent the last year or so looking deeply into the current state of standards and matching those to the most pressing clinical issues and processes that were identified by our diverse set of stakeholder representatives. We've identified gaps in the standards and the implementation of the standards that we really felt are needed to address in order to support advances in interoperability, price transparency, care coordination, medication management, and burden reduction.

And we feel that while we've made inroads and we are presenting the HITAC and, in turn, the ONC with recommendations that this kind of work is potentially quite valuable to go on in the future. And we really ask at the end of our report who or what body will assume the responsibility to perform this sort of broad overview of the existing standards, document the gaps, and how those standards are supporting interoperability and other health IT challenges.

What body is going to be in a position to make the sort of specific recommendations for the advancement of standards as well as policy levers? So, again, our task force winds up its charge feeling good about the work that we've done but knowing that this kind of work could and perhaps should continue in the future. We've identified a roadmap of additional areas to look into.

And I think all of the task force members would be happy to consider further work in this area or applying to participate in future task forces to address some of the additional areas that we've identified and others that will arise naturally over time. The next slide, I think, is the end of our presentation. Again, we decided not to go deeply into each of the areas of recommendation knowing that we've been here before and everyone has had a chance to review the specific wording and details of the report. So, with that, Ken, would you like to add something before we open it up to questions?

Ken Kawamoto - University of Utah Health - Member
No. Let's go to questions. That sounds great. Thanks.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Okay. Sorry, go ahead.

Carolyn Petersen - Individual - Chair
No, go ahead, Terry.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. So, Ken and Steven, first of all, thanks so much for the incredible work. It was a pleasure to be on this task force but boy, you guys worked hard. And I really appreciate the output. I'd like to circle back to your last set of questions and that really is I'd love to hear from other folks on the task force of how we think this work is going to continue because I think all of us who participated in it came away really convinced that this type of high level overview of gaps in standards and knowing how to match those with priorities and high value clinical processes is just critical to moving interoperability across the continuum of care.

So, I guess the question I would have for the task force and to you and Ken is if you had a magic wand, how would you sketch out a process where this would continue to work? And who do you think is best suited to further this work? Thanks.

Ken Kawamoto - University of Utah Health - Member
Steven, do you want to take the first shot at this?

Steven Lane - Sutter Health - Member

Well, sure I can. I think, as we said, the task force model seems to have been productive. And I think with the kind of broad participation that we've seen and connecting that to the work of the HITAC, I think it's a good model. And, again, it could be continued with another round. It could be created as a standing workgroup of the HITAC or by some other mechanism within ONC. Obviously, the ONC leadership knows what they're able to do and what they're able to support.

I think one of the real key elements that allows us to have the success that we have had has been really good support from ONC from the team there, from Lauren and the whole group there. and I think that one of the things that we've asked for is the opportunity to come back and meet with Steve and perhaps Elise and talk through this. Obviously, the ONC has a lot of plans and we'll be talking more about this coming up in our agenda.

There are clearly multiple models that would allow this sort of work to go forward. And I think the model that's been found has been good. We'll talk about this also with your presentation, Terry, about the USCDI. These are two areas where we've had very fruitful task forces making useful observations and recommendations in areas where the work is not done, where this work will be continuous. So, I'd like to hear from Ken and certainly from other members of the HITAC about your thoughts.

Ken Kawamoto - University of Utah Health - Member

Yeah. So, I think we were just sort of looking at what was successful and what may be our areas of improvement and our process. I do think we were very successful in identifying what there was general consensus on in terms of unmet needs and what needs to be done. I think the question mark in my mind is how will our recommendations move towards implementation. And with that in mind, I wonder if there's an opportunity to try to make that a little bit tighter.

So, specifically, are there areas that, for example, ONC, CMS, or other federal partners are planning to move forward on and specifically seek guidance that align with areas we've identified as gaps? It would be very helpful if there was a bit more coordination and understanding that the recommendations, we come up with will, in fact, drive where the industry moves. And I think that would be helpful and perhaps help us identify which of the remaining priorities we perhaps take on first or create a separate task force on or continue the ISP Task Force on but start with those first. So, that's just a thought in terms of if we have a next iteration of this what we may want to do that we did not necessarily do this time.

Carolyn Petersen - Individual - Chair

And Denise.

Denise Webb - Individual - Member

Yes, thank you. Great report. The task force did a lot of hard work. And I really think there is a strong linkage between the work of this task force and, obviously, the areas that ONC is responsible for in terms of the standards advisory, the USCDI, and how that all flows into the conditions and maintenance of certification.

And so, I think it's a part of the fabric that has to continue. And there is such a broad landscape of areas that we haven't even touched on yet. One that I was thinking about here recently is really the integration of physical and mental health and the huge opioid epidemic across the US and how the electronic health record has not been particularly good in terms of standards and processes for integration of sensitive health information.

So, I think there is so much more work that has to be done in the area of identifying these gaps and making recommendations that feed into the other areas that ONC is responsible for. So, I think it's important to continue this work.

Carolyn Petersen - Individual - Chair
And I see on the chat we have a question from Jim Jirjis. How does this task force work with the newly named RCE responsibilities?

Steven Lane - Sutter Health - Member
That's certainly an interesting question. This is Steven Lane. The good news is we are a part of a tight committee of folks who are working in the area of health IT and especially interoperability. And I think there is some cross pollination between the RCE that I'm also working with and the work of the HITAC. But I think your point is well taken.

Clearly, the RCE and the ONC are going to be working in very close coordination to advance the TEFCA. And I hope that the recommendations that come out of this work as well as USCDI will inform them. I'd love to hear from ONC what their thoughts are as well.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology-Executive Director, Office of Policy
Yes. Steven, thank you. I think it's a great question. So, I think all of the work that's being done through this final report and also USCDI will help us generally at ONC as we think through use cases that need to be examined from a standards perspective as well as future thinking of where there might be gaps or areas that should be addressed to support the advancement of health IT generally.

When we think about the RCE, with the RCE, I think there is a large scope of areas that they will be helping ONC think through in order to operationalize the common agreement. Part of that is thinking about the standards and the use cases that would need to be supported. In the TEFCA, we talk about it in terms of exchange purposes.

So, I think having information about the standards that are necessary or gaps that might exist are all information that can help feed into the work that the RCE is doing as they help us round out the common agreement with the additional required terms and conditions that they will be helping to develop that will accompany the minimally required terms and conditions and, of course, the technical framework that needs to support the common agreement landscape overall. And I tried not to use any acronyms in there so sorry for the long terms but hopefully that provides kind of an overview.

Clem McDonald - National Library of Medicine - Member

This is Clem. Could somebody spell out RCE?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology- Executive Director, Office of Policy
Sure. Recognized Coordinating Entity . And not to turn this into a TEFCA conversation but since you asked, Clem, I'll just provide a quick overview. So, the Trusted Exchange Framework and Common Agreement is a requirement from Cures that congress has asked us to put together. In particular, the development of a common agreement that can be signed onto to help facilitate network to network exchange. We've put out Draft 1 and Draft 2 as the HITAC knows because they commented on both.

And one of the other parts of executing on that congressional directive is for us to operationalize this common agreement. And we think the best way to do that is to work with the private sector. So, we put out a cooperative agreement announcement and have since awarded that cooperative agreement to what we call the Recognized Coordinating Entity .

That includes, for example, Sequoia Project and several others that will be working together to provide the functions needed. And what they will do are things like helping to put together components of what would be necessary to build up the actual common agreement.

And then, also once that's finalized then, you start actually having entities come on who want to participate in the TEFCA landscape to make sure that the QHINs are actually doing what they're supposed to do and also to support the onboarding process for those qualified health information networks to come on board and to actually work together to support the network to network landscape.

Carolyn Petersen - Individual - Chair
And a question from Jim Jirjis.

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Yeah. Just a quick follow up question. Given that RCE, as I understand it, has programmatic responsibility for moving forward all of the aspects of TEFCA and that includes oversight in some of the areas this committee is focusing on, I'm just curious if there are plans to sort of formalize how the two work together so that it ends up not being competitive but, in fact, this committee is sort of a SME, if you will, that feeds that committee that executes. Is there opportunity to clarify that or is it already done?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology- Executive Director, Office of Policy
So, I can start and then, if Steve or others also have thoughts as well. Generally, what we are doing now is the RCE has just come on board in, I think, the beginning of September of last day of August. But they were just awarded in September pretty much. And they are now coming on board. They just had their webinar for the public to hear about what they're going to be doing and what they're going to be focusing on.

And part of that will be thinking through how to move from the concept of supporting operationalizing the common agreement to what are the particular processes that would be needed. And all of the

information in the report and the work that's being done through this task force can be shared with them so that they can take that into consideration as part of their work stream. In particular, the technical aspect will be part of what they will be helping us with.

We did release a QHIN technical framework as part of the Draft 2 release for TEFCA. But the goal of that really was to provide some initial thoughts and some thinking around the technical framework that would be needed to support TEFCA. The Recognized Coordinating Entity will help us take that to the next level and also to receive stakeholder feedback and engagement along the way so that by the time we get to that common agreement draft being released that we have some stakeholder feedback. And then, we'll also be releasing that for comment as well.

So, throughout all of these steps in the process, one of the main things that we're focused on at ONC is to make sure that we're getting the right feedback in to us as well as to the RCE so that the TEFCA can be successful. And I think you raise a good point in terms of making sure that the work of the task force is part of that conversation so sharing that information with the RCE as well. And that's something that we generally do and we'll just make sure that we do that with them and talk through some of the work that the task force has done as well.

Seth Pazinski - Office of the National Coordinator for Health Information Technology- Director, Strategic Planning & Coordinating Division
And this is Seth Pazinski. I just wanted to connect on some of the conversation around what's next. I want to highlight for the HITAC that there is a requirement in Cures for the committee to annually review and publish the priorities for the uses of health IT and relay the standards and implementations back. So, along with the HITAC annual report, it's another aspect of ongoing HITAC work.

I think that the process for what that actually looks like, I think, is an opportunity we're looking to take the feedback from today. And when we get into the HITAC 2020 planning conversation, get your feedback there as well on how to incorporate that now. With the receipt of the final report and the recommendation from the HITAC on the ISP Task Force's work to date, we'll kind of establish our baseline for moving forward on an annual basis.

Steven Lane - Sutter Health - Member
Thanks, Seth. This is Steven Lane. I do want to sort of bring us back around to any further specific comments or questions about the draft final report from the Interoperability Standards Priorities Task Force because one of the things we need to do today is vote on this and ideally, turn this from a task force report and recommendations to a HITAC report and recommendations based on our vote today.

Carolyn Petersen - Individual - Chair
And we have a question from Aaron Miri.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Good morning. It just occurred to me, first of all, great job on this task force. I think you guys have done a fabulous job of incorporating a lot of the comments from the last HITAC meeting into this. And as I'm reading through it and really took some time to think about it, it makes a lot of sense what we're

proposing. I would ask a question and this comes from a discussion that I had with Dr. Anne Schuchat of the CDC regarding some general surveillance challenges that currently exist with interoperability challenges and gaps, especially in gaps in care.

Should there be a process here to fast track a data element or two or such for cases of national emergency such as an outbreak like SARS, like Zika and others where the committee would, beyond its periodic basis, be able to meet on an ad hoc basis to approve a data element for the purposes of interoperability? Is that needed now or is that something we work on in the future?

Steven Lane - Sutter Health - Member
Aaron, this is Steven Lane. I'll respond initially to say that I think that the notion of data elements for exchange and the process by which those are reviewed, approved, and required really falls under the USCDI work and the task force that we'll be hearing from later from Christina and Terry has specifically looked at that question and trying to find that balance. But I think it's a key question. I think it really does fall under USCDI.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Sounds good. Thank you.

Carolyn Petersen - Individual - Chair
Do we have other questions or discussion? We have a vote coming up on the draft document. So, please, HITAC members, if you have questions or concerns, this is the time to bring them forward. Going once, going twice.

Clem McDonald - National Library of Medicine - Member
This is Clem and I had my mute button on. But I was going to suggest that for real true emergency of information as mentioned, I'm not sure it should be required to go through any committee approval but rather just some governmental approach that could just do it because any delays could be very harmful.

Carolyn Petersen - Individual - Chair
Go ahead.

Ken Kawamoto - University of Utah Health - Member
I think there are some lessons learned with some of these other prior emergencies and what didn't happen but this is a big industry and ecosystem. Thinking through if it's not through something that USCDI would get engaged – anyway, I think it would be important to think well, we, obviously, don't want a highly bureaucratic process but what would be the process to make that all flow through. I think that would be – and maybe it's thinking the thought experiment is for these recent issues that arose where we know what did happen and what could have been done differently.

Carolyn Petersen - Individual - Chair
Okay. Do we have other questions or discussion? I see Terry O'Malley has a question.

Terrence O'Malley - Massachusetts General Hospital - Member

Yeah, Terry O'Malley. Just because we're bleeding into USCDI, the issue of sort of emergency pathways through USCDI was raised last year but not really commented on this year. So, it's not addressed in our presentation coming up. But perhaps that's something we should consider as an issue for discussion in the task force that specific issue.

Ken Kawamoto - University of Utah Health - Member
Are there any further comments or questions about the report?

Carolyn Petersen - Individual - Chair
I don't see any hands raised in the cue. Last call for further questions or discussion before we vote. Okay. Well, seeing that we have finished up our discussions, we need a motion to approve the report or whatever else the committee wishes to do.

Ken Kawamoto - University of Utah Health - Member
This is Ken. Assuming that I'm not prevented from doing so, I'll motion to approve the ISP Task Force recommendations and report as the HITAC recommendations and report.

Carolyn Petersen - Individual - Chair
And is there a second?

Terrence O'Malley - Massachusetts General Hospital - Member
Second.

Carolyn Petersen - Individual - Chair
Okay. We have a motion and second to approve the Interoperability Standards Priorities Task Force final draft recommendations and report. Would all of those in favor of approving the motion say aye.

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And all of those against the motion, please signify by saying nay. And are there any abstentions? Okay. It looks like we have voted to approve the final draft report and recommendations. Thank you so much Steven and Ken and the task force for your service on this work and we look forward to seeing this go ahead.

Ken Kawamoto - University of Utah Health - Member
Great. Thank you, everyone.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology-Executive Director, Office of Policy
Agreed. Thank you, Carolyn. And to Dr. Jirjis's earlier point, once the transmittal letter is finalized, we'll go ahead and send the report over to the RCE as well.

Carolyn Petersen - Individual - Chair

Thank you. It looks like we're running about a half an hour early, which is good news as that gives us more time for discussion on our remaining items. So, with that, I think we will move to the US Core Data for Interoperability final draft recommendations and vote with Christina Caraballo and Terry O'Malley as the co-chairs. So, in this group, the recommendations are broken into four natural groupings. And we'll look to vote on those in groups rather than all in one report. So, with that, I'll hand the mic over to Christina and Terry.

Terrence O'Malley - Massachusetts General Hospital - Member

Great. Well, thank you very much, Carolyn. And thanks, again, to the ISP Task Force for their incredible work and their extraordinary example of brevity in their presentation. We will try to match it but I don't think we're going to achieve that degree. And it's really also appropriate that we follow ISP because I think USCDI and ISP are sort of a natural partnership. And over the course of our deliberations, we actually shared several issues that bounced back and forth between the two groups.

So, I think it's an important interchange to keep open and I look forward to continuing something like that in the future. So, what we're going to run through today are the first three items are the usual introduction slides. The meat of what we're going to cover is really the summary of the draft for motion model for ONC.

And, again, this is going to be very brief and our discussion of the task force commentary and recommendations, which is going to be the substantial part of our time. And then, hopefully, we'll have some discussions. So, this is just a reminder of what our task force was charged with doing. And it was really good. It helped provide feedback for ONC's draft of a data element promotion model. How do data elements emerge, get promoted, and, ultimately, make it into USCDI?

And so, that was what our task force focused on. And it was really broken down into how does this process work, what's the life cycle, what's the data element information that's needed at the time of submission, and what specific criteria are needed to advance the data element. And then, obviously, we got to talking about anything else we wanted to.

But first and foremost, what we tried to do was to add details to the process and also come up with some help for the user who is going to be submitting data elements to help create some clarity around the process and make it a bit easier to engage in.

So, this is the list of the folks on the task force. And, again, many thanks to all of them. They've done a tremendous job. And a specific call out to Al Taylor and Adam Wong who are our ONC support who were just fantastic. And we wouldn't have gotten where we've gotten without their guidance and their help and keeping us moving along. So, we had a bunch of meetings, 11 phone calls, several after our HITAC meeting in September, which added several new twists to our presentation, which we will go over today.

So, this is really the intro and the summary of what we came up with. The task force was presented with a promotion model by ONC, which universally everyone thought was excellent. There was very little in it that we were criticizing. We thought it was clear, succinct, it made it easy to follow. After our HITAC

meeting in response to task force members and others, some issues were raised around the length of time of the promotion model.

And so, those three bullets here are really the highlight of what we're going to be discussing. So, the most important one is how can we make a promotion model more agile and quicker without sacrificing the need for really technical maturity for the data elements so that when they're put into play, they work.

So, that was one and that's probably the principle one. The other one that we wanted to add because it was raised with a series of questions that we had no answers is to add an annual review process to USCDI to just see how the process itself works. And we'll go into that in some detail at the end. And also, with that, a user's guide, which we referenced earlier.

And then, finally, we just tried to make more clarity around some specific details of the promotion process, particularly how to get from one level to another. So, that's where we're going. And so, let's head for the next slide. This is a summary slide from the ONC promotion model. And I'm just going to walk through it. The transmittal letter has a few pages in the beginning that go into the proposed model that ONC sent to us.

And we put it in the transmittal letter in the beginning but did not put it into the slides here because it was very long and detailed. But I'd like this as a summary slide. And if we think about the four levels, there is the comment level, Level 1, 2, and the USCDI progression up to increasing specificity and technical maturity.

And then, across the top was a cycle timeline in cycles. And the cycles in this process were approximately one year long and they were the amalgamation of the standards advancement process and the USCDI advancement process and the need for public comment and review and publication. And so, it seems from ONC's perspective to have those two linked just made workflow much better. And then, the other important part of this diagram are the arrows.

And the arrows going from comment to Level 1 and then, Level 1 to Level 2 and Level 2 to USCDI sort of the traditional pathway. But you can also, in this pathway, go directly from comment to Level 2. And that's an important part and it just has to do with the readiness of the data element or data class. What you cannot do is go from comments directly to USCDI. And these are important pieces. And these are pieces that we maintain in our revised timelines.

So, the next slide is a much less elegant slide outlining the process that we are going to propose. And it really, again, has sort of three pieces. It's got a set of milestones and it's got the levels, the comments, Level 1, Level 2, USCDI as before. And then, there's a process bar on the right. And it's really for the first three advancements, promotions. It's really ongoing support by ONC and review by ONC and submission of supplemental data.

So, it's an evolving process. And then, the final in the slightly darker green is USCDI where ONC does a final review of very important characteristics of the data element data class. And the HITAC gives its

recommendations as well. So, down the left-hand side under the milestones, if you start from the bottom and work up, the process is meant to be very broad and open starting at the base, again, as many people as possible to submit data elements.

But they have to have some rational for submitting them. And we asked the submitters to justify why it should be a national exchange priority. We don't ask for a lot of data but we ask for at least a statement. And then, as you go up the milestones, they're just progressively more complex attempts to specify the data element, test the data element, put it into production. And as you track those milestones up, you move from one level to another.

So, the attempt here, and you'll also notice there is no timeline, there is no cycle time, there is no estimated time, this is really Sheryl Turney's recommendation that we produce a promotion model that is independent of time and based solely on meeting clearly defined benchmarks, which we're calling milestones. So, this is our outline. We're going to go into more detail in subsequent slides but this is just to orient you to the major difference between the ONC proposal and our proposal.

So, Christina and I are going to separate these up. And I'm going to talk about the first two and then, Christina is going to go into more detail about the promotion process and the criteria. And then, I'll come back to public submitter and annual review and then, finally, the user's guide. And each of these – these are the four sections on which we are going to vote. And what we'll do in the voting is we'll go through the entire section some of which have more than one or two recommendations and then, come back for the discussion and then, the vote on the block of recommendations as a whole. So, that would be our plan. So, moving ahead then.

So, the task force also articulated what it thought were the really important parts of a promotion model. Sort of a merger of pieces and functions and characteristics. And so, we wanted it to be public facing, open and acceptable to anyone at all and to have as few barriers as possible to submit data elements from whomever felt they were important.

But on the other side, getting out of this process was a very high bar of technical specification and clear confidence that this data element has made it through production and works and is not going to jam the gears when it's released for implementation. And it's a tension between the open process getting as many things as possible in and yet the requirement for really great confidence that this is a data element that can be exchanged without difficulty.

And then, we also wanted to make sure that we made it clear to people who were submitting data elements what they had to do to help them not only plan but also to know where things were going. We also wanted to make sure that there was a process for ONC to move elements appropriately clearly, transparently through the promotion process.

And then, more feedback, advanced notice. And the last bullet is really the key. The newly adopted data elements are ready for implementation. And that's really where we're trying to get to. So, if I could have the next slide, please. I have one more slide and then, Christina is going to go into the details of the promotion model. So, here's an overview of the model that we're proposing.

So, the similarities are that there are still four data element classifications. And the next two that we submit that it's an open process and then, it's a searchable public facing work space, those are some work that ONC will need to do to create almost an ISA like platform. I'm not quite sure what to call it but it would be something like that where it's open, searchable, and can be added to by folks.

And then, Christina is going to talk specifically about the promotion model based on specific milestones. And then, we're going to go through the other parts of this as we go through the rest of the talk. So, with that, I'm going to pass it on to Christina who is going to take you through the six recommendations that make up the promotion model based on milestones. Christina.

Christina Caraballo - Audacious Inquiry - Member
Thank you, Terry. So, going through our six recommendations, which is going to be our first bucket – so, we'll go through six and then, I think, pause for a vote – but starting with this, this is really our model and this is where we've got the details of our promotion process and outline the milestones. Our first recommendation is really this introduction of this concept of meeting milestones as opposed to specific timelines to progress.

So, the HITAC indicated that the proposed promotion process is really too slow. In the ONC provost model, as Terry shared with us, the advancement from one level to the next requires a minimum of one year. We really thought that this process though level two should be shortened as much as possible. In order to address this, we recommended these milestones in the following bullets you see here.

So, first is that the promotion process occurs solely based on meeting the required milestones without minimum promotion cycle time. So, no timeline limit – when it's ready, it moves forward. Second, this is decoupled from the promotion process, from the standards advancement process. Then third, that the public status of all data elements in the promotion process happens quarterly with a public comment period. We'll get into more detail on our recommendations about the public comment and soliciting feedback, but this is just the concept here with the milestone slides.

So, moving to the next slide, this is really our overview. We had discussed specific criteria that would need to be met to advance the data element through the process, really where the details all live. Once that criteria are met for each milestone, then the data element advances.

This would also serve as guidance for data element sponsors, the submitters and the community ventures that are working to move a data element through the process and hit the milestones to eventually promote to USCDI. So, our buckets for this were just the general administrative requirements and then the actual promotion milestones for each level. So, comment to level one, level one to level two and level two to USCDI.

So, moving on to the next slide is our recommendation number two, which is the administrative requirements. We had recommended that this – the kind of obvious stuff that the submission form must be completed. Adherence should be made regarding acceptable standards, code sets, and value sets. So, there has to be a bar of what these standards look like, providing sufficient additional detail as needed

as a requirement and then responding to ONC feedback regarding submissions required for further promotion.

Moving on to our next slide, recommendation three – this is really where the data element is kind of getting a little more testing and starting to get more information collected. So, just a comment level to level one – you have to have justification exist so that a data element is captured and ready for national exchange – sorry, not ready for national exchange but exists for capture and there is a need of our national exchange.

There are applicable use cases involving the data element. Projects are currently underway. There are interests. This data element is currently captured discretely or in more electronic systems with preliminary understanding of how often the data element is collected, that a context standard actually exists for this data element and the standard is supported by an established SEO that uses a public balloting process. Implementation guides exist where the data element lives and this is really to demonstrate stability. There have been pilots, connect-a-thons, and/or production use of the data element.

This kind of criteria I've outlined here is really showing that there is interest by someone and work is being done in the appropriate channels that could start a foundation for the data element to move through that USCDI promotion process.

So, moving on to the next slide, which is our recommendation four, which is moving from level one to level two, this is really where we raise the bar and start to just kind of step up the game for testing and getting the data element ready for primetime and national exchange and starting to collect more information and doing more testing. So, requirements here are that the exchange of the data element has been successfully tested at scale among several distinct and different EHR platforms and systems in a production environment using the content standard that was cited in the submission process and the transport standards.

Here, sufficient testing to satisfactorily meet the requirements of the proposed use cases and the applicable settings is demonstrated and there has been sufficient testing to meet the requirements of the proposed use cases in several applicable settings to move from level one to level two.

So, moving to recommendation five – this next recommendation has two slides. This is where we are demonstrating two things to move from level two to USCDI with the milestones has to do with technical maturity and national applicability. So, for the technical maturity, this is when the exchange of the data element has been successfully tested at scale between distinct and different EHR platforms and systems in a production environment sufficient to establish the feasibility of the majority of anticipated users.

And then the second part of this milestone, kind of the benchmark criteria to meet is the actual national applicability. First, the data element has evidence that supports the quadruple aim, a lot of talk on what actually justified national applicability and how we would justify this led back to how does this meet the quadruple aim. So, it's a really key piece in our discussions, then just providing information on the estimate number of stakeholders who would use this data element or data class.

Moving on the next slide, the other criteria we're gathering here are that when all the known restrictions potentially limiting the standardization of the data element have been addressed. All the known restrictions limiting the use of the data element have been addressed and there is an estimate of the overall burden to implement among the different stakeholders. Concern was raised that there could be issues supporting multiple complex use cases that might present significant challenges to implement. This is really just looking at all of the data elements coming through the process and moving to USCDI and evaluating holistically as well.

So, then if we move to the next slide that is the last in this bucket, this is the final review process for the data element to move into the USCDI. This is after all of the criteria and milestones have been met. We've got a list of candidate data elements that have passed all the benchmarks and are ready for evaluation. There are two key components to the review. There's the review of the data elements meeting the criteria and the process itself.

So, for this, we have broken down in the previous slide all the milestones for advancement and for the review, the key things that the HITAC and then ONC will then look at include the technical maturity, barriers to implementation, adoption, and use, alignment with identified national priorities and industry readiness. That's kind of our evaluation and review criteria. Then the process as we discussed as a task force – we really felt that the HITAC should be more of an advisory role to more efficiently perform the review of the data elements and ONC should develop and generate the list.

So, our process is kind of a cycle here – it starts with ONC providing the HITAC with the proposed draft of data elements that meet the criteria for promotion into the USCDI. HITAC then reviews the candidate USCDI data elements and provides recommendations to ONC and then ONC publishes final decisions taking into consideration both public comment and HITAC recommendations.

And with that, I will pause and turn it over to Robert and Carolyn for a vote on recommendation six or discussion – actually, probably open discussion first.

Carolyn Petersen - Individual - Chair
Yes. Let's go ahead with questions for discussion about the first six recommendations that Christina and Terry have presented. That will be the first vote. I see Denise Webb has her hand up.

Denise Webb - Individual - Member
Yes, thank you. I appreciate the task force's deliberation based on the feedback we provided at the last meeting and subsequent to that. This looks really good. The one thought I had, though, while these changes you're proposing here in the process will offer the opportunity for the private sector and those stakeholders that want to advance a data element or elements or class, they will have the opportunity to accelerate that at whatever pace they're able to and likely will have the motivation in several cases to do so.

What concerns me, though, for this to work well is ONC having a major role in the review process and making a decision on when something can advance to the next level will need to be adequately resourced

and have lean, efficient processes to get these reviews done. I almost think in some respects that there should be a maximum bar on when they have to respond back. So, not completely eliminating the timeline in this. Oftentimes, the private sector will be very fast in advancing something and doing everything they need to do and then it shifts the government entity. It seems like that's the long pole in the process.

So, just something to consider – obviously, for this to be successful, ONC is going to have to be adequately resourced with the right skillsets and processes, lean processes to keep this on track.

Terrence O'Malley - Massachusetts General Hospital - Member
This is Terry O'Malley. Denise, thank you. That's a great comment. It's one of several additional pieces of work that we're going to be asking ONC to take on in our proposed recommendations. So, we're going to come to a few more later on. I think your point about ONC being adequately resourced for this work is very critical. So, thank you.

Carolyn Petersen - Individual - Chair
And now, we'll go to Steve with ONC.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator
Good timing. All right. Thanks. Can we flip back to recommendation one? I think this may just be an opportunity for a little bit of clarification relative to some of the recommendations that were made or teed up. So, I believe – we can certainly clarify this – that there's alignment relative to if the evidence that Terry and Christina were discussing for level one and level two classifications were provided at any point in the year, that decision can be made on a rolling basis. I think that's what I'm taking away from some of the bullets that are noted there. Is that fair?

Christina Caraballo - Audacious Inquiry - Member
Yes, that would be correct.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator
I think there's alignment there. The one point to clarify on the – that's really where there's a decoupling between the promotion process and the standards version advancement process that we included in our proposed rule – ultimately, a fresh version of the USCDI would be created and as we laid out for everyone to consider, there would need to be a predictable cadence for that. Yearly seems sufficiently ambitious for that kind of cadence. That version of the USCDI would then be something that would flow into consideration for standards version advancement on the regulatory side as we proposed.

So, anything else prior to what gets included in the fresh version of the USCDI is something that we would be interested in doing on a rolling basis. I think to Denise's point as well, we're looking at how we can automate things, how we can help with the classification determinations based on the objective criteria that are included in some of these recommendations so that it isn't such a burden on staff and that

stakeholders know in advance this is the evidence that we need to submit and if we submit this evidence, then it should be a relatively straightforward process – famous last words.

So, that's just one dynamic that I wanted to indicate in terms of – there's a decoupling that I think exists that we can be clearer about and I appreciate the task force bringing it up and highlighting it. There's a point, though, where it is connected in terms of having a version of the USCDI that can be locked down as a formal new version for consideration as part of the standards version advancement process. That's a little bit of the cycle timing that we always need to keep in mind to give industry stakeholders, including the HITAC, an opportunity to weigh in on what should be included in that new version of the USCDI and then kind of working backwards.

So, as we look at the classifications, that's an area where I can agree, we can be nimbler with everybody else. There's a certain point, though, where there's going to be a cutoff every year to say here's everything that we've been able to classify up until the point where we need to talk about what goes into the new version of the USCDI.

Christina Caraballo - Audacious Inquiry - Member
Steve, one thing I wanted to clarify is when we were thinking of this – we've had a lot of unknowns about the fear of not knowing how much is going to go through the process the first time, like are we going to have millions of submissions, over-exaggeration or a couple, a handful. We just don't know.

So, we took the approach of how do we get a data element ready for evaluation? How do we get it to the point where the HITAC and ONC and the public can comment on everything that's ready and meets all the criteria, has met all the milestones that we've outlined and has really teed up for primetime for evaluation. We were really focused on that promotion to get to that point and got less caught up on the actual new versions, from my point of view. Terry, you can add to that as well. We're trying to make it a process that is more black and white at least to get to that knowledge that a data element is ready for USCDI.

Terrence O'Malley - Massachusetts General Hospital - Member
I agree.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator
Yeah. And I totally appreciate that point. I think I was just trying to identify that there is a balance there in terms of what you just laid out, Christina. You can view the USCDI process in isolation and walk through, "Here are the criteria for level one. Here are the criteria for level two." At some point, there's a more formal, industry-known predictable process where the experts on HITAC get a chance to weigh in.

The public gets a chance to weigh in and we tee up, "Here are the data elements that are ready for that next version of USCDI to graduate at that cycle." That's all I'm trying to identify. I just want to make sure there's not misaligned expectations in terms of the recommendations coming out, which I think are

valuable clarifications in terms of how we might process them in the future relative to the two things that we would be looking to implement in parallel.

Terrence O'Malley - Massachusetts General Hospital - Member
Steve, this is Terry. I think your comments are spot on. It's a nice continuation. We tried to speed the process up as much as we could, but recognized – although, I don't think we ever articulated, so, thank you for articulating it – the fact that it runs into a bunch of regulatory requirements, plus good practices that have to be in place. So, your comments are great and we appreciate them. We perhaps can add something to that effect in our revised transmittal letter when it gets to that point.

Carolyn Petersen - Individual - Chair
Okay. If we can now go to Jim Jirjis.

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Yeah. I had a quick question. I love the process and I understand it's difficult to be prescriptive about timelines. One of the questions I had was really about process. If there is a data set that makes sense for USCDI that is a win-win-win for clinicians, providers, insurance companies, lab testing facilities – I get that that can move fairly quickly – part of the requirement is demonstrating its practical use.

But in situations where there is a win-win-lose, where one of the players that's required to participate stands to lose a great deal or spend a lot of money, isn't that where some of the delays can come in in this model and are there any thoughts about how to address that should it occur? That's the thing that can drag that process out over years if there's a player that's really not down with it.

Terrence O'Malley - Massachusetts General Hospital - Member
Yeah. Jim, this is Terry. That's a concern the task force had, among several. So, hopefully, we'll come back and address that, at least in a general way when we're talking about the annual review. Part of the challenge of trying to build a new model is not knowing how it's going to work or if it's going to work or what problems it's going to run into. One problem that it could run into would be that a key piece of the process – perhaps it's a standards development organization or someone who has a proprietary value set they don't want to share, that could derail the process, but we weren't sure. We put it into the annual review, but your point is well-taken.

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Well, I look, for example, just to add to that, a lab testing company or a device company – it may be a lose for them to have to invest in rearchitecting their devices. That may not be a standards group that moves slowly. That may be vested business interest not wanting to participate, some of the stuff the Center for Medical Interoperability is trying to address, for example.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you very much. Food for thought. Appreciate it. Thank you.

Carolyn Petersen - Individual - Chair
And if we can now go to Aaron Miri.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member

Thank you. I appreciate this. It's really good work, again, I want to echo. I also want to dovetail a little bit on to what Jim just said. I think it's important. I'm approaching this with my CIO hat on. Is there a way within this process not just for folks to stymy up the process because they have an interest that goes in a direction opposite the rest of the group, but to make sure also that we don't end up in a situation that we have with all of these various registries that we have to publish to?

I'm thinking of registries that are mandated for various service lines that can only have data manually entered into it. You can't automate anything. They refuse to allow an API and you have to do it, right? So, it's forcing the physicians to have to retype and re-key-in everything because of the registry to this one certain service line.

So, to the degree of it, is there a way within this we can create like rules of the road, like do's and don'ts, like you will make sure this data element can traverse via API and there can't be other dynamics in there that gum it up? I can see it getting to a situation where we have dozens and dozens of proposed data elements but they all have various unique criteria around them and it may be helpful to have a rubric as to what these must conform to to be able to do it.

Terrence O'Malley - Massachusetts General Hospital - Member

Again, Aaron, thank you. That is another important issue. I'm wondering if I can ask ONC to chime in on that. It's a critical piece. I think you've raised a great point that it's not just the data elements and their readiness. It is the ecosystem that they're being dropped into and its readiness and willingness to move for them.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member

Exactly. Well said. Exactly.

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator

This is Steve. I'll take that as my cue to chime in. So, it's a really important point. I think that's where especially to assign it to a particular level classification, that's where, I would say, distinctly within level two, that type of assessment would be included relative to the data element and the bidirectional exchange of that data and the other parties that would be a part of that exchange. Those would be important factors to keep in mind.

We certainly have that experience with public health early on as part of what used to be called meaningful use, where you had rapid acceleration in the technical capabilities of senders but not necessarily in receivers in all cases. So, we want to make sure that balance is there and I think that would be appropriate to mention to look at from a level two assessment.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member

That would work. Thank you.

Carolyn Petersen - Individual - Chair
Okay. Do we have additional questions or discussion from the HITAC members? I don't see anybody in the queue. So, please raise your hand if you'd like to participate. Okay. Well, seeing that we have no more questions or discussions about this first group of recommendations, can we have a motion, please, for a vote?

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Motion.

Carolyn Petersen - Individual - Chair
And is there a second?

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

Carolyn Petersen - Individual - Chair
Okay. We have a motion and a second to approve this first group of recommendations – recommendations one through six on the USCDI final draft recommendations. Would all those in favor of approving them, please signify by saying aye?

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And all those opposed, please signify by saying nay. And are there any abstentions? Okay. That sounds good. Terry and Christina, if you want to move on to the next group of recommendations, that would be great.

Terrence O'Malley - Massachusetts General Hospital - Member
Certainly. That's great. Thank you. This one is a shorter one. This is a one-slide topic. It was raised at the HITAC meeting in September that we needed to be more explicit about obtaining public feedback. This is our attempt to address that. Again, following the theme of adding more things for ONC to do, we were suggesting a quarterly public comment and with that, an update of the status of each data element in the process so that the submitters know where their data element lies and that there's an opportunity for public comment. Then we specify what that content might be that you would want to solicit.

So, this is really our recommendation that we have. We have an explicit feedback mechanism that's part of a data element review and public comment. I think we can have a discussion of this one and then a vote.

Carolyn Petersen - Individual - Chair
Okay. If any HITAC members have questions or comments, please raise your hand in Adobe. Going once, going twice… Okay. I don't see any discussion or questions. So, if we could have a motion, please.

Steven Lane - Sutter Health - Member
I'd be happy to move – Steven Lane.

Carolyn Petersen - Individual - Chair
And is there a second?

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Second, Aaron Miri.

Carolyn Petersen - Individual - Chair
So, we have a motion and second to approve recommendation seven, which relates to the public submitter feedback in the promotion model. Would all those who vote in favor, please signify by saying aye?

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And all those against the motion, please signify by saying nay. Are there any abstentions? Okay. We've approved recommendation seven. Let's go on to the next group.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay. Thank you. The next is the annual review. This is following along two trends. One is yet more work for ONC to do. It is the way that we dealt with all of the uncertainties that we came up against as we thought through this process, all of the things we didn't know – we didn't know if the volume was going to be high or low, whether the process would work, whether we're going to get too many data elements that all look alike. We sort of listed out our concerns and then tried to create an annual review process that would address them. Obviously, the first one is does the process work? Is it actually leading to elements getting through to USCDI? Can we identify what the roadblocks are?

And then as part of that process – this is an issue raised before – is there ever going to be a need for prioritization function? If you only have one or two data elements moving through the system, then bandwidth is not going to be an issue, but if you've got 15 or 10 and there is a difficulty in perhaps implementing them or barriers to implementation, then you might need a prioritization process. So, we suggested we figure out how to do that.

The same goes for harmonization. Harmonization, the attempt to group data elements that are sharing similar concepts and the decision is whether you need more nuance or whether you need more constraint. Clearly mentioned earlier in the ONC proposal was what do we do with data elements that aren't moving anywhere, that are just sort of gumming up the works. So, a process for that.

Other things that were raised – again, we address each of these on a slide – but whether the business models that underpin the standards development work and creating the value sets, whether they're

adequate and whether they're going to be sufficient to support the work that USCDI is going to require – and then finally, another job for ONC. So, if we could have the next slide, please.

So, in checking out if this works, we thought – and by no means is this an exhaustive list but it's ones that we came up with – we just want to see what data elements get where and how long it takes them to get to the next level, how long it took them to get through the whole process.

The final two bullets are an important way of measuring if the process works because you'd want the process to be receiving high priority data elements for processing. If they're not advancing, you'd also like to know that. That was the annual review for, "Does the process work?" You can think of other elements. But here's what we came up with. Can I have the next slide, please?

So, the next one – is this process going to be necessary? We don't know if a prioritization process is necessary, but if it is necessary, we thought we would want to consider the quadruple aim, how broadly applicable is it, specific use cases, particularly high value use cases, and a value proposition for adopting a data element.

So, using those criteria, if you had a tie among data elements that had made it almost to USCDI but only one could get in, then criteria such as this. But really, this is going to be something probably the HITAC and ONC will need to consider in more detail. The first step is going to be to find out whether we need it. Next slide, please.

The same thing goes for harmonization. We don't really know whether there are going to be many data elements that are submitted that are similar, particularly if they are addressing different use cases. We didn't come down on one side or another other than to say that when possible, try to get consensus on the smallest data that you can get your hands on, thinking that parsimony was probably going to be better than everything. Next slide, please.

Stalled data elements – so, the concern is if you've got data elements that aren't moving anywhere, they're just sitting taking up space in this public work area. That wouldn't be a good thing. We'd probably figure out a way to park them somewhere else. We just called that somewhere else a stalled data category. You get into it when you don't advance.

Since we took the timeline away, we just needed to have an – we need to calculate an average advancement time based on our annual review of how long it takes data elements to get to where they have to go and just create some criteria that say if you haven't moved after X-number of average advancement times, then you get put into the stalled data category. You can get out of the stalled data category if more information is submitted on that data element's behalf and it looks like it has a reasonable change of advancing. So, next slide, please.

So, is the upfront work being done? This is a concern that Ken Kawamoto raised. That is a lot of the standards work is either voluntary or involuntary but paid for privately. The question is if those business models for creating the standards, if they're adequate to meet the requirements of USCDI and it's really – we didn't know. We don't know, but we thought it would be important to look into that. If ONC found

that there were apparent delays in data element advancement due to challenges of the various business models that are out there, that they would note it and intervene as possible.

Finally, the last slide in this annual review set is then another flip side of the high priority data element saga and that is if there are high-priority data elements that are missing – we're suggesting ONC ought to look into ways to promote them or get them into this process. Again, more work – and if they find that they're not advancing – again, to address what tools ONC may have to help get communities of interest to move the data elements forward – when you do priorities, however, it raises – the initial question is whose priorities are we talking about. That's a discussion in and of itself.

So, if one were to set up a set of priorities that are important for the country – quadruple aim might be a good start – then what do we need to support that and do we have them? Are they moving? That's seven of seven on the annual review. So, we can open this set up for discussion.

Carolyn Petersen - Individual - Chair
Okay. Thanks, Terry. HITAC members, if you have questions or comments, please raise your hand and I'll start going through the queue. Okay. I'm not seeing any hands come up. Again, please, if you have any comments or anything that you'd like to discuss about the annual review piece of the USCDI that's being proposed, please let us know by raising your hand in Adobe. Okay. I see Aaron has a question.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Yeah. I just want to re-raise what I said earlier about a process for escalation or some sort of emergency review outside the annual process. I don't want to lose sight of that.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay. So noted. I think, Aaron, maybe we can talk offline. It's a critical issue. It is one that was raised last year. Actually, it was raised even before in the Standards Committee around Zika – is there a process for fast-tracking? I think that's worthy of a long discussion.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
I agree. And then also, to channel I'm sure what Clem is going to chime in with, something in research as well, right? If in research something comes up that's critical, because of some other syndrome or surveillance issue that's been identified, how do we help?

Carolyn Petersen - Individual - Chair
Okay. Steven Lane, you had your hand up for a minute. Do you have a question?

Steven Lane - Sutter Health - Member
I was really just wanting to support this. I'm being quiet because Christina and Terry are doing such a great job. These recommendations really came out of a lot of discussion and thought on the part of the task force. I think the absence of comments or the bulk of these comments should not be seen as a reflection of the lack of support.

Carolyn Petersen - Individual - Chair

Great. Thank you. So, I don't see any raised hands in the queue. I'll give it another three or four seconds for any last thoughts. Okay. Seeing no other questions or comments, could I have a motion please regarding recommendation eight, dealing with the annual review part of this process?

Steven Lane - Sutter Health - Member
So moved.

Carolyn Petersen - Individual - Chair
And may I have a second, please?

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Second.

Carolyn Petersen - Individual - Chair
Okay. We have a motion and a second to approve recommendations 8A through F for the annual review part of the USCDI draft recommendations. All those in favor of approving this group, please signify by saying aye.

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And all those opposed, please signify by saying nay. Are there any abstentions? Okay. We have approved the recommendations 8A through F. Let's move on to the final group.

Christina Caraballo - Audacious Inquiry - Member
Okay. Great. So, our next recommendation grouping is recommendation nine. This is around the concept of a submission and advancement user guide. This has really been something that was at the heart of our discussions early on and really lived through the whole task force conversation about this need for guidance for the interests and submitters to be able to get a data element through this whole process. So, we thought it was really important to have more of a formal user guide and for ONC to create this as a base.

So, for the next recommendation and the next four slides, we are really just providing details for each of the key sections in the user guide, which include the actual identification of a data element, the justification for a promotion, the extent of use and the actual technical pieces, the potential impact and the potential barriers.

What you'll see in the next slides as kind of the bucket questions of what we've gone through in all of the previous slides and we just wanted to put it together in our recommendations. So much work and thought went into the idea of this user guide and building it out. A lot of the slides, I said, will reflect the content that we've seen in here for meeting the different criteria to meet milestones to get from the different levels into USCDI.

Other key concepts in this user guide that we are recommending is that ONC provide examples of successful applications to make it so that users can better understand what is needed and what it actually looks like, kind of a way to all be on the same page. So, if we go into recommendation nine, the first slide, section one, this is the general information – one thing to note as we go through this – as I talked first, we said we wanted this to be very dynamic. Terry mentioned earlier that this was kind of a platform that you could continue to add to.

So, these are the criteria that would need to be fit or met to get all the questions answered, everything done, all your boxes checked to be ready for USCDI. It's a list of all the questions and criteria. This is section one, as you see here. Section two on the next slide goes into the actual justification for the data element promotion, why it should be captured and available. It's looking at the use case descriptions and kind of painting the picture of the why it matters.

Section three is this slide and the next and it goes into the extent of the use and actual technical specification and requirements, looking at how the data element is captured and gathering more information about the capture and the actual content standards that exist and are cited.

So, moving on to the next slide to more detail in section three of the use and technical requirements – it's gathering information about the existence of this implementation guide that we discuss, citing that specific implementation guide and where it lives, identifying existing connect-a-thons, pilot testing SEOs, pilots, production use of the data elements – really, getting as much information that we can gather into the one place, looking how the exchange of the data element has been successfully testing on the different platforms, citing this use as best we can and looking how the exchange of the data element has been tested at scale between multiple platforms.

Moving on to the next slide is starting to document information on the potential impact. So, is there evidence that the data element supports the quadruple aim, which was mentioned earlier in this presentation? Then an estimated number of stakeholders that would use this data element.

Section five goes into the potential barriers and collecting as much information as we can regarding the restrictions on the standardization of the data element, the use, and looking at providing an overall estimate of the burden to implement.

So, I will pause there on our recommendation nine concept of the user guide with a list of starting point questions from the task force.

Carolyn Petersen - Individual - Chair
Okay. HITAC members, if you have a question or comment, please raise your hand in Adobe. We will start this round of the discussion. Okay. I'm not seeing any hands raised. Are there any other comments or thoughts that you or Terry have, Christina, to share about this part of the recommendations?

Terrence O'Malley - Massachusetts General Hospital - Member
To paraphrase Steven Lane, we're taking silence as meaning concurrence.

Carolyn Petersen - Individual - Chair
Okay.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Actually, this is Aaron. I want to add one quick thing. Sorry. I don't mean to jump in at the last second. In a comment that came up last HITAC from the general public regarding potential gaps in the continuum of care, is it worth asking a question up here under potential impact showing what evidence will help mitigate or reduce any burden to the continuum of care? I'm thinking in my head if we add this data element X, then suddenly we'll be able to exchange data better with LTACs or whatever it may be. It may be worthwhile to put out there in the world how this will help reduce the burden on the continuum of care.

Terrence O'Malley - Massachusetts General Hospital - Member
Great comment. Thank you. We'll figure out how to work that one in.

Carolyn Petersen - Individual - Chair
Okay. I don't see any other hands in the queue. I'll give it another few seconds in case anyone has any last-minute thoughts or questions. All right. Well, seeing no further discussion, I am wondering if we have a motion to approve this group of recommendations.

Steven Lane - Sutter Health - Member
Enthusiastically moved.

Carolyn Petersen - Individual - Chair
And is there a second.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Second.

Carolyn Petersen - Individual - Chair
Okay. We have a motion and a second to approve the recommendations related to submission and advancement of the user's guide. All those in favor of approving these recommendations, please so signify by saying aye.

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And all those opposed, please signify by saying nay. Are there any abstentions? Okay. We have approved the fourth group of recommendations related to the USCDI final draft recommendations. Terry and Christina, did you have any wrap-up comments or anything else to share?

Christina Caraballo - Audacious Inquiry - Member
We have one more recommendation.

Carolyn Petersen - Individual - Chair

Okay. Let's do it.

Christina Caraballo - Audacious Inquiry - Member

So, our final recommendation is that we're proposing a pilot use case to actually test this model. There have been lots of discussions about the unknowns regarding the USCDI promotion model and we really thought it would be beneficial for ONC to pick a data element group to go through this process and identify any early issues, create examples for the user guide and look at other things to consider.

So, we are proposing for consideration because of their importance and broad stakeholder support and complexity that ONC pilot the social determinants of health domain. One of the reasons we picked this is because the data class has lots of data elements at multiple levels. So, it would be a good one to kind of take through this process. It was also identified by Ken and Steven's task force as a high-priority use case for future consideration. I can open it for discussion. Thoughts, comments?

Carolyn Petersen - Individual - Chair

Okay. I don't see any hands in the Adobe up. Denise Webb?

Denise Webb - Individual - Member

Just a quick question – so, you're proposing social determinants of health. Can we assume that the USCDI already sufficiently addresses the data elements from medication and pharmacy and the other priority area around lab order results that were proposed by the priority task force?

Steven Lane - Sutter Health - Member

I don't think you can. Our task force made some very detailed recommendations that would really need to be added to USCDI for their full implementation.

Denise Webb - Individual - Member

All right. That's why I thought I'd bring that up because if we're going to go along with priorities, it seems like it would make sense to trial run this on one of the high-priority areas proposed by your and Ken's task force.

Ken Kawamoto - University of Utah Health - Member

This is Ken. If I could comment, I think philosophically, the question would be what the important ones to choose are, which would be this option. We could also try to choose something that we feel should be a slam dunk, where it really already should be there or maybe it's already made it into the USCDI because that would help address the question of if the process is too onerous and would things that we currently would think of as obvious struggle to get past it? That's potentially if we wanted to choose an "easier" option, how would that look, for example?

Christina Caraballo - Audacious Inquiry - Member

So, what about moving this recommendation to just recommend that ONC pilot one or two use cases to kind of inform and get information to feed into the user guide. We could use it as examples instead of

our recommendations. So, maybe consider some of the use cases within the ISP Task Force as a starter but not specifically name one.

Denise Webb - Individual - Member
That sounds much better.

Ken Kawamoto - University of Utah Health - Member
I like it too.

Carolyn Petersen - Individual - Chair
And we have a comment from Aaron Miri.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Hello. I love this idea. I think it's great to do a test run. One comment and one question – the comment would be it may be helpful for us to define out quickly what social determinants of health is. I think we all know what it is, but unfortunately there's a lot of industry noise on SDOH and our fantastic friends in marketing sometimes take it to left field. It would be great to say what is SDOH so everybody knows clearly this is what we're talking about.

Then to echo what Ken said, we should look at some element of SDOH that would seem common sense but maybe would have difficulty. I'll give you just an idea – patient reported outcomes, PRO data – mapping that would be very interesting to see where it lands and what the gaps are with that. You would think that would be common sense. As I've seen in evidence and practice, it's very tricky.

Carolyn Petersen - Individual - Chair
Do we have other comments or questions from HITAC members? Jim Jirjis, please?

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Yeah. I just wanted to support the earlier comment that the recommendation for the test run is not something that is complex and hasn't been mapped before, but in fact, it's something that is in use right now in communities that's relatively simple and straightforward so that the complexity of the intervention is not what gets in the way of our testing the actual process for USCDI.

So, the thing I would add, if I heard correctly earlier, was starting with something that largely doesn't have operational risk and complexity to test our model and how we walk it through. If we try to map something that's not clear how they're going to use it or how it's been done, that might not be testing our processes as much as something simpler and clearer.

Christina Caraballo - Audacious Inquiry - Member
One thing I'll add is I don't think this test necessarily means that the data element is going to land at level two or even ready to be into USCDI. It's kind of a broad list of data elements at different stages might be a way to go so we can kind of see where they land, what's needed, what the gaps are. That was one of the reasons that we just threw social determinants of health in here as an example because it's

known that it has associated data elements that would come in at different levels within the process and what does that look like.

Ken Kawamoto - University of Utah Health - Member

Maybe it's not an either/or thing, right? Maybe it's do the slam dunk. How would this go through? For example, what if we didn't have weight in USCDI. How would that go through the process and go from there? That should be really, really simple, like, "Oh yeah, that's how we would fill this out," and then it would obviously go through and then it would start incrementally doing harder things.

The tests should be for things that we feel shouldn't make it through, it doesn't make it through for things we feel should be obvious to get through easily. It should get through easily for things in the middle is where most of the tweaking would be.

Steven Lane - Sutter Health - Member

We just received a public comment from Becky Grundel, who's part of the Gravity Project and has been really working diligently on social determinants of health and getting those ready for promotion. Terry has been pretty involved in that effort. I've attended some of the meetings as well. This is a great and well-orchestrated stakeholder group that really has been promoting this work. I think, again, it supports looking at this as a pilot use case.

Christina Caraballo - Audacious Inquiry - Member

And actually, on the Gravity Project call last week, they had started discussing what it would look like to go through the USCDI process. So, excellent point, Steven. I didn't have anything additional. But as we were going through making our recommendations, we talked to different stakeholder groups that had a vested interest in understanding how to get through this process.

So, there could be some groups that are kind of super users or champions that could identify stakeholders that would want to help move their balance through this process and could probably come up with a list of a few to share but not getting stuck on the actual use case but more the recommendation off the conversation there.

Carolyn Petersen - Individual - Chair

Okay. Do we have additional questions or comments from HITAC members? I'm not seeing any hands in the queue. Okay. I don't see any hands raised. Terry and Christina, do you want to keep this recommendation as it is or do you want to suggest doing something else with it based on your earlier comments in the discussion?

Terrence O'Malley - Massachusetts General Hospital - Member

I think the comments have been great. I'll perhaps offer a friendly amendment to say such as social determinants of health and then another bullet providing another example of a well-established high-value data class. I think they both would test different parts of the system.

Carolyn Petersen - Individual - Chair

So, our USCDI Task Force Co-Chairs are suggesting that they would modify the recommendation 10 on the screen to note that social determinants of health is one of a couple that could be included in this proposed pilot use case. I'm wondering if anyone has a motion around that suggestion or if there's more discussion. Please raise your hands.

Andrew Truscott - Accenture - Member
Is this something the Co-Chairs want to take away and discuss and then come back?

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Carolyn, this is Lauren – if it helps any, I can put in the public chat the friendly agreement just so that we have it in text for everyone to see.

Carolyn Petersen - Individual - Chair
That would be great. Let's do that.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Terry, I'm going to ask you to repeat that again just so that I get it correct.

Terrence O'Malley - Massachusetts General Hospital - Member
All right. So, in front of social determinants, put in, "Such as…" and continue – so, then add another second bullet saying, "And other well-specified data classes of high value." I guess well-specified being the important term. Strike out the high value. Just say that it's well-specified. We'll argue about what's high value.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
"And other well-specified data classes?"

Terrence O'Malley - Massachusetts General Hospital - Member
Yes.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Okay. Does that capture it for both amendments?

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
I think it does. This is Aaron.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Okay. I see another comment from Denise.

Denise Webb - Individual - Member
One concern I would have with the way that's worded – is that implying that social determinants of health is a well-specified data class?

Steven Lane - Sutter Health - Member
I think that's overstating the state of the art.

Denise Webb - Individual - Member
Right. If we're going to say, "Such as social determinants of health or other well-specified…" That just implies that it's well-specified. Grammatically, that just –

Terrence O'Malley - Massachusetts General Hospital - Member
Maybe it should be, "Or a well-specified data class."

Denise Webb - Individual - Member
Yes. That sounds better. Thanks.

Carolyn Petersen - Individual - Chair
And Lauren is just bringing that text up on the chat so we can all see it.

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

Carolyn Petersen - Individual - Chair
This would be a second bullet point to go with the social determinants of health bullet point just identifying proposed pilot use cases to test the USCDI model. Is that a fair summary, Terry and Christina?

Christina Caraballo - Audacious Inquiry - Member
It looks good to me.

Terrence O'Malley - Massachusetts General Hospital - Member
Yes. Thank you.

Carolyn Petersen - Individual - Chair
Okay. Do we have any discussion about this revision? Please raise your hands in Adobe. Okay. Seeing no hands raised in Adobe, do we have a motion to adopt the revised recommendation – revised as noted in the public comment chat?

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Carolyn, I will add that amendment to the final transmittal letter.

Carolyn Petersen - Individual - Chair

Okay. Thank you, Lauren. Okay. If we don't have a motion, then do we need to have further discussion about this point? What are folks not comfortable with or what else would you like to do with it? Hello?

Terrence O'Malley - Massachusetts General Hospital - Member
I'll make a motion to accept.

Carolyn Petersen - Individual - Chair
Okay.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Second.

Carolyn Petersen - Individual - Chair
So, we have a motion and a second to accept to approve recommendation number ten for the proposed pilot use case to test the USCDI model as shown on the screen was the revision that adds or a well-specified data class. Could all those in favor of this recommendation of approving this recommendation, please signify by saying aye.

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Chair
And could all those opposed please signify by saying nay? Are there any abstentions? Okay. We have approved this revised recommendation ten dealing with the proposed pilot use case to test the USCDI model. Do you have any further comments, Christina or Terry?

Terrence O'Malley - Massachusetts General Hospital - Member
No. Just thank you and thank the ONC staff for all of the help. We really appreciate it.

Christina Caraballo - Audacious Inquiry - Member
Yes. I wanted to say a special thank you to my Co-Chair, Terry O'Malley, who has been absolute pleasure to work with and just making this really fun, the whole task force. Two years of this has been a lot of wonderful conversation, learning. An extra thank you, Terry.

Terrence O'Malley - Massachusetts General Hospital - Member
Thanks, and to Christina too. I think that's a wrap, folks.

Carolyn Petersen - Individual - Chair
Okay. Thank you so much for the presentation and all the good discussion around the recommendations. It's great to see that we've wrapped up another of our responsibilities. At this point, we will move into the final part of our work plan today. This is the HITAC 2020 planning. Robert and I took your feedback from the previous meeting and worked in concert with ONC to bring it all together for a summary. Today, I will present that and then we will have a discussion.

So, if we could have the next slide, please. So, I think to hear a review of the priority target areas that we're familiar with as defined in the Cures Act, that's interoperability, achieving the health information technology infrastructure that supports electronic access exchange and use of health information. Secondly, privacy and security – that's promotion and protection of privacy and security of health information in health IT.

And finally, patient access – that is the facilitation of secure access by an individual and their caregivers to such an individual's protected health information. We also have the opportunity to bring up any other target areas related to these three that we as a HITAC think are an appropriate target area to be considered on a temporary basis of giving notice to Congress that we want to do that. Next slide, please.

So, the purpose for our discussion today is to look at potential topics as a starting point for what we want to do next year, to acknowledge the work that we're already committed to and see where that fits into our calendar over the next 15 months or so and to discuss some opportunities for other work that we can undertake next year and beyond. After I've gone through the review, we're going to focus on four questions that I'll share with you now.

First, what topics would you add, remove, or change based on what we present? How would you frame HITAC and/or the ONC focus within a topic. What topics should be addressed in 2020 and what are better addressed later on, for example, after some part of the final rule has been implemented? Finally, which topics are ready for a task force and which topics would benefit from further definition or hearings or more discussion at the HITAC level. So, if we could have the next slide, please.

Okay. It looks like I'm having connection problems but I will work off a slide deck. So, to review how this initial topic was developed, we reviewed transcripts from prior HITAC discussions about our interests in future focus areas. We reviewed HITAC recommendations including what was in the fiscal year 2018 annual report.

We considered legislative requirements, existing work plans, and emerging issues. Some of that is related to what we are developing in the fiscal year '19 HITAC Annual Report and other things that we are aware of. And there was a discussion of input from the HITAC Co-Chairs. My screen is flashing like we're having a connection problem. If you could please advance the slide to five, assuming that HITAC apparatus is still working. We'll now look at the planning for HITAC 2020. Next slide will be slide six of this group.

So, our current HITAC 2019 and 2020 plans involve the following priorities. We have the Interoperability Standards Priority Task Force. We just had that presentation and they will be wrapping up the transmittal letter around the HITAC recommendations and report. We also have the USCDI Task Force. Again, they'll be wrapping up that transmittal letter and sending that on to the National Coordinator. The Annual Report workgroup is in the midst of putting together the annual report for 2019 and starting to think about what comes beyond that. We had that presentation in September and we will update you further on network at the November meeting.

We have a new EHR reporting program task force. This is work to create a new task force to provide recommendations on draft EHR reporting program criteria. That is for the coming year. And then of course pending release of the criteria. Finally, we have the federal health IT strategic plan covering five years from 2020 to 2025. ONC will present public comment draft of the strategic plan for the full HITAC feedback. Again, that's another activity for next year that is pending release of the strategic plan.

If we can go to the next slide, please, we can see this kind of in a timeline approach. As you can see, we're starting where we are now on the left in October. That shows that we're wrapping up the ISP and the USCDI and the Annual Report will continue for the next few months. We anticipate early in 2020 the EHR reporting program task force and the federal health IT strategic plan work, of course assuming those come out. Then the annual report will continue through the rest of next year for the next addition. If we could have the next slide, please.

We'll now come into potential topics. Again, these are things that we've gathered from our prior discussions last month and last year and other things we're aware of. So, go to the next slide of potential topics. I'll review some of the things that have come up and some potential HITAC actions. We can look at priority uses of health IT and related standards. Continuing our work on priority uses of health IT and related standards, things like the ISP Task Force or perhaps a new task force that could continue some of that work.

Prior authorization – we could establish a joint HITAC NCVHS Task Force. We had presentations earlier this year about that and some updating and that was something that was of interest at that time. We can do more work with the core data for interoperability. This is something that we would have to determine pending ONC's consideration of the work that we wrapped up today and the final rule publication. Similarly, we could do more work on TEFCA. Again, that would be pending ONC and the RCE work planning.

We can look at final rule implementation guidance. Of course, this would be pending publication of the final rule. Price transparency and the intersection of clinical and administrative data standards is a topic that's come up a number of times this year in various discussions. One potential action we could take would be to establish a new HITAC task force or we could continue ISP Task Force work addressing price transparency.

There is data privacy and secondary uses of data and a potential action in this area could be convening a HITAC hearing on the secondary uses of data. We should note that several of these items, particularly the prior authorization, the price transparency, and the data privacy activities would be contingent on additional ONC coordination across HHS. That's something we can recommend but it's not necessarily something we can determine we will do today. Could we have the next slide, please?

We also have some other potential topics. We can look at consumers and patients' perspective on health IT and health data. We can look similarly at researchers' perspective on health IT and health data. There is payer to provider health information exchange, public health emergency standards, data segmentation for privacy. That was a very small part of deliberations of the health IT for the Care

Continuum Task Force deliberations earlier this year. We didn't get very far into that. That could be something we could do in 2020.

Standards for de-duplication of data from multiple sources – machine learning and artificial intelligence and then finally, the intersection of medical devices and health IT. And as you'll note by the asterisks by some of these topics, some things are contingent on ONC coordination across HHS.

So, if we could go to the next slide, please – this is the time when we want to get into some discussion about these options and to think a bit more about what we might look forward to going forward. I'm wondering if Elise has any comments before I bring up the discussion questions and we start the main discussion.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology-Executive Director, Office of Policy
Thank you, Carolyn. I thought that was a great presentation. I think from ONC's perspective, we're really excited to hear the thoughts of the HITAC regarding what areas you think it might be helpful for us to consider as we are putting together charges for the upcoming year. You guys had a very busy last year between reviewing the rule and providing policy thoughts there as well as work around TEFCA standards annual report.

As we go into the next year, as Carolyn mentioned, there are some areas in the beginning part where we have already spec'd out the annual report but we want to make sure that throughout the year we're thinking about how to construct the HITAC charges so that we're meeting the interest areas that you've identified and addressed in some of the annual report areas, but also the areas that ONC is working on or thinking about or see as emerging issues that we want to stay on top of, whether that's through a task force or, as Carolyn mentioned, potentially through a hearing.

Of course, as ONC thinks about the charges that we would put forward to the HITAC, the other part of it is to consider the health IT that does that. Some of these areas are quite broad, as we all know, and involve many different aspects of the health sector and the health spectrum. So, as you are discussing these, it would be helpful for us to know what the health IT aspects are of some of these issues for which the input of the HITAC can help inform our work.

Other than that, we're really excited for the discussion and welcome any thoughts.

Carolyn Petersen - Individual - Chair
Okay. So, if we could go to the next slide, we'll bring those discussion questions back up again so we have them in front of us. Again, we're looking for topics that we should add, remove, or change, thinking about the framing of the HITAC and/or the ONC focus within a particular topic. I know some of these points are quite broad.

Specifically, what do we want to do next year and if we also have some thoughts about what might be best delayed until 2021 or beyond or perhaps something to consider after implementation of the final rule or some other work that's in play.

And then finally, we should be thinking about whether we want to form additional task forces or perhaps try to call some hearings. What is the format with which we propose to go forward with our new work? With that, I see that Aaron has his hand up. We will start there and I will moderate the discussion. Go ahead, Aaron.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
Thank you very much. I appreciate the opportunity to talk about this. I'm going to step on a stool that I've stepped on many times here for this committee, which is I'm a strong believer and advocate that we need to continue to look at the privacy and security dimensions around interoperability, all the 21st Century Cures charges, for lack of a better term, particularly around secondary use of data.

I've recently heard from a number of very high profile public and private leaders about the concerns there and a lot of industry noise around potential misuse of data even though I want to believe that everyone has the best intention at heart and this is for the right reasons, I think it would help us to clear this up, otherwise you're going to continue to have this mishmash of state law versus federal regulation around these topics because it's very important to the general public. I would vote for that, please.

Carolyn Petersen - Individual - Chair
Thank you. Let's go to Andy Truscott.

Andrew Truscott - Accenture - Member
Thanks very much. This is a good robust list. I echo what Aaron was just saying. I'd also like to add I think when we talk about price transparency and data that was on the site bunched up, I think we should probably pull them apart and consider price transparency separately from a health IT perspective about how to calculate consistently and to communicate consistently and uniformly pricing information and make sure we are crystal clear on what we mean by that.

Carolyn Petersen - Individual - Chair
Okay. Thank you. Let's go to John Kansky.

John Kansky - Indiana Health Information Exchange - Member
Thanks. So, you had great lists that you went over on the previous slides. Three things I saw as I went by that I wanted to highlight in order of priority – I think the TEFCA ecosystem is going to be rolling out in unpredictable ways and it would be great if HITAC had the opportunity to give some objective input observation or gather information from the healthcare system on how that's going early in the process so that we can feedback any course corrections or encouragement to ONC.

The second one was the information blocking rule as that roles out. Similarly, at the right point in time, I guess that one is fairly obvious, just we'll need, I believe, to give some attention to feeding back on how that's being implemented.

Then finally, a little less obvious, maybe, is I wanted to call out payer to provider health information exchange as an important topic that I saw on the list and obviously, that has a big bearing on the – the CMS role has a significant bearing on that one, but I wanted to call out those three. Thank you.

Carolyn Petersen - Individual - Chair
Thanks, John. Let's go to Jim Jirjis.

Jim Jirjis - Clinical Services Group of Hospital Corporation of America (HCA) - Member
Yeah. I want to first of all piggyback of payer to provider plug because I think there are so many win-wins in that space of provider, patient, and payer. It really allows us to actually move forward faster with less vested interest problems. We're already having, as a provider group, we're having payers come to us wanting to really explore that space. I want to make a plug for that. The second one is standards for de-duplication of data from multiple sources.

As we run into receiving CCDs, we see so many problems processing them with duplication, for example, that we think that's a next necessarily high-value item as TEFCA comes on board. Then lastly, it's kind of related to machine learning, artificial intelligence.

As we all start doing real time data processing and decision support with some of the more contemporary real time advanced analytics, medical devices and health IT, there's so much opportunity in information models and data standardization in those devices that if we're going to use signals real time, there's enormous lift to processing those signals. That could really open up the door for a whole segment of machine learning, artificial intelligence, and real time advanced analytics.

Carolyn Petersen - Individual - Chair
Thanks, Jim. Let's go to Steven Lane.

Steven Lane - Sutter Health - Member
I want to also reiterate some of the things that have been said with regard to importance of HITAC engaging on TEFCA, the final rule, information blocking – I want to specifically talk about the secondary use of data. There's another facet to that, which is, perhaps, the flip side of that, which is the repurposing of data. Sometimes with the consent of the data owner or data source and sometimes without, we're struggling with that a little bit. There are folks in the industry who feel the information blocking rule will give them courage to repurpose data in any way they'd like.

I think we really need clarification on that. Unless it becomes a free-for-all, we really need to work towards some sort of a framework and methodology that will allow data to move with metadata that specifies why it is shared and what purpose it is allowed for. I think this comes up especially in the payer provider space where there is persistent anxiety on the part of providers that their data be used for specific purposes in the realm of healthcare operations and perhaps not for others.

I also want to throw my weight behind the notion of de-duplication of received data. I want to take that further because that is a critical step along the path towards integrating received data and then utilizing it within the received system or application. We have a long way to go with regard to efficient and

consistent integration utilization of exchanged data. Part of that really involves a need for a deep focus on the mapping of data that is required to achieve true semantic interoperability.

This was a topic we spent a lot of time on in our ISP Task Force. We made specific recommendations around it. One recommendation was we need to dig in deeper. Today, we rely on LOINC and other standards to help us with that, but there's clearly need for deeper work on information modeling that would really benefit from continued input and discussion of the HITAC and focus on ONC.

Carolyn Petersen - Individual - Chair
Thanks, Steven. Let's go to Sheryl Turney.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Thank you. I wanted to throw my point of view into the payer to provider space, obviously. I think I agree with Steven's concern. There is persistent anxiety, especially over the secondary use of data and repurposing of data. We face that on a daily basis. I do think that merits having some concentrated effort to focus on and come up with some policies and approaches and maybe methodology for how we can try and put some guardrails around the scenario so we can move this forward.

It's especially important with some of the other topics people brought up, as for instance AI and sharing of data insights – in order to share the insights, the data has to be exchanged and has to be actionable within the systems we're sending and receiving from. We're still not there yet.

Also, I would like to put my weight behind the price transparency effort. We need to come up with some standards or approaches for sharing prices that are common so that when members or patients see the pricing, they know that it's the same regardless of potentially the payer or if they're a self-pay, they are looking at consistent data and it's not going to be confusing for the consumer, which today, it definitely is. People don't know what's built into those prices. They're still surprised by medical bills. I do think we need to tackle that project.

The other one I've spoken about multiple times – it's probably a component of many of these – I do think we still need further consumer education about their authorizations for the use of data and what that means especially regarding secondary uses and also some of these repurposing of data. I do agree with the statement Steven made.

We are constantly surprised by especially the innovation vendors who don't understand how healthcare really works as a business and they often are combining things and repurposing things in a way that not only doesn't make sense but doesn't work that way. We really want to make sure the information people are getting is accurate. What's available today is complex already. So, let's not complicate it more and more it more complex by allowing the way the data is used to be inconsistent amongst all the healthcare participants.

Carolyn Petersen - Individual - Chair
Thanks, Sheryl. Let's go to Ken.

Ken Kawamoto - University of Utah Health - Member
Thanks. All these topics are great. Two observations – one is that as might be expected, there's high overlap in this list with what we discussed in the ISP Task Force this year and made recommendations on. Figuring out how we can leverage the work that many of the task force members and HITAC members spent quite a bit of time on, I think, would be useful. This includes things like price transparency, where we spent a lot of effort and the need for de-duplication and facilitated reconciliation with unique metadata, identifying data to be carried across systems so it's easier to identify de-duplication.

We've spent a lot of time on payer provider data exchange, in particular in the pharmacy domain. We did spend time on prior authorization, for example. I think there's a lot that we actually spent quite a bit of time on that we should leverage.

The other observation is that in the ISP Task Force, one of the recurring themes was that it's really hard to boil the ocean, but maybe we can focus on really important areas of clinical care healthcare that can allow us to focus. An example of that is we currently already share blood pressure but we don't provide information on if it was done using a regular blood pressure measurement or an AOBP which is much more accurate and has different goals and thresholds or a 24-hour blood pressure, home blood pressure. There are implications of that data and how it should be handled and managed.

Even taking something like that is an example of if we try to solve all of that at once, we're just not going to get there, whether it's exchanging that data in TEFCA, for example, it's not going to miraculously be the case that everyone is going to say, "Oh yeah, home blood pressures. Let's make sure we share that and label that," because it should be interpreted differently than an office blood pressure.

An idea there, for example, ISP had identified focusing on chronic conditions with the highest morbidity and mortality and figuring out what should be done there. That's one access for prioritization, to say for some of these really thorny issues, let's not try to figure out how to boil the ocean. Let's say what we need to help manage hypertension, which affects 70 million Americans. That's a much more tractable process than saying how we get all data semantically interoperable. Thanks.

Carolyn Petersen - Individual - Chair
Thanks, Ken. Let's go to Denise.

Denise Webb - Individual - Member
Hello. So, I have to say I endorse and agree with a lot of the recommendations my colleagues have made. I want to ring in on the idea of having a separate task force on price transparency. I think that's a place we can go deep and wide and it's a high area of interest, especially for consumers.

I also hear in my circle of CIO colleagues that while the electronic health records have gotten better at exchanging data in particular areas that is usable such as allergies, meds, immunizations, they continue to see challenges with the flow of data occurring between systems that are not usable and not easily integrated into their electronic health record. Some of these things we've addressed, we've talked about like in the ISP Task Force around lab results, but some others that I've heard is around family history as another example.

I really think the work around priority uses of health IT and related standards and USCDI are critical areas we need to continue to focus in. Last but not least, I agree with Sheryl on consumers not really understanding what's happening to their data and secondary uses. While we all as consumers should have a right to our data and to get it the way we want to in whatever app we're using, there really do need to be protections. I'm hearing in my CIO circles that they're very concerned about the balance between providing all the data to the app the consumer wants to use and then the third-party developers not having any enforcement around their uses of that data.

Those are the primary things I think we need to continue working on and then, of course, the common agreement, we're going to need to continue with our TEFCA task force to address that when it finally comes out.

Carolyn Petersen - Individual - Chair
Thanks, Denise. Let's go back to Steven Lane.

Steven Lane - Sutter Health - Member
I want to piggyback on what Denise said and highlight the opportunity we have with the new EHR reporting program coming down the line to utilize that as a way to collect data regarding how the various vendors are supporting these key functionalities, especially around data integration, utilization, the mapping that's required for true semantic interoperability. Also, looking at the USCDI, making sure that in the reporting program, end users and the public at large can really see how vendors are tracking to the advancement of the USCDI. I think that would be very important.

Carolyn Petersen - Individual - Chair
Thanks, Steven. I would say from my perspective, priority concerns for 2020 and beyond, we definitely need to keep our eye on privacy and security. That's one of our target areas. Although it's an issue we've been talking about seemingly forever. It's an area that continues to evolve with concerns for providers and patients and other stakeholders.

I think concerns about secondary uses of data and the repurposing are also paramount, particularly as we move into the capabilities as data moving through apps and this notion of third parties that don't have the same responsibilities as those bound under HIPAA. I'm intrigued by Steven's comment about a framework or methodology that brings data and metadata about them, helping us understand where they're supposed to be going and what they're there for and how they can be used. That would be a fresh approach. I think something where the members of this committee have a great deal of expertise to contribute.

I'd also like to see us be able to do some follow-up work, re: TEFCA and the final rule and other things we've worked on this year. There's definitely an area there, perhaps not for oversight but certainly for observation and comment.

I don't see any hands in the queue right now but I see that Adi had posted in a comment in the public chat area. Adi, did you want to follow up on that? If you're speaking, you're on mute. Okay. Perhaps Adi

is not on audio. Thank you for responding. Are there other comments from HITAC members with regard to 2020 and beyond? We've provided a list of topics that have come up in various areas that have come up in the past year or so, but if there's something else someone wanted to mention today, now is the time to do it as we begin our deliberations about the future.

Aaron Miri - The University of Texas at Austin Dell Medical School and UT Health Austin - Member
I would say one more thing – this is Aaron – we didn't mention it too much but it's critically important – items around patient education. That could dovetail into privacy and security and other areas, but not forgetting the patient dimension is critical and something we heard from the general public in our last HITAC.

Carolyn Petersen - Individual - Chair
Thanks, Aaron. Ram has his hand up.

Ram Sriram - National Institute of Standards and Technology - Member
I'm just wondering about genomics information, integrating that into EHR. How important is that, especially when you're talking in the future about the personalized nature of medicine?

Carolyn Petersen - Individual - Chair
Thank you.

Ram Sriram - National Institute of Standards and Technology - Member
I'm adding to it because a lot of topics are already covered in the previous things you mentioned. Particularly, I am interested in the AI and machine learning, I think that is huge potentially in healthcare and we need to figure out how that fits into our mission here.

Carolyn Petersen - Individual - Chair
Great. Thank you. Steven Lane, your hand is up again?

Steven Lane - Sutter Health - Member
Just piggybacking on Ram's comment – integrating genomic information is the first step to actually utilizing that information in decision support, alerts, reminders, etc. That's a step along a very long path.

Carolyn Petersen - Individual - Chair
Great. Thanks. Are there any other comments from HITAC members? Okay. Do we have any thoughts or feedback at this point from ONC?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology-Executive Director, Office of Policy
Sure. I can start and then Steve also has thoughts. I think this has been a great conversation and extremely helpful for us as we're thinking through the next stage and working towards TEFCA, for example. Now that the Recognized Coordinating Entity is on board and the stakeholder engagement that will happen there and then the goal of having the common agreement our for public comment. All of those things show our commitment to our ongoing engagement with the HITAC on these issues and I

think that's going to be really important. The EHR reporting program is also mentioned and also highlighted in some of the areas we are planning for FY 19-20 as well.

I think overall, a lot of what I heard were really specific areas related to health IT. There's a larger construct around many of them in terms of the health sector, but really specific to areas health IT might be able to help address or inform or education and align to a lot of the work ONC has been working on, for example, patient access, one of the key areas we've been working on as part of our 4006 work under the Cures Act and also through some of the provisions we included in the proposed rule. I thank everyone for all of their thought and input they provided. This would be a really helpful start as we are thinking through the charges for the upcoming period. Steve?

Steve Posnack - Office of the National Coordinator for Health Information Technology- Deputy National Coordinator
Sure. Elise covered most all of it, as usual, eloquently. The one thing to keep in mind too given the comprehensiveness of the list is aiming for the best impact and highest impact we can have together. All of you that have participated on HITAC – forewarning for the new folks – your time is really valuable to us and this is a part of your day job now. To the degree that we're able to use your experience and your expertise to help advance something, we want to make sure that it is aimed toward the highest impact items that we possibly can.

There are a lot of different topics raised today that the HITAC can have a grading effect on in terms of the recommendations and shining a spotlight and overall discussion in industry that can occur. There are others that may be better positioned for us to figure out how to work with NCVHS or do some other type of public-private engagement like Elise noted as well. So, we'll help rack and stack and slice and dice all the various topics with you. Appreciate the total discussion today.

Carolyn Petersen - Individual - Chair
Great. Thank you both, Steve and Elise, for providing that immediate feedback for us and also to the HITAC members who have brought forth their ideas about where we should go next year. I know it seems like we finished up the final rule, but before we know, we will be starting on the next thing. It's great to have input from the full committee in terms of where we need to be looking for the next thing.

Cynthia Fisher - WaterRev, LLC - Member
This is Cynthia. I would like to comment and thank Elise regarding her mentioning patient access. A big part of this is to really deliver broad access and for patients to get their information. But I think as we move forward into 2020, it would be really helpful to also keep in mind that patient and physician relationship as it relates to this health information and look at what deliverables and timeframes and metrics and importance such as real time access and independent doctors as well as **[inaudible] [03:01:42]**, looking at imaging and how workflows can be optimized and how **[inaudible]** soft dollar costs of the challenges for patients and get their images and tests and then relaying them to physicians outside of where the original may have been.

I think we would be beneficial to embrace also into the committee some prioritization from natural end users, the consumer and the physicians that need readily available access and prioritization out of what we can deliver. I want to provide that for an opportunity to incorporate that in 2020-2021.

Carolyn Petersen - Individual - Chair
Thanks, Cynthia. I appreciate that comment. Seeing no other hands in the queue in the discussion on 2020 planning, I will hand the mic back to Lauren for the public comment.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Thank you, Carolyn. Operator, at this time, can we open the line for public comment?

Operator
Yes. If you would like to make a public comment, please press star-one on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star-two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Our first comment comes from Shelly Spiro, Pharmacy HIT Collaborative. Please proceed.

Shelly Spiro – Pharmacy HIT Collaborative
Thank you. Can you hear me okay? Okay great, thank you. My name is Shelly Spiro. Good afternoon. I'm the Executive Director of the Pharmacy HIT Collaborative, representing over 250,000 members of the majority national pharmacy associations, including pharmacy education and accreditation. Our members include key pharmacy organizations involved in health IT, including the National Council for Prescription Drug Programs or NCPDP and 17 associate members representing e-prescribing, health information networks, transaction processing networks, pharmacy companies, pharmaceutical manufacturers and other organizations that support pharmacist services.

The Pharmacy HIT Collaborative's vision is to assure US health IT infrastructure will better enable pharmacists to help optimize person-centered care. Our mission as a leading authority in pharmacy health IT, the collaborative advances and supports the use, usability, and interoperability of health IT by pharmacists to help optimize person-centered care.

A major focus of the collaborative is to ensure pharmacists in all practice settings – community health systems, hospitals, managed care, behavioral health, and long-term post-acute care are integrated into the national health IT infrastructure. On behalf of the pharmacy profession, the collaborative over the past nine years has dedicated our efforts to define the and promote the use of standards within clinical documentation systems used by pharmacists. The collaborative supports the efforts of interoperability standard priorities, task force final draft reports of the USCDI final draft recommendations.

We encourage ONC to recognize the high level of national adoption of the pharmacist electronic care plan. These efforts in the codification and standardization of pharmacist-provided clinical services is

exemplified by sharing structured and standardized data following USCDI and CCDA and FHIR standards. I respectfully submit it. Thank you. Shelly Spiro.

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

Thank you, Shelly, for your comments. Operator, do you have any other comments in the queue?

Operator

There are no comments at this time.

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

Okay. With that, I will turn it back to Carolyn for any closing remarks, Elise or Steve as well. If we get any additional public comments, I'll let you know.

Carolyn Petersen - Individual - Chair

Great. Thanks, Lauren. I want to thank all the HITAC members for the excellent work we had today in wrapping up some work related to the ISP Task Force and the USCDI Task Force work. It was great to be able to look at those final recommendations and approve those so that we can move them on to the National Coordinator.

I know I speak on Robert's behalf as well when I share our gratitude for the 2020 planning. It's really important we take an active role in our future and defining the work that we undertake as a committee. I'm very pleased to get the discussion we had today. Speaking for the Annual Report task force, we will be presenting on what we have done with the discussion at the September meeting in November and also look forward to getting your feedback on the status of the report at that time. With that, I will hand the mic back to Lauren for any other public comments and closing remarks.

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

Thanks, Carolyn. Just double-checking, do we have Robert on the line? Okay. I just wanted to remind everyone that our next meeting will be on the 13th of November. Again, that is a virtual meeting. For members of the public, you can find all of the materials from today's meeting on the HITAC page on healthit.gov. Then just a quick administrative reminder to the committee members – if you have not submitted your travel reimbursement from the meeting in September, please do so as soon as possible. That is all have. With that, I'm sure everyone will appreciate an hour or so back to your day and we will adjourn and talk again next month.

Carolyn Petersen - Individual - Chair

Thank you.

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

Thanks, everyone. Have a great day.