Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

September 9, 2020, 9:30 a.m. – 12:30 p.m. ET

VIRTUAL
# Speakers

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carolyn Petersen</td>
<td>Individual</td>
<td>Chair</td>
</tr>
<tr>
<td>Robert Wah</td>
<td>Individual</td>
<td>Chair</td>
</tr>
<tr>
<td>Michael Adcock</td>
<td>Magnolia Health</td>
<td>Member</td>
</tr>
<tr>
<td>Christina Caraballo</td>
<td>Audacious Inquiry</td>
<td>Member</td>
</tr>
<tr>
<td>Tina Esposito</td>
<td>Advocate Aurora Health</td>
<td>Member</td>
</tr>
<tr>
<td>Cynthia Fisher</td>
<td>PatientRightsAdvocate.org</td>
<td>Member</td>
</tr>
<tr>
<td>Valerie Grey</td>
<td>New York eHealth Collaborative</td>
<td>Member</td>
</tr>
<tr>
<td>Anil Jain</td>
<td>IBM Watson Health</td>
<td>Member</td>
</tr>
<tr>
<td>Jim Jirjis</td>
<td>Clinical Services Group of Hospital Corporation of America (HCA)</td>
<td>Member</td>
</tr>
<tr>
<td>John Kansky</td>
<td>Indiana Health Information Exchange</td>
<td>Member</td>
</tr>
<tr>
<td>Ken Kawamoto</td>
<td>University of Utah Health</td>
<td>Member</td>
</tr>
<tr>
<td>Steven Lane</td>
<td>Sutter Health</td>
<td>Member</td>
</tr>
<tr>
<td>Leslie Lenert</td>
<td>Medical University of South Carolina</td>
<td>Member</td>
</tr>
<tr>
<td>Arien Malec</td>
<td>Change Healthcare</td>
<td>Member</td>
</tr>
<tr>
<td>Clem McDonald</td>
<td>National Library of Medicine</td>
<td>Member</td>
</tr>
<tr>
<td>Aaron Miri</td>
<td>The University of Texas at Austin Dell Medical School and UT Health Austin</td>
<td>Member</td>
</tr>
<tr>
<td>Brett Oliver</td>
<td>Baptist Health</td>
<td>Member</td>
</tr>
<tr>
<td>Terrence O’Malley</td>
<td>Massachusetts General Hospital</td>
<td>Member</td>
</tr>
<tr>
<td>James Pantelas</td>
<td>Individual</td>
<td>Member</td>
</tr>
<tr>
<td>Raj Ratwani</td>
<td>MedStar Health</td>
<td>Member</td>
</tr>
<tr>
<td>Steve Ready</td>
<td>Norton Healthcare</td>
<td>Member</td>
</tr>
<tr>
<td>Abby Sears</td>
<td>OCHIN</td>
<td>Member</td>
</tr>
<tr>
<td>Alexis Snyder</td>
<td>Individual</td>
<td>Member</td>
</tr>
<tr>
<td>Sasha TerMaat</td>
<td>Epic</td>
<td>Member</td>
</tr>
<tr>
<td>Andrew Truscott</td>
<td>Accenture</td>
<td>Member</td>
</tr>
<tr>
<td>Sheryl Turney</td>
<td>Anthem, Inc.</td>
<td>Member</td>
</tr>
<tr>
<td>Denise Webb</td>
<td>Individual</td>
<td>Member</td>
</tr>
<tr>
<td>Amy Abernethy</td>
<td>Food and Drug Administration</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Name</td>
<td>Organization</td>
<td>Role</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>James Ellzy</td>
<td>Defense Health Agency, Department of Defense</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Adi V. Gundlapalli</td>
<td>Centers for Disease Control and Prevention</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Jonathan Nebeker</td>
<td>Department of Veterans Health Affairs</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Michelle Schreiber</td>
<td>Centers for Medicare and Medicaid Services</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Ram Sriram</td>
<td>National Institute of Standards and Technology</td>
<td>Federal Representative</td>
</tr>
<tr>
<td>Donald Rucker</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>National Coordinator</td>
</tr>
<tr>
<td>Steve Posnack</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>Deputy National Coordinator</td>
</tr>
<tr>
<td>Elise Anthony</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>Executive Director, Office of Policy</td>
</tr>
<tr>
<td>Andrew Gettinger</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>Chief Clinical Officer</td>
</tr>
<tr>
<td>Avinash Shanbhag</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>Director, Office of Technology</td>
</tr>
<tr>
<td>Lauren Richie</td>
<td>Office of the National Coordinator for Health Information Technology</td>
<td>Designated Federal Officer</td>
</tr>
<tr>
<td>Laura Conn</td>
<td>Centers for Disease Control and Prevention</td>
<td>Presenter</td>
</tr>
<tr>
<td>Alix Goss</td>
<td>Imprado Consulting, a division of DynaVet Solutions</td>
<td>Presenter</td>
</tr>
</tbody>
</table>
Call to Order/Roll Call (00:00:00)

Operator
All lines are now bridged.

Lauren Richie
Good morning. Good morning, everyone. Welcome back. I hope you all had a nice summer break as much as you were able to, and glad to have you back and looking forward to today's agenda. Just one quick housekeeping reminder. If you haven't already, and obviously some of you are already on Adobe, but just a reminder that we did send out an email with instructions for downloading and installing the latest version of Adobe 11.0. So, if you're having trouble, just make sure you're using the latest version for today's call and moving forward. So, with that I am going to get us started with roll call, starting with Carolyn Petersen.

Carolyn Petersen
Good morning.

Lauren Richie
Robert Wah.

Robert Wah
Present.

Lauren Richie
Michael Adcock.

Michael Adcock
Present.

Lauren Richie
Good morning. Christina Caraballo.

Christina Caraballo
Good morning.

Lauren Richie
Good morning. Tina Esposito. I believe she said she was going to be late. Cynthia Fisher.

Cynthia Fisher
Good morning.

Lauren Richie
Good morning. Valerie Grey.

Valerie Grey
Good morning.
Lauren Richie
Good morning. Anil Jain.

Anil Jain
Good morning.

Lauren Richie
Good morning. Jim Jirjis.

Jim Jirjis
Good morning.

Lauren Richie
Good morning. John Kansky.

John Kansky
Good morning.

Lauren Richie
Good morning. Ken Kawamoto.

Ken Kawamoto
Good morning.

Lauren Richie
Good morning. Steven Lane.

Steven Lane
Here.

Lauren Richie
Les Lenert.

Les Lenert
I’m here, thank you.

Lauren Richie
Great. Arien Malec.

Arien Malec
Good morning.

Lauren Richie
Aaron Miri
Good morning.

Lauren Richie
Brett Oliver.

Brett Oliver
Good morning.

Lauren Richie
Great. Terry O'Malley.

Terrence O'Malley
Good morning.

Lauren Richie
James Pantelas.

James Pantelas
I'm here.

Lauren Richie
Raj Ratwani.

Raj Ratwani
Good morning.

Lauren Richie

Abby Sears
Good morning.

Lauren Richie
Good morning. Alexis Snyder.

Alexis Snyder
Good morning.

Lauren Richie
Good morning. Sasha TerMaat.

Sasha TerMaat
Good morning.
Lauren Richie
Great. Andy Truscott.

Andrew Truscott
Good morning.

Lauren Richie
Great. Sheryl Turney.

Sheryl Turney
Good morning.

Lauren Richie
Great. Denise Webb.

Denise Webb
Good morning.

Lauren Richie
From CMS, Michelle Schreiber?

Michelle Schreiber
Good morning.

Lauren Richie
James Ellzy? Ram Sriram? Laura Conn?

Laura Conn
Good morning.

Lauren Richie
So, she’s on. Jonathan Nebeke? Not yet? Okay. Amy Abernathy. Adi Gundlapalli. Okay. I’ll circle back, and hopefully the others can join us a little later. Also, on the ONC side, we are joined by Dr. Rucker, our National Coordinator; Steve Posnack, or Deputy National Coordinator; Elise Sweeney Anthony, our Executive Director of Policy; Dr. Andy Gettinger, our Chief Clinical Officer; and I believe… oh, and Avinash Shanbhag, our Executive Director of Technology at ONC. So, with that, I will now turn it over to Dr. Rucker, for a few opening remarks.

Welcome Remarks (00:03:47)

Donald Rucker
Yeah, hello, everybody. Let me extend our welcome back from the summer break. I know we worked folks pretty hard last year, so hopefully the summer break made up for some of that. A couple items. Obviously COVID and the Coronavirus is I think front and center. We’re going to have an update today on
electronic case reporting on that. We do have a Web page on some things related to Health IT and COVID on our Health IT.gov website. A couple other pieces, we're going to be talking about some of the recommendations from the task force on the Intersection of Clinical and Administrative Data, which I think we see as one of the opportunities to make Health IT intrinsically and innately more efficient. A couple other things, the tech forum, I hope some of you had the chance to go to that. I know some of you did. That worked out very well, we thought. A new platform for us to try and we plan on using that in the future. We've been doing some funding activities.

Some of that includes work with HL7 as well as a funding notice for a small grant, $2.5 million in aggregate for something we were calling the STAR health information exchange program, and hope to have some awards there relatively soon. That's to advance the capabilities of HIEs which we found to be really central in getting high-quality longitudinal data in COVID as opposed to simple point-in-time reporting data. So, many of the things that you need longitudinal data for include what the course of the disease is over the population, how long does it take for positive results to turn negative, to develop immunity, things like duplicate rates, readmissions. A lot things that really require you to follow patients over time over a dense network of all different types of caregivers. So, HIEs there.

A couple of HITAC staffing announcements: As folks know, members can serve up to two terms, and we'd like to recognize Cynthia Fisher and Arien Malec, very strong contributors, both reappointed. We expect some more appointments from Congress later this fall. Our three-year terms for cochairs are coming up for Carolyn and Robert who've done just an absolutely spectacular job. Every meeting, just really amazing. They'll be stepping down as co-chairs at the end of the year, I guess the next two meetings technically. So, we're putting out a request for volunteers who might want to serve as HITAC co-chairs, and then based on that and various other policy considerations, we'll make some choices there. We'd like to get those in the next couple days, so if you're interested or want to volunteer one of your colleagues, please contact Lauren by September 16th. And with that, thanks to Robert and Carolyn. Let me turn it over to Carolyn and Robert. Thank you very much.

Carolyn Petersen
Thanks, Dr. Rucker. It's great to be coming back as a full committee after our nice three-month break over the summer, although I know for individuals who are serving on the Intersection of Clinical And Administrative Data task force and the Annual Report workgroup, it was really not time off so much as really hard focus on the work in front of us and we do appreciate all that effort put in over the summer. I think we have some interesting updates this morning to share with everyone and I'm looking forward to the meeting.

Review of Agenda and Approval of June 17, 2020 Meeting Minutes (00:08:40)

Robert Wah
Thanks, Carolyn. This is Robert, and I share the welcome to the committee coming back from our summer breaks. I don't think it was a typical summer, so I don't think everybody had a typical summer break either. I was asked to testify in the House budget committee on government IT procurement processes in July, and I appreciate Dr. Rucker's assistance in preparing that testimony for that budget committee hearing.

We have the agenda before you that you see displayed on the screen. We've already talked about the
two workgroups that we'll be discussing today as well as the presentation from CDC on the electronic case reporting. We do have a piece of business to accomplish, which is to approve the minutes of the meeting of June 17, 2020. At this point, they have been distributed for your review. Are there any comments, suggestions, or corrections to the meeting minutes? Hearing none, I'll ask your vote for approval. All those in favor of approving the June 17, 2020 meeting minutes, please signify by saying aye.

[Unanimous Aye’s]

Robert Wah
All those opposed say nay. Any abstentions? All right. They are approved. And so, I think with that we'll proceed to our first presentation by the CDC and I think we have Lauren Conn and Adi on? Is that right? I'll turn it over to them.

Centers for Disease Control and Prevention Presentation (00:10:28)

Laura Conn
Good morning. This is Laura Conn just doing a sound check.

Lauren Richie
Yes, we can hear you.

Laura Conn
Great. And I'm not sure, Adi are you on? He may be joining us a little bit later, but I'll go ahead and get started and start by thanking the HITAC and ONC for the opportunity to come back and update on the progress and success of this multi-stakeholder activity. We were here in April as we were ramping up an accelerated implementation phase for electronic case reporting. Just want to recognize along with CDC, we have strong partnerships with the Association of Public Health Labs, the Council of State and Territorial Epidemiologists, the CDC Foundation, and our state and public health agencies in order to operate the electronic case reporting activity, but also very strong engagement with our electronic health record vendors and our health care organizations in implementation. Next slide.

So, just as a reminder, or for those that may not have heard our introduction earlier in the year, electronic case reporting is about automating the mandated reporting requirement of health care providers that exists in all U.S. states and territories. This automation takes advantage of data that exists in the electronic health records and happens behind the scenes. Therefore, it doesn't interrupt care delivery. And when information of interest to public health is matched in the electronic health record, a case report is created and sent to a shared services platform that's operated by the Association for Public Health Labs, where those reports are processed and when reportable, they're delivered to the appropriate state and/or local public health agencies for action. Healthcare also receives information on the reportable condition back from public health, therefore closing the loop here between health care and public health. Next slide.

At the start of the Coronavirus pandemic, eCR was just beginning to scale beyond a few implementation sites. The eCR Now initiative identified and executed a strategic path to support acceleration of rapid implementation and remove barriers to doing eCR. Next slide. Identifiable patient level reports are critical for prompt public health investigation activities. We know that there are a number of reporting asks of
health care related to this response. There’s hospital capacity data, there's syndromic surveillance data that's aggregated data to provide situational awareness, primarily coming from emergency departments and urgent care settings. There's the electronic lab reporting or lab test result data, and while it's a patient-level data report, it often does not include contact information or other basic demographic information on the patient.

So, pairing together the electronic lab reports and the electronic case reports begins to give public health that fuller picture of the data needed to take action. So, the electronic case reports include critical clinical data for this outbreak management, including contact information to accelerate contact tracing, including race and ethnicity and comorbidities, things that have proved important to know about the cases of COVID, occupation in order to track spread in our essential workers or specific workplace settings. Travel history was important early in this response and I think as we move forward hopefully into the fall, it will be clear the importance of tracking medications and immunizations for COVID as well. Next slide.

I introduced you to these three elements of eCR Now in April, but I'm thrilled to provide an update on the progress of them today. So, the three areas are rapid cohort-based COVID eCR implementation for provider sites that had electronic health records that had capability to do electronic case reporting. The second, an eCR Now FHIR app for those healthcare organizations where their electronic health records didn't yet have capability, and the third was building a trust framework to support the appropriate exchange of this critical data between health care and public health. Next slide.

The key features of this element include organizing groups together for supporting rapid implementation and specifically implementing a standard ask for patient data. This goes back to the comment on multiple asks of data and multiple asks by different organizations, so the electronic case report was identified by all public health as the data needed for submission of reportable condition reports, and this is a standard ask for patient data. On the bottom here on the left is what I showed you in April, the initial implementation sites. They added COVID as a condition very quickly, but we knew we needed to extend to more sites. The map on the right shows the current sites that have implemented electronic case reporting for COVID. There are over 4,800 facilities now sending electronic case reports. It's pretty impressive. Let me tell you a little bit more about that. Next slide.

Some said at the start public health's not ready, but guess what? Public health got ready, and now all 50 states, D.C., and eight large local health departments can receive these electronic case reports. In fact, 57 of those 59 have received an electronic COVID case report from one of the live sites. As of the end of last week, those 4,800 plus facilities have sent over 1.65 million reportable COVID case reports to public health. Next slide. But as I said, only a limited number of EHR products had eCR capabilities ready to go in January of this year. So, the second element was identified to support those EHR products and health care organizations that didn't yet have eCR capabilities. The eCR Now FHIR app was developed such that all EHR products can now implement eCR. It works with FHIR DSTU2 and R4 APIs and is now being implemented a number of major commercial EHR products. This effort was another step to remove the barriers for implementation. Next slide.

The third element is quite remarkable. APHL has worked to build a nationwide trust framework to include the E-health exchange, care quality, common well members and those connected to them in order to enable electronic case reporting. This means that there are no additional legal agreements that need to
be put into place in order to exchange this data. There is an APHL organization agreement if an organization is not expected connected to one of these networks and there are no additional costs to implement using case reporting using these shared services. Next slide.

So, please help us add more blue pins to the coverage map. Here's the call to action. For healthcare organizations and providers, I hope that you can see the benefit of moving to electronic reporting. It will fulfill the mandated reporting requirement, reduce the burden that manual reporting puts on your organization, and can increase the communication between healthcare and public health. There's a number of steps there that can initiate the start of implementation with us. And for EHR vendors, we've been told by some vendors that until electronic case reporting is in regulation, it will not get the support of their leadership that's needed, but your clients are really asking for it. We're hearing from them every day. We are doing what we can to make implementation easier for you and for your clients, and we are asking vendors who have not made this a priority to please do so. To support COVID response for the following winter, especially with the worries of what influenza might add, we really need to get to a nationwide eCR as quickly as possible.

Next slide is our contact information. I do want to recognize Steven Lane, who's on this committee. He's been one of our premier eCR champions in helping to get the word out amongst the healthcare community and helping to recruit and support this effort. And if the committee would allow, I'd love to have Steven give his perspective on engagement in the activities that eCR has pushed forward. Thank you very much.

Robert Wah
Thanks, Laura. And I don't know; I think Adi was on the app, and I'm not sure if he was on audio as well, but I want to give a chance to Adi if he wants to add anything else besides what Laura's gone through?

Lauren Richie
Hey Robert, I don't think we have him on audio.

Robert Wah
Okay. I see him listed on the app, and I thought the pop-up said that he was in. But anyway, okay. So, let's open this up for discussion. Thank you very much to both Laura and Adi for giving us this update of this great work that's being done at the CDC on electronic case reporting. The first hand I see is Steven Lane, and thanks also to Steven for keeping us abreast on the activities of this area. Steven.

Steven Lane
Thanks, Robert, and good morning, everyone. I hear a bit of an echo there. Oh, that's better. I just wanted to really thank Laura and Adi and the whole team that's been supporting the rapid implementation and advancement of the electronic case reporting framework. It's really been an honor and a pleasure to work with that team over the past six months in advancing this, and it's really remarkable how much process has been made. I mean, those of us who have been around Health IT for a while appreciate how slowly things can turn in our world, and this has just been amazing. We went from four pilot sites at the beginning of the pandemic to now a much broader expanded network of engaged providers, public health organizations, vendors. We've been able to expand the trust framework through E-health exchange and
care quality. There are multiple technical solutions, so it's just been a remarkable progress so I'm glad that the team was able to come and share that with this committee.

As Laura said, there really is a need for increased engagement. I mean, we clearly are seeing a phenomenon that we've seen prior with EHR adoption and adoption of other technologies where the early adopters who were able to jump in and do so voluntarily have done that, and now we're at that point where there needs to be more push to help people get on board with this solution. Some of the EHR vendors as we've heard have been a little slow to engage. You know, there's now a FHIR app that can be put in very easily. A lot of providers have had trouble prioritizing this or getting it through their compliance review. I mean, our organization was able to implement this literally in three days and it's been done quicker. I think the fastest now is U.C. San Diego at two and a half days. So, it's pretty remarkable. If there were some sort of regulatory support for this that would really push people to implement it, I think it would move that much more quickly.

I do want to comment on something that Laura didn't say. The vendor engagement has been remarkable for those who have engaged, and many of them, the EHR vendors, have really gone out of their way to make this cost-free for implementation for the sake of supporting the response to the pandemic. There is also in parallel a process going on whereby the eICR HL7 standard, the document itself, is being reviewed and they're looking at whether or not there's a need to add any additional data elements to that. So, if people have comments in that regard, they should certainly contact Laura and the CDC about that. This has really been clear that there is a broad need for exchange of data between providers in public health, and eCR is one piece of that, as Laura said, along with ELR and syndromic surveillance, etcetera. There have also been some novel solutions put together leveraging standards-based interoperability to support the push of other data beyond patient-specific case reporting to send situational awareness data about capabilities, capacities from the health systems into public health.

And then just recently, there has been implemented the ability for public health to pull data as needed from provider organizations using the care quality framework. So. There’s clearly been a lot of innovation in this space to support provider public health interoperability as we’re intending to support on the TEFCA framework over time, and I think it shows a real opportunity for us to provide funding and support to advance those solutions and ideally moving towards more standardization. Today it's been very challenging for provider organizations to keep up with all of the requests and demands for data from various public health agencies and changing demands from the federal to the state to the local. I think the more we can take proven technologies such as eCR, build on them, and advance them so that folks have a single on-ramp if you will, an ability to exchange this data for these use cases, it will be most helpful.

So, thank you again, Laura, for all that you and your team have done, and thanks for the opportunity to provide some additional input.

Robert Wah
Thanks, Steven, and thanks for your help on keeping us up to date on this. Next hand I see is John Kansky

John Kansky
Thank you. Laura, in the interest of advancing eCR across the country, just a suggestion is to attempt to engage health information exchanges one at a time or as a group. and I know that that would complicate
and create kind of a hybrid approach. In Indiana, we are working with our State Department of Health at their request to respond with eCR transactions on behalf of healthcare providers across the state, because the public health department determined that would be kind of an effective way to get a lot of coverage quickly. I don't know how effective that approach would be in other states, and obviously it gets to the philosophical question of interoperability through intermediaries versus directly through point-to-point sources, so I just wanted to add that to the mix.

**Laura Conn**

Thanks, John. And we do have a number of eCR flows coming through HIEs today. We have flows in using the HIE in Wisconsin, the Kentucky HIE, and certainly taking advantage of the connections and relationships that the HIEs do have with the healthcare organizations in their jurisdictions we see as a huge advantage. I appreciate your comment.

**John Kansky**

Great. Thank you.

**Robert Wah**

Thanks, John. Next, I see Aaron Miri's hand.

**Aaron Miri**

Good morning. And Laura, good to talk to you again, and Adi as well. And I also want to recognize Dr. Lane for a lot of the help he has done behind the scenes here, helping to guide me through some of those hurdles that were identified. And so, I want to give a little bit of coloring on exactly what some of those challenges are as an organization and navigating some of those as well as I also had a follow-up question for you, Laura. But regarding the overall experience, so about a month and a half, two months ago, we did try to embark here at UT Austin going down the route of implementing eCR and working with our respective vendors in the community to get that done.

What's amazing and interesting is even before you get to electronic case reporting, the importance of public health data and how that's used and the disparity there with public health data, what we found is often missed in that people, whether they're in the public health authority side or they're even at the vendor side, don't understand that some of these public health elements, a lot of the stuff that we have talked to the USCDI group and others here on the HITAC. They just simply don't understand. And so, when you present to the EMR vendors that maybe aren't as readily on board, "Hey, this is what's important," you get a reluctant, "Well, that's great, but we have this pipeline of other stuff we have to do first. So much so that for all of you that know me on the HITAC, I don't take no for an answer, and so we kept going all the way up the chain to the very top to say, "Hey, what is the deal here, right?"

In the case of UT Austin, we have brought back all of our students. We have Longhorn football kicking off this Saturday. My team is in charge of all the contact tracing for that effort, and in tying back to the public health authority here. This would have made things a lot simpler and saved hours and hours and hours of work on that side, as well as the patient care side. But to that end, it took us even explaining how public health data even works and the predominance of fax machines still in the industry for us to even get to the conversation of eCR. So, I say all this for the HITAC's benefit of understanding that for each of you that are in the position to leading a prospective health enterprise of some sort, to be able to transmit data,
we have got to think of a way to create a little cheat sheet of conversation and make this a conversation so that eCR becomes a priority, because this absolutely would make a difference.

I applaud the CDC for going out there and really trying to blaze trails with each of us and all of the organizations and make things happen, but it's going to take a collective effort around public health. To what Dr. Lane was saying, even potential regulatory or legal items to enforce and mandate this. Public health information exchange has been a mess, and I've been not holding back my opinion on this for the past six months during our various HITAC calls. But this is an opportunity for us to really shine. Now, for Laura, a question for you that I have a follow-up: you alluded to common well and care quality and conversations there. Is that something that is definitely on the near-term horizon? Because that may be a way to get around some of these barriers that we're having with respect to vendors.

Laura Conn
So, the trust network for those in those networks is in place today, and actually, Steven can probably speak more eloquently than I being the chair of care quality and the work that was done there, but from a readiness standpoint, those networks are usable today

Aaron Miri
Great. Thank you.

Steven Lane
I agree. And if you have any issues, Aaron, just let me know. We have been incredibly flexible and responsive in terms of putting that trust framework into place, and care quality is very open to making changes as needed. So, just let me know.

Aaron Miri
All right. I'll be back in touch. Thanks, Steven.

Laura Conn
Thanks, Aaron.

Robert Wah
Great. Thanks. Next, Raj.

Raj Ratwani
Thanks Robert. Raj Ratwani from MedStar Health. So, my question, I think, builds off of what Aaron was just describing and what Steven was talking about. So, as I hear the presentation, this seems like a no-brainer in so many ways and so I'm wondering about what are some of the barriers here? And what's the challenge to wider spread adoption, whether we know that? So, if you think about organizations that have maybe considered eCR but didn't fully engage, do we know what some of those primary barriers are? Then perhaps we can have a broader discussion about how the HITAC can support overcoming those barriers.

Robert Wah
Laura, do you want to take that on? It looks like Steven may want to comment on it as well.

Laura Conn
Sure. And to be honest, I feel like that when we've been able to engage in that dialogue, in that conversation as Aaron spoke to, we have been able to move the dial forward with implementation. For those organizations that haven't that we've talked to have been primarily a resource constraint in that pulling together the team that was needed. In fact, we encountered one that had actually furloughed their informatics staff. And so, while there was interest, they just didn't have the capability. But from an interest and an understanding and a sort of no-brainer standpoint, I think you're right on. I think it's getting to the right organizations and the right people in those organizations that can make the decision to move it forward. Steven, do you want to add to that?

Steven Lane
Yeah, I think capability is a key issue. Prioritization is another, and I think the distraction, frankly, that providers are experiencing by the varied and changed demands for data in the context of the pandemic. The other thing is really how do you align incentive? In California, for example, our state public health department has really been struggling to keep up with the demands related COVID. They already had some technology challenges going into this and while they were engaged in one of the early digital privilege pilots, once we shifted to doing rapid implementation of COVID-19 specific electronic case reporting, it really sort of has pushed them close to the brink along with everything else that they've been having to deal with. So much so that in California we still have not been given permission to stop our parallel manual reporting process for COVID-19 or any other reportable diseases.

There are other states where the health departments have been able to get to the point they've analyzed the data coming in through eCR, have said that yes indeed this is sufficient for our case reporting requirements, and they said, "You can stop the parallel manual process." So, here again, there may be an opportunity for regulation to encourage folks over that hump. I mean, one of the things that I've learned in doing this over the last six months is the tremendous diversity and independence of the public health agencies with regard to what they can and do demand and how they want to receive their data, but there is really a crying need for standardization in public health reporting and data exchange bidirectionally. I think the eCR standard is a great opportunity and something that we can build on, along with the established EMR and syndromic surveillance feeds.

But I think that's one of the big challenges is for a provider organization even in the absence of fees to support the implementation and maintenance of this connectivity in the absence of a direct benefit of being able to stop their current burdensome, expensive, and unreliable manual reporting process. It's a hard sell beyond the initial enthusiastic adopters.

Robert Wah
Great. Thanks. Raj, did you want to come back on something here?

Raj Ratwani
Yeah. I had my hand raised. So, yeah. So, those are really, really great comments and so I sort of heard three things there. I heard a prioritization challenge, which I fully recognize, and I think that's an important one for us to think through, incentives, and then capabilities. I think the first two, prioritization and
incentives, those are challenging ones that in many ways can be organizationally specific and maybe harder for something like the HITAC and the ONC to address but there are certainly ways do that. Capability is one that is really troubling to me because what I think and others have articulated before through research and other means is that as things like eCR and other apps that need to integrate with EHR rise, those organizations, those healthcare facilities and healthcare systems, that have the capability will be able to leverage those. And those that don't cannot, which is an obvious statement.

But what maybe is not so obvious is that widens the discrepancy and disparity in what we can deliver to our patients. So, there's a big opportunity there for us to do something to enhance the capabilities for the organizations that don't have it so that when things like eCR arise, everybody has the necessary capability to tackle this if they so choose. So, I would love any thoughts on that if people have them, but we're seeing this in many fronts, you know. A new app of some sort, a smart app is developed, or a new capability is developed, or a new mechanism's developed, it needs to be integrated with the EHR and the big healthcare systems that have the resources and capabilities can do it, and the rest cannot. And that continues to be a really big struggle here.

Robert Wah
Thanks, Raj. Next I see Denise Webb.

Denise Webb
Yes. Good morning. This is Denise Webb. Laura, thank you for all the work that you and your team have been doing on eCR, and I certainly, having worked previously in public health here in Wisconsin, appreciate the importance of public health reporting and public health getting the data they need to do the job before them. I know you noted that Wisconsin is one of the HIEs that is participating in this endeavor in terms of getting the public health data they need, and that has been a goal and a vision for Wisconsin to reduce the number of point-to-point interfaces and the burden on the health system and healthcare providers in terms of getting data to public health. So, we had leveraged the HIE here quite heavily.

But I just recently in the last two weeks joined as an interim CIO at a specialty clinic in Indiana that serves a number of patients statewide, and I know these smaller clinics are challenged from a resource standpoint, and it really also comes down to the cooperation of the vendor. So, I'm really curious on whether there is a published list somewhere that indicates which vendors besides the two big vendors mentioned in your slide are actually participating and making changes to make eCR work. And also, to acknowledge that the pandemic has created challenges especially for these smaller clinics that just have limited resources but have all the same types of systems that they have to support. So, I'd like to facilitate this for this group that I'm working with, but kind of need to understand who, which vendors are really working on this and which aren't.

Robert Wah
Thanks, Denise. Laura, do you want to respond to the list of vendors that she's talking about, or any other comments?

Laura Conn
Yeah. We're working with a number of vendors. I'd be happy to talk to you individually, any of you, about the space where your vendor is and/or go with you to talk with your vendor about their capabilities. We
haven't published a list publicly of where their capabilities are. I think we're trying to go about this collaboratively and work together, and a number of them do have plans and are in the works, but also still communicating with them to please prioritize and accelerate the implementation of their capabilities.

**Denise Webb**
That would be great to have a conversation offline sometime after this meeting because I know even as John pointed out the importance of the capabilities that the HIEs have in helping with this, it still requires the cooperation of the vendor community even to go through the HIE. So, yeah. I appreciate it. Thanks.

**Robert Wah**
Thanks, Denise. Arien Malec, next.

**Arien Malec**
Thank you for that and thank you, Laura for the presentation, for all the work that the team has done. It's just been really tremendous work. Just to pull the thread on a number of the comments, when we looked at eCR in the context of the Duke-Margolis report on interoperability for public health and COVID, our framework was obvious things that you could do in the next month. And we looked at ECR, and it was just right outside the threshold. I think right now it definitely falls in the obvious things you can do and should do this month. Now, I want to sort of connect the dots on the importance of case reporting for – I think sometimes people look at public health and their eyes glaze over. And even in the time of COVID, there are so many things going on at public health and their eyes glaze over. And even in the time of COVID, there are so many things going on that connecting the dots is hard for people, but this capability combined with electronic lab reporting is the difference between the ability to detect a case but let community spread continue and the ability to detect a case and quickly conduct case investigation contact tracing and get ahead of community spread and reduce the replication number.

And so, I don't think it's too much to say that capabilities like eCR now are a critical part of the return to work, return to relative economic normalcy, until we have widespread vaccination. Which brings me to maybe the second thread. So, one thread to pull on is better establish the why so that we can help address some of the prioritization issues between EHRs and health systems that have too many demands and too many things they're being asked to do. And as a health system, I would expect that getting patients into clinic, getting patients into practice has both mission and margin implications. And again, anything that can be done to address community spread is net good for both mission and margin. The second thing is the prioritization, and I think it would be incredibly helpful for ONC with CDC and with the White House task force on Coronavirus to publish a roadmap and help organizations prioritize all of the capability that they're being asked to do, because almost all these organizations have N number of units of work and are being asked for N plus infinity amount of labor.

With respect to incentives, I think the regulatory timelines for putting things into a certification process are long and involved and requires things like in the best case IFRs and the worst case long comment periods, but it would be helpful to publish, again, accelerated guides, talk about roadmaps for certification, provide the bread crumbs for organizations that are wondering how to prioritize this to let them know that there are certification approaches coming into place. And the last one is a mix of a set of recommendations both for Congress and for the White House, but there are areas where granting capabilities both to public health authorities and to provider organizations, again in conjunction with a roadmap, would be extraordinarily helpful for addressing some of the resource limitations and constraints,
particularly on underserved populations or organizations without the financial wherewithal to get this work done.

So, like a lot of things, there's almost an infinite set of things we could do. I think it would be helpful to put together a prioritized list and then start arranging all of the metaphoric levels of power in a consistent direction. And in my experience, that kind of work drives slow but steady progress and it's pretty clear that slow but steady progress is what we're going to get in this crisis. So, thank you very much and thank you for the CDC team for all the work you've done. I believe it's incredibly important for helping us all return to work and relative normalcy. Thanks so much.

**Robert Wah**
Thanks, Arien. We're running a little bit over, but we think we've got enough time in our schedule and this has been a great conversation, so we're going to go ahead and continue. Les, I know you probably have some comments about your CDC colleagues here, so let's go to Les next.

**Leslie Lenert**
Thank you. Yeah, so I really think that this is outstanding work, and particularly the depth of the number of organizations that are reporting and the ability to get a clear nationwide picture as to what's going on with the pandemic. So, I have two question areas. One is as we're sort of more about the maturity of the system, what have you been able to learn about the data quality, and where are the gaps in that currently? And that data quality having two attributes, both the accuracy of the terms, and then the timeliness and the lag in the reporting, and whether the impact that electronic reporting has had on the availability of timely data both at a local and at a national level?

And Laura, again, congratulations. This is just absolutely outstanding. And then the second question is as we look to create this integrated network that looks at not only the extent to which COVID is ravaging our country, but our ability to respond and the capacity that we have to respond, what opportunities for improving the efficiency for health care providers do we have by merging sort of these efforts for eCR with a reporting hospital capacity through an HSN or other federal pools that allow an assessment of the not only how many cases we have at any one particular time, but the severity of those cases and the demands that they are posing and are likely to pose on the health care system?

**Robert Wah**
Laura, do you want to take this?

**Laura Conn**
Sure. Thanks. Les, I appreciate your comments. On the data quality, we are doing a few things. One is that as we're implementing, we're doing some initial checks and have an ongoing dialogue with the production site and the public health agencies receiving those data for obvious things that need to be addressed. In the middle term I would say – and it's underway – we have an evaluation plan in place and we are working on getting data sharing agreements in place with some public health agencies in order to share data with an evaluation team that has been supported by the CDC Foundation in order to do a deeper dive into the accuracy and timeliness questions.
Anecdotally, I have things that I can share from New York City or from Utah where the case reports were coming in before the lab reports because the lab reports are batched and then they were the next morning able to connect those and have the contact information and could immediately start doing contact tracing, as opposed relying only on the lab reports and having to start the calls back to the provider to get the patient information in order to make those calls. So, we certainly want to do this in a more systematic way and get the word out there. I would say we're sort of midstream of that initial evaluation currently.

Your second question related to how do we integrate all these data streams and hospital capacity, eCR has been actually for the last couple months having many conversations with the National Healthcare Safety Network and how can eCR help identify cases that would need to be reported into these other data streams, and how should this work together. So, I think you're right on in your question. We're having those discussions. If there are those that have additional thinking and want to participate and join us in discussions of how do we take advantage of the data, both the data ask or reduce the data ask and take advantage of the data sources that are out there in order to help integrate these data to answer these questions, please do contact me. We are working on this exact topic as we speak.

Robert Wah
Great. Thanks, Laura. I think we'll start wrapping this up. Aaron and Denise, we'll start with Aaron.

Aaron Miri
Yeah, just really quick. So, just a couple things I want to articulate because I think Raj put up a few points here and Denise asked a question. So, Denise, the only way to answer your question quickly would be to look at the EHR vendors that actually have FHIR capability. I want to say in one of our hakas, there was actually a great document that was put together that actually kind of laid that out. I want to say it was either the interoperability one or the TEFCA one. That would also answer the question. The biggest technical challenge in talking to some of these vendors that I've realized, and I've gone all the way up to the head of product to figure out what is going on is, that they have technical debt they have to overcome before they can even implement a FHIR app of any sorts, and you're looking at middle of next year for some of them before they can even consider it, much less prioritize it. So, I think there are a lot of considerations here that have to be given.

The other angle to this, to answer now Raj's question, is around patient safety. In this case, it's about timeliness of detection and response. I'll give you a real-world example. So, one of the issues you're seeing colleges across the country that are doing contact tracing and surveillance on their students coming back is the fact that making sure you get lab results and that you do the contact tracing immediately thereafter and that time doesn't get away with you. You still have to transmit that data to the public health authority and vice versa, and then mash the results together to figure out what is my true N number of infected people, what's going on, and where did they come from, particularly the students who are transitory of any sorts. So, there's a lot of risk here by the delay of time and thus exposure to the public if you don't get in front of this. That's a huge value proposition for eCR.

And if you go before COVID-19, it was the vaping crisis, right? And we had a major issue here in Texas we were trying to get in front of, and I can go all the way back to the day of Zika and Ebola and all these things about time dependency. So, Raj, to your point, it is about the exactly the same arguments you
made very articulately around EHR safety. It is about patient safety and making sure it's the right place, right time, and matches the political aim appropriately. Thank you.

Robert Wah
Great. I'm trying to figure out, Abby Sears, do you have your hand up?

Abby Sears
I did. I just wanted to add that we're doing this in a lot of states and we're seeing a lot of what Steven Lane kind of spoke to around in some cases we're able to reduce the manual entry for our provider groups, and in other places they're still being required to manually enter. So, I think there are some real opportunities there. I think the second thing I wanted to add was we're really struggling with patient matching related to some of this. Our matching rates are impacted with equity issues because our Latino and our Black Americans both are not matching at the same rates as our White population. So, that's continuing to be a little bit of a struggle for us and we're trying to find pathways to improve that.

And the other thing I would say is that this is working so well, and the opportunity is so immense that we're really excited about continuing work around not just COVID-related activity, but really beginning the process of strengthening this infrastructure on a national framework for movement of surveillance data beyond just COVID as well. And so, I think the long-term opportunity here is huge, and obviously the imminent pandemic is what we're all very focused on, but there's a lot more that we can do with this and I think Laura and the CDC team have done just an absolutely fantastic job. And the leadership of Steven and others of helping us, really show that this can be done really pretty swiftly and pretty low resource requirement. But the thing we really have to kind of contend with is if you can't match up the patients, then there is an inherent risk in that as well, and we've got keep working through that.

Robert Wah
Thanks, Abby. Our last comment from Denise.

Denise Webb
Yes. Thank you. In fact, my comment and question was related to the patient matching that Abby just talked about. I believe ONC conducted its last listening session, wasn't it Monday this week? On the patient identity, patient matching, and is likely in the process of preparing its report back to Congress and recommendations. And hopefully, I think Laura did present at one of those listening sessions and hopefully this information is going to shake some of the recommendation that might influence removing that ban that is currently in place related to appropriations from spending any money on solving this problem, because it really does come down to patient safety and quality of care. So, just wanted to make sure that that's being reflected in the report that's going forth.

Robert Wah
Okay. Great. Well, thank you, Laura and I know Adi has been online listening and commenting on the public comment line but not on the audio. So, thank you both for this presentation. As you can see, there's a lot interest on behalf of the committee and I think on behalf of all of us as physicians, providers, and patients, so we appreciate all of this.

Next, we have the workgroup on the Annual Report, and so I'll call on Aaron Miri and Carolyn as co-chairs
for that to present the next session. I also want to thank everyone that's been writing to me on the private chat line about an update for the Commons Project, and I'll post something in the public comment area in a little bit about the update on that, so I won't take time away from the meeting. With that, I'll turn it over to Aaron and Carolyn.

**Cynthia Fisher**
Hey, Robert.

**Robert Wah**
Yes?

**Cynthia Fisher**
This is Cynthia Fisher. I can't get into the screen to raise my hand, so I just wanted to make a mention as we go to this contact tracing and we go to the possibilities of this big data share, I do think there's worthwhile conversation and more than the conversation is the risk of substantial loss of privacy that people are really unaware of. I think the Zika pregnancy reporting is one that most women had absolutely no idea, but now we're into contact tracing, and at which point on the slippery slope does it stop and go into reverse? And I just want to put out there that one could imagine malicious intent of other aggressive countries, of some form of terrorism, of some form of traceability that would be really a non-appropriate outcome of all of this too. So, I think that protections for people and their privacies and their ability I think is worthy of a big, big plan from both CDC and HHS. I would just pose that for Dr. Rucker to say that I don't think that most people are aware of how much privacy has been lost in all this process and the point of no return.

**Robert Wah**
Thank you, Cynthia. I realize that's a tangent to this electronic case reporting, but I do appreciate your comment. I don't think we're going to be having a conversation about privacy specifically right now. We're a little bit out of time and I hate to cut you off, but I still appreciate your comment and it will be noted, and I think it's a topic that we will continue to discuss in this forum. But I would like to go ahead and turn it over to Aaron and Carolyn for their report on the Annual Report workgroup. Actually, before I do that, I want to make sure if anybody is not on the app and can't raise their hand but is on the committee and just on the phone, do exactly what Cynthia just did, which is just call out and we'll get you recognized. Thank you. Aaron and Carolyn, why don't you take it from here.

**HITAC Annual Report Workgroup Update (01:01:40)**

**Carolyn Petersen**
Go ahead, Aaron

**Aaron Miri**
Okay. All right. Well, welcome, everybody. I think we just had our blip for the week hopefully there. Pleased to present to you guys our update on the Annual Report workgroup. Again, I want to thank everybody's efforts here and that great discussion that we just got through with a very salient topic. I think those and others that we have been discussing here on the HITAC are reflected in this report in this update, and so again I want to thank all of you and I hope you are all staying safe and sound, your families are staying safe and sound during these times. Carolyn, anything you want to add?
Carolyn Petersen
Just really excited to be able to present the latest report on where we are at with the Annual Report and looking for more feedback.

Aaron Miri
Yeah, all right. Let's go into it then. Next slide, please. All right. So, in our workgroup update today, we'll just go through meeting schedules and next steps, of course a discussion of potential topics list which is what you all are interested in, for our report that's due this coming up spring. Next slide. These are all the folks who are part of the workgroup. I can tell you that they have been doing phenomenal work and I always say this, and I always feel like I'm not doing it justice. I really appreciate the ONC team, everybody on this list, and then a whole lot of people not on this list helping have been just been working insurmountable hours doing research and figuring out what some of these dynamics are. Just like we went into the depth on public health reporting just a few minutes ago, each topic is talked about and debated just like that, so I appreciate everybody on this list and those who aren't even mentioned on this list. Next slide.

All right. Next slide. So, this is our meeting schedules for the workgroup. Obviously, we have another one coming up here on the 16th and the 30th of this month, but we definitely want to take a few moments to update the general HITAC and also to continue to please encourage to you send in your thoughts and comments as they come up. Even if they aren't for this report for this year due to a respective item, they are put on a parking lot. So, your feedback is definitely appreciated, it's important, and we take note of everybody's comments. They're very important to us so that everybody feels heard and the HITAC really has a cumulative work product at the end of the year. Next slide.

And then, for the full committee obviously, we're updating you guys today on the 9th and on the 21st we'll be coming back with even more meat on the bone. And in November, hopefully as we review the draft and approve it come early Q1 of next year. Next slide. So, our next steps here are we're going to be developing the draft crosswalk of topics with the gaps, opportunities, and recommended activities across all the target areas of the workgroup. And of course, we'll bring this back to you all on October 21st of this year to talk about it with the larger HITAC. So, with that let's kind of get into some of the meat here. Next slide.

So, one of the target areas here is technologies that support public health. Imagine that. We're going to be mentioning items here around the exchange of clinical data for public health purposes, privacy and security for public health purposes, vaccine tracking – which obviously will be a very important topic here in the very near future – patient matching for public health purposes, and also the international exchange of clinical data for public health purposes. That goes along the lines of cyber security, privacy, varying international law, those sorts of things. Next slide.

Around interoperability, we're looking at the items here around the exchange of health data, more broadly along the healthcare continuum, of long term post-acute care, behavioral health, and some home and community-based services; looking at the association between EHRs and patient safety; exchange of social determinants of health data (SDOH); increased health equity across populations, locations, and situations; sharing data with research community; establishment of a common metadata nomenclature
and use; and correction of incorrect data and the ramifications of exchange of incorrect data. As you can imagine, public health and interoperability go hand in hand as we just spoke about. So, a lot of these items I think, with that previous conversation in mind, can pop in your head various scenarios that can occur as these issues play out. After this item, I'm actually going to turn it over to Carolyn if you want to pick the ball up from here.

Carolyn Petersen

Great. Thanks. If we could have the next slide, please. So, this brings us back to another few topics in another of our target areas, privacy, and security. Again, we're looking at protections for data generated outside of the HIPAA framework, including federal privacy laws and regulations beyond HIPAA. In this case, certainly patient-generated health data is part of that, but also other things that are coming out of some of the new technologies that are going into place related to COVID and other innovations. There is privacy and security of synthetic data and also the Internet of things. Next slide, please. And in the target area of patient access to information, here we have patient-controlled data collection, access, and sharing. And, again, this has do with the right of patients to be able to access their information and also to direct where that will be shared and the permissions and other things that are associated with that. Next slide, please.

We also have some topics that we carried forward from last year's report. If you will recall, there were things that came up that either were still too new and emergent to really be included meaningfully in the Annual Report, and also some other ideas that didn't seem to fit directly into the Health IT sphere, but were things that we wanted to keep on the radar in case those were issues were going forward. And here, we'll just briefly mention those again. In the area of interoperability, that would be federal activities including the ONC Cures Act final rule and the TEFCA program, health information exchange standards, the unique device identifier, Health IT support for opioid epidemic response. I know it's been some time since the workgroup was looking at some of that. And patient matching and verification. And then on the next slide, please.

A few more topics to look at in the landscape analysis from the previous report. Under privacy and security, we have international and state data exchange and privacy considerations. That would include the effect of things like the JDPR and the California Protection Act as well as potentially other state legislation, cyber security, and machine learning and artificial intelligence in healthcare. And finally coming to patient access to information, the use and sharing of PGHD and the prescription of apps that is sometimes referred to a digiceuticals in some areas. The next slide, please.

So, this is just a very brief roundup of some of the work we've been doing in our meetings. We have one next week. We would welcome your attendance if you are able to do that. We also encourage you to send us feedback about these topics by e-mail. We've had several discussions within the full HITAC over the last few months and of course last fall where we acquired some of these topics we're carrying forward, and we feel that we are really starting to narrow it down and focus on the text of the document and put some scope around it, some limitations. But we're very eager to get any feedback you have by email. So again, that can come to Aaron and I or to Lauren, who will pass it on to us. And I see we have Val's hand up. Do you have a question?

Valerie Grey
Hi, Carolyn. Yeah, it's Val, and I'm sorry, it sounds like you're most interested in getting feedback by e-mail. I just had a quick recommendation that we consider telehealth under the interoperability topics of interest. I think it's a very timely topic, and I think that it would be really interesting to learn more about how much of telehealth that's delivered is integrated with EHRs and HIE, and how much is sort of potentially occurring in data silos.

Carolyn Petersen
Thanks, Val. We do have that included in the landscape analysis already, but we appreciate hearing that you support that, because we also think that it's a pretty big deal, especially here with regard to everything that's been happening with COVID. But thank you. Did you have any other thoughts, Aaron?

Aaron Miri
No, I want to echo exactly what you said, but I also want two seconds, and I've been doing this every meeting just to kind of get telemetry back. But thank you, Dr. Rucker, and to the administration of all of HHS. As you heard from the CDC earlier to this, from a provider healthcare perspective, there's a lot of things we didn't know about COVID, a lot of things we still don't know about COVID, but I appreciate the federal agency's response in trying to help us, boots on the ground. And so, these Annual Report workgroups, as we meet and go through items, it's interesting how many of these topics intersect items that a lot of us have just been barreling through and trying to get to the other side. And so, I just want to take a second and also thank all of HHS, because it has been making a difference. It really has been.

Carolyn Petersen
Well, thank you all for your attention. We do appreciate any input or feedback you have via email. And with that, I will hand the mic back to Robert for the next presentation

Robert Wah
Okay. Thank you, Carolyn and thank you, Aaron for your work on this committee, along with all the rest of your workgroup members. Our final presentation is on the Intersection of Clinical and Administrative Data, and that task force has some draft recommendations they will be discussing, so I'll turn it over to Sheryl Turney and Alix Goss.

Intersection of Clinical and Administrative Data Task Force Draft Recommendations (01:12:47)

Sheryl Turney
Thank you, Robert. Okay. This is Sheryl Turney, and Alix is my co-chair. I represent HITAC and she is a member of NCVHS, so we thank you all for the ability to present to you today. We can go to the next slide. In our agenda today, we're going to review our charge, the task force members, as well as highlight our guiding principles and ideal state that we put together. And also we're going to review our draft recommendations, and then solicit your feedback and questions. All right. If we could go to the next slide.

On this slide, you'll see the task force charge, both the detailed charge and the overarching charge. The focus has really been up to this point on our focus area, which was prior authorizations, and we are currently at the point where we are broadening that discussion to include the broader intersection of clinical and administrative data. As you may know, our task force has been a little bit different than some
of the others that have come before HITAC, because we're not responding to a single paper or recommendation. We're creating the paper. And so, it has been a little bit of a challenge in terms of doing that, but I'm going to tell you a little bit more about how we went about this challenge as we move forward.

So, we can go to the next slide. This represents the list of task force members, and we really want to thank all of the HITAC and NCVHS, as well as other folks from ONC and other aspects of the HHS who have participated in our work. Our task force has also heard from quite a number of groups. Those include the American Health Insurance Plans (AHIP), AHIMA, which is the American Health Information Management Association. We've heard from AMA, CAQH CORE, CMS, CoverMyMeds, EHRA, which is the Electronic Health Records Association. Humana, Premier Inc., Regions, Surescripts, and X12. They've all presented to our task force, but also we've received written input from a number of other stakeholders as well, and we're taking all of those into account as we've looked at the current landscape.

If you can go to the next slide, I'm going to describe a little bit about what our report outline looks like. In our last meeting, we talked a little bit about our scope and approach, and in today's meeting we're going to talk a little bit more about what our guiding principles and ideal state are for the intersection of clinical administrative data, and also really provide an overview of each of the recommendations that have come out of our discussions to date. This is really important because as we've looked at this problem, there has been a lot of material that's been presented, stories that have been shared, use cases that have been looked at. And pivoting to the broader intersection of clinical and administrative data has really been the key, and really required the foundational components that we had put together already for the prior authorization focus, which allowed people to look at something a little bit more real from the perspective of how the interaction occurs with both the clinical, administrative, and other healthcare constituents that are involved in the process.

So, next I want to move to the next slide, which is going to talk a little bit about the ideal state. And with this process that I talked about, as you may recall what we reported previously is that we had small groups that formed as a result of our task force, and we really put together a basic clinical workflow and sort of used that diagram. It was based on a durable medical equipment to help drive the data classes and understanding of the current standards and the current state, the issues that come up in the process in the work flows and all of the different systems that support the process from start to finish that are all very disparate. So, these are what drove these guiding principles in ideal state, and essentially what you see on this slide is really the ideal state that we have crafted for the work on prior authorization, which is really an end to end closed loop process, reduces the burden across all stakeholders including not only the patient and the clinician, the care, and also all of the other ancillary care providers in the spectrum including caregivers.

We looked at creating an environment where it accounts for the vast majority of situations, it leverages existing investments, and then we tried to put the appropriate knowledge where it needs to be and to identify gaps that need to be closed. All right. We can go to the next slide. So, as a result of this, we created an outline, if you will, of the guiding principles that were going to guide us in our work. And the guiding principles really focus on patient at the center. Patient at the center is really the ability for our process solutions to remove roadblocks, support the coordination of timely care, reduce burden, and improve the patient experience, and ultimately improve the outcomes.
Now, we saw that there were a number of principles that need to be in place in order to achieve this guiding principle. No. 1 would be to reduce the burden on the patient or the caregiver so that they don't have to be the driving force in terms of moving the prior authorization forward, and increase that ability for transparency so that there are less variations that are not aware for the patient, so that cost information can be more specific and more accurate when they look at cost, so that decision making for treatment options between the clinician and the patient can be considered, and so any restrictions due to prior authorization and denials and work that's required in order to reverse a denial can be addressed up front.

Also, this idea was to look at multiple insurance plans and see how they account for the coordination of benefits and how that is handled within the patient center to lessen the burden on the patient and then to look at tools that exist or patients that will less burden and provide solutions to overcome either digital gaps or gaps in access or socioeconomic and literacy barriers. because all of those currently exist and are things that patients are having to deal with it in addition to trying to get that care.

Then we looked at transparency. Transparency with the goal of increasing patient and provider access to real-time information so that when you're looking at the status of a prior authorization, all of the care continuum participants can see what the status of that prior authorization is and not just know that it's just pended, but understand what's missing, what data needs to be collected, and where that is in the process in terms of decision making if it can't be made immediately or near real time. And then ensuring the providers and patients have access to this information along the care continuum and the prior authorization approval process.

Then we looked at real-time data capture and workflow automation. Here, the idea is not to increase burden but where data is presented initially if possible, it should be captured and reused when it makes sense. Sometimes it doesn't, and we discussed that at length as well, but the idea being that if we can capture and reuse as much as possible, that's going to reduce the burden on all of the participants in the care continuum. And the idea here is to regardless of the venue, hopefully the prior authorization process should be able to be handled in a similar fashion. So, just because you have a different EMR system or just because you have a different payer system, hopefully the ability to connect that data at the member level is going to allow the process by which a provider or a patient has to interact with the system to be consistent across all of that care continuum.

And then looking at the work flows that are geared to support these processes, also ensuring that there is this understandable path and that all the participants in the care continuum have the ability to understand what the work flow is and what the insurance coverages are and what is required in order to support the justification for that prior authorization process. Some of which can be generated by an EMR system, some which may not be able to be. And when data cannot be supported based on what's generated in the system, how would that be created to the degree that it minimizes the burden on all of those that have to collect that data.

And so, the idea is that in the ideal state, we should have hopefully a minimum of prior authorization transactions. We did acknowledge that a lot of movement to value-based payment is lessening the burden for prior authorizations, and many payers are eliminating those burdens in those types of arrangements. So obviously, the ideal state would be to have the minimum set of procedures require prior authorization, and then those procedures that do require it have known data requirements and the ability
to know where that data should come from should be obvious and also easy to collect so that the provider and the patient can provide the data upon which a decision will be made.

Then the next component, looking again from left to right here, is measurable and meaningful. Here we’re looking at processes that will be measurable so it can be tracked over time, the idea being that there is currently a significant burden that everyone has spoken about and much has been written about both the patient and the provider and the payers as well, in terms of having burdens. So, the prior authorization process reform and improvements should really be driven so that patient safety is taken into account, it's evidence-based medicine, and reducing burden across all the stakeholders. Also, any measurements of burden should be quantifiable and reflect real-world evidence or real-world experience of stakeholders so that hopefully after these recommendations are put in place, there is some evidence that the burden has been reduced and that there is clear improvement in the process.

Then also looking at how prior authorization responses should be tracked in order to provide some sort of metrics or surveys and recognition some prior authorization transactions may not be feasible to be fully electronically supported for one reason or another, but the goal of the ideal state should be not to default to what happens in a current legacy systems, which often requires phone calls or general pends of prior authorizations or a lot of faxed material that doesn't always go to the right place.

Then we’re looking at continuous improvement. So, the prior authorization process should embrace a concept of evidence-based data driven continuous improvement, really a learning health care system as we talked about at HITAC and others over time. In order to support this principle, we really looked at a standard framework should be developed to provide transparency for decision rules that govern the prior authorization process and for reducing burden among stakeholders. This will be very important to help establish processes that might need to be regularly reviewed. There was a lot of talk about how often prior authorization rules are changed, and how that's communicated to providers and patients over time and minimizing again the burden that comes with that process, and that payer review and communication processes should be established with some kind of cadence for an update process.

And then the next item that we looked at was really information security and privacy. Really this guiding principle focused on the foundation that security and privacy considerations are really intended to benefit this design of processes and technologies. There's a lot going on in this area right now which we have talked about in this forum and other forums that we have looked at, but in order to support this principle, the ideal state really should include the adherence to current health information and patient rights. The laws and regulations that impact these, like HIPAA, the privacy and security breach notification rules, 42 CFR, Part II Confidentiality, Substance Abuse Disorder in Patient Records. And the complexity of this is impacted by state laws, and in some cases there's data use agreements between health care providers and clinicians.

At the end of the day, the objective should be that we focus on minimum necessary data sharing, and that that data should be verified and authenticated in a way that is able to be standardized so that multiple systems that have to utilize that same data are able to authenticate the person across the spectrum. We have many things today like the interoperability rule that speak to all of those things still developing processes in order to ensure authentication and credentialing occurs in an appropriate way. But
harmonizing federal regulations primarily which govern these types of activities is really going to be important.

And then the next item we talked about was aligning to national standards. As we have noted and this HITAC has noted, there are many standards today that impact the ability to share clinical administrative data. We have all of the payment transactions that have standards. We have HL7 that has standards and implementation guides. There are standards within the USCDI, and the ISA has standards. And there's many codes that have standards related to them. But still with all these standards, there's inconsistencies relative to how the payment information and the information for clinical reporting align when you're submitting data for prior authorization. So, looking at how we align standards and standardizing the data in the code sets in order to improve the process, and standardizing attachments to support data that is required in order to make or support decision making is going to be really important. And then educating all of the healthcare participants in the process relative to the harmonized standards is also going to be an important factor.

And then finally, last but not least, designing for the future while solving the needs of today. The idea that we've talked about many times is unfortunately there are some systems that are very mature and others that are very immature. So, really the ability to meet people where they are is going to be significantly important as we look at the intersection of clinical administrative data. We have health systems with varying degrees of sophisticated systems, and we have providers who have varying degrees of sophistication with their systems, and the capabilities to link that data together varies significantly as well. So, although we looked at creating a floor of standards and then hopefully a ladder that will allow this standards and harmonization to occur and the maturation, if you will, of the ability to support the interaction of these two systems, it is something that isn't on day one going to be a magic bullet, because it will take some time for some of the systems with less mature capabilities in order to come up to speed.

So, policies and incentives and potentially participation in pilots or alternative ways of helping those participants take part in the process will be extremely important. So, that is a little overview of our guiding principles and ideal state, and now I'm going to turn it over to Alix who is going to review our recommendations. Alix?

**Alix Goss**

Thank you, Sheryl. Hopefully, everyone can hear me. This is Alix Goss. Fabulous overview. I really want to applaud you for so eloquently synthesizing about four months' worth of detailed discussions in small groups and full task force vettings. You really set up a beautiful framework for me to jump into our set of recommendations. I think also the earlier discussions that we had around electronic case reporting very much resonated for me, and I hope that there will be some synergies that you'll feel through the guiding principles and ideal state discussion that Sheryl just walked us through and the recommendations I'm going to walk you through. So, if we can go to the next slide, please.

So, this is a list of recommendations. It is prior authorization focused as Sheryl noted. We are currently finishing up that body of work and moving into the broader intersection conversation, and I kind of want to set the stage here before I walk through each one of these recommendations, describe to you the essence of the recommendation, and then we'll come back and run through these as your questions indicate. So, just to set a few stage points, in this recommendation list, they're in no particular order. They
The recommendations as I've said to the task force, what's going to be different this time? How is the prior authorization journey going to be improved because of the work that we do? And we can make recommendations, but as you sort of heard a little bit from Arien's comments on eCR, there are a number of levers that we can tap into. So, we've thought about levers from the government perspective and being able to advance Health IT certification frameworks as well as programmatic incentives and expectations that not only move the dial for government-related efforts, but also set a tone in the direction for the industry to think about and incorporate in their own private sector products and business models. But ultimately, we really want to use those levers that are at our disposal to get the bang for the buck because we don't want to wait forever, and we don't want to necessarily go to rule making because that can also take a very long time.

And ultimately, if we didn't have this framework of government tools in the toolbox we might need to go to the congressional stage, but we hope never to have to do that. We really want to ensure that we're aligning with today's efforts and the tools that have been developed so far. Like we've referenced USCDI, we've talked about FHIR. That is becoming more commonplace thanks to our interoperability rules. We've clearly had to balance a few things as we've thought about these recommendations. Sheryl did not couple of these points in her guiding principles and ideal state setup.

There are a diversity of statuses in the breadth and depth of the technology implementation and capital that is available to organizations to enhance their systems. So, we've been very mindful of the ramps that might be needed for the communities that are the "have" communities versus the "have not" communities, and how do we effectively bridge those. Because although we're living in today's world, we really want to envision the tomorrow and bring everybody along in that continuum while respecting the realities of the boots on the ground. So, we had to balance recommendations that aimed at what was right and ideal, but also recognizing that we would have that progression. So, as we've worked to keep the patient at the center and promote transparency, we're trying to address known challenges. And so, without further ado, I would like to start walking us through the 13, the baker's dozen, so to speak, of the current prior authorization recommendations. I would expect that we'll have more once we've completed the broader intersection discussion.

So, if we could go to the next slide, please. It's Recommendation 1: To prioritize administrative efficiencies in relevant federal programs. This is really about the ONC and CMS joint capacity to establish relevant certification criteria and programmatic aspects that really help to further the administrative efficiencies.

Recommendation 2 is about establishing a government-wide common standards advancement process. In today's world we have the HIPAA rules and we have the Cures rules. Although the cure rules are recently adopted or promulgated, there's a great progression of thinking within the marketplace about how to establish a common framework on which we can evolve using sub-regulatory instruments. Another part of the theme in Recommendation 2 is really driving home the testing and piloting aspect. This has been a long-standing gap within the HIPAA framework. It's been addressed a little bit more so within the FHIR
environment, but we recognize that we do need to engage in more robust testing and production pilot use to help us with having a very solid foundation for our standards which we use as our regulatory guidances. Please advance to the next slide.

For Recommendation 3, the converging of health care standards. This talks about code sets, the content, and the services. This is really about this idea that Sheryl mentioned earlier that's also encapsulated in our charge about this idea of capture once and reuse as appropriate. And we always want to keep that caveat in mind, because not all desired uses are permitted in the continuum of the data flow. We think that for Recommendation 3 it would be terrific to have ONC and the National Library of Medicine with their colleagues in CMS bringing in other applicable players such as the standards bodies to really look at a consistent set of standards for the code sets, the content, and the services to really help with the multiple work flows around clinical and administrative aspects. So, that converging will also take some convening.

Recommendation 4: Provide a clear roadmap and timeline for the harmonized standards. It's one thing to get everybody around a table to start working on a set of standards like we proposed in Recommendation 3, but when you look at Recommendation 4, this is about letting the transparency aspect come through and letting the industry know the game plan, create some predictability and understanding. So, having a roadmap for the village, so to speak, I think is very important to keep us all on the common page moving forward, especially when we think about those pilot and production usages that really need to raise the national floor for technology, and more especially workflow modernization. Next slide, please.

Recommendation 5 is to harmonize the code and value sets. This is another layer on top of Recommendation 3 and 4 that I've just mentioned. This is about the mapping or cross-walking that happens when we have those disparate or disconnected standards that may be used in some settings but not others, but the data still needs to port across settings. So, the Recommendation 5 would help with creating a much more of a common framework or mapping. And value sets and code sets are not just – I wanted to make a distinction here. Code sets are often recognized and promulgated directly within our national standards framework, whereas value sets sometimes can be more embedded into a standard, a technical transaction, or exchange capability may have its own value set. So, there's broader than just our usual CPT, HCPCS, ICD sort of normalization with SNOMED, etcetera. There's also those value sets used within a transaction standard we want to think about. Next slide, please.

Recommendation 6 is to make the standards – referencing code sets, content, and services – open to implement without licensing costs. One of the barriers that we thought might be best addressed is the end user licensing of adopted standards and making sure that that is not burdensome in the ecosystem, so we maybe have opportunities as we've done in other code set realms to address the licensing barrier. Next slide, please.

Recommendation 7 is to develop patient-centered workflows and standards. This really gets at the heart of our design principles that we've been think about, not only from put the patient at the center but also the privacy and security concept. Those two tenets are really at the core foundational design considerations for everything we should be doing downstream. And so, we're recommending that we work with federal actors and standards development organizations to prioritize and develop standards that are really designed around that patient access and involvement, so that there's this aspect of the
administrative standards and that clinical can really work much more effectively together if we take the patient-centered view. Next slide, please.

So, I'm at Recommendation 8, and I appreciate your patience everyone. I'll get through the last handful of these and then we'll open up for discussion. Recommendation 8 is about creating a standardized member ID, and this is maybe a little bit of a workaround from having an individual identifier, but we would recommend that we would create and incorporate standards for member ID cards because this could go a long way in helping patients and providers and payers in easier reconciliation of who's front and center within the clinical and administrative exchange.

Some of you may be all too familiar with our Recommendation 9, which is that we would like to name an attachment standard. There has been a long-standing set of conversations in the industry for the better part of two decades about the need for an attachment standard. Originally it was claims attachment, but now it's much more generic. It could be used with a prior authorization, some even think with the eligibility, that may help us moving information around and resolving clinical and administrative gaps in the continuum. And so, the recommendation here is coming forth with alignment to the current HIPAA mandated version of 5010. Next slide, too.

Recommendation 10 is really a nod to the industry in that we would like to create regular review of prior authorization rules, and that we would think that ONC and CMS with other actors could establish consistent processes and guidelines to apply across all of the federally controlled plans, but that we could also have an ability to have federal leadership in establishing transparency in the prior authorization processes via published metrics on authorization, denial rates, rates of appeal, and metrics on appeals. This would take strong degree of collaboration with the industry. and from what we've heard I believe that there's some ecosystem approaches that are already taking on regular reviews of their prior authorization rules in the medical necessity aspects, so we'd like to bump that up to a new level of transparency. Next slide, please.

Recommendation 11, this is establish standards for prior authorization workflows. This is really getting at the trigger in the workflows of the electronic health records, meeting the clinician and the patient in that interaction and having the electronic health record tools work synergistically with that team and having the APIs be enabled and the application programming interfaces be enabled, because this would drive efficiency and reduce burden. Next slide, please.

Recommendation 12 is to create extensions and renewal mechanisms for authorizations. So, if you notice that there are times when prior authorization are once and done and pretty straightforward. There are other times when a patient scenario is pretty complex, and we need to at times have the prior authorization renewed or extended to continue the care delivery. So, we're looking for a way to have a better mechanism for that renewal process.

The final recommendation is to include the patient in prior authorization. And by no means is this meant to be last. This is bringing it home with one of our key thoughts, which is that the patient needs to be at the center of the process and needs to have transparency but also have the ability to sometimes provide the critical piece of information, that patient-generated data that's needed to connect the dots between the
provider and the payer in justifying the additional elements to support approval of the prior authorization. And so, Recommendation 13 is regarding that inclusion.

I've now run you through rather quickly. Despite some background noise, I hope you been able to hear me clearly. I've run you through the baker's dozen and I think at this point, Sheryl, we're looking to open it up for questions from the committee, so I'm going to turn it back over to you.

**Robert Wah**
Okay, thank you both. This is Robert. This is great work. I appreciate you going through that baker's dozen two different ways for the group, and we appreciate all the work you've done. I see some hands starting to raise, so first question or comment is from Ken Kawamoto. Ken? Ken, you might be on mute.

**Ken Kawamoto**
Sorry about that. I was double muted. Can you hear me now?

**Robert Wah**
We got you.

**Ken Kawamoto**
Yeah? Thanks. Thank you. Great presentation and recommendations. The making the standards available for free, I think that really should be a goal and I know we've discussed this in various forms, including the ISB Task Force last year. I do think it's a really important goal. I think there was a mention of FHIR being free and the government supporting it, the National Library of Medicine supporting it. Just to clarify, that is free, but I don't believe there's any government support like there is for, say a SNOMED national license. But I do think that's the right model because it's not clear if that approach is necessarily sustainable when there is basically this dual desire to make standards free and also to not pay for it. So, I think it's important that it be free to the end user, but I do also think it's important for this this committee to consider and support that there needs to be considered national resources and infrastructure, and to support and fund it. Thanks.

**Robert Wah**
Thanks, Ken. Next comment is from Clem McDonald. Clem?

**Lauren Richie**
Clem, you may be on mute. We can't hear you.

**Robert Wah**
Yeah, he might be on mute, or hopefully dialing in.

**Lauren Richie**
He was typing in the chat box a bit earlier, so I'm not sure if he has audio or not.

**Robert Wah**
Yeah, as everyone knows, it's complicated because we have the Adobe Connect application which you can be on and you can type in the chat box and all that stuff, raise your hand, but to be heard on audio
you need to dial in and if you're dialed in, you need to be off mute. So, a lot of steps. Clem, I think you're dialed in. Hopefully, you hear us, and you get off mute and can participate. Clem, the operator says you're dialed in, so. Okay.

Clem McDonald
I think I figured it out. Can you hear me?

Robert Wah
There you are. There you are. Welcome. Welcome. You're in.

Clem McDonald
So, I had a couple of comments or thoughts. Your suggestions were all good, but extremely ambitious and they probably deserve a little more specificity, and the general idea of just waving the hands at harmonizing I'd say has never worked. And one should be a little bit more specific about what should be harmonized with what and/or replaced or done in some joint fashion. Apropos of the idea of the differences in the clinical standards and the business standards, or the insurance payment standards, there's a push from NCVHS to resolve that and there should be some interaction I think between your subcommittee and that committee with the idea of trying to unify the coding systems. But I think not just harmonize, but to actually push them together in some happy fashion over time. So, it would be really worth looking at that.

You had so many different questions. I think the idea of free is very important, and I support Ken's suggestion, because I'm from NLM and NLM does not supply base support to HL7, and so it would be very helpful for HL7 to continue success with some base government support. Thank you.

Robert Wah
Thanks, Clem. Alix, did you want on to respond to that?

Alix Goss
Yeah, just a couple of comments on that in regards to the NCVHS interaction and unifying the coding systems. Yes, we will. There's certainly some synergy there. As the standards subcommittee has looked at the overarching vocabulary landscape and done a really robust environmental scan with the support of National Library of Medicine. There are a number of us that were involved in that work that are also on the task force. But one of the other things I think is important to understand is that the report that we will generate will come to full HITAC for review and comment. We're looking to evolve that current body of work that Sheryl and I have just presented, get some feedback today, and then continue to evolve that as we dive deeper into the intersection of clinical administrative global topic.

But we also anticipate that the report that is finally submitted to HITAC will then also be sent to NCVHS, and there is a corresponding project to the task force's charge here in that HITAC has its authorities, NCVHS has its authorities, and NCVHS and the standards subcommittee in particular is looking to receive the full report from ICAD as a major input into our thinking. We're calling it the convergence project in NCVHS, and vocabularies are also the responsibility of the standards subcommittee. So, there is a big thinking there around not just the transactional flows under HIPAA, but also the code sets. And so, I think that I appreciate Clem's feedback, especially the point about needing more specificity. I did
glean over things today in consideration of time, and additional details will come forward to you as a part of our draft report submission, but I think generally that the feedback of trying to be as specific as possible is something that we should take back.

We've walked a fine line in crafting recommendations to push the envelope but also not get in the way of how things are necessarily done. If the policy goal takes hold, figuring it out is the next layer, and so we've been mindful to not step too much into that path. But as I sort of think about conversations that I've been having with Alexis and Anil and Arien and Sheryl and some of the other members off in our small working group discussions, I think that the specificity aspect is something we need to think about much more concretely in this next iteration on our recommendations.

Clem McDonald
Okay, and if I could, there's one last thing I forgot bring up is the attachment thing I think is also a very good idea, but I don't know if you're aware of there's probably 20 years of joint work between X12 and HL7 over two or three iterations of creating an attachment standard, and it exists now in HL7 in collaboration with X12. And I don't know if you're aware of that or if that's – is that something…?

Alix Goss
Oh, actually, Clem, I'm painfully, painfully aware of that and I think that I've heard a collective "could we please get an attachment reg?" from the industry ad nauseum. So, I applaud you're bringing up that multi-decade collaboration between X12 and HL7. It's not just in the HIPAA realm. They're also extending it in the FHIR realm.

Clem McDonald
Super. Well, you know, that's going to have a gestation like 20 times that of an elephant if it ever gets out. Okay.

Robert Wah
Okay, as the OB/GYN, I'm going to step in on the gestation comment, I guess. But all right, thank you, Clem. I think the next hand is Carolyn Petersen.

Carolyn Petersen
Thanks, Robert. Let me again echo other's comments. Wonderful, wonderful work, and I did have a sense of how much was behind it being able to sit in on a few of your meetings, so thank you so much for doing all of that. Particularly over the summer, when we might have had some other uses of our time that might have been more fun. I'm really interested in this last recommendation that gets at the patient centric-ness and the importance of keeping patients at the center of all of this. And I'm wondering if you can give us a little more background as to some work that's been done around that, or what you see might be helpful going forward to ensure that that recommendation really takes hold and is implemented through whatever comes next. I'm thinking perhaps in terms of standards development or working with vendors, or what do you see on the horizon that patients can be doing and patient advocates to help further this work?

Alix Goss
I actually heard that as a two-part question, and I suspect Sheryl may also want to dive in here, but if I heard you correctly, Carolyn – and by the way, thank you for your participation in several of the meetings
and reflecting on the hard work of the committee, because they have been doing a tremendous amount of work over the summer in addition to our weekly calls they've been doing. We've had three to four small groups running parallel to crank the wheel.

The patient center aspect, I think I heard that there's some sense of curious what we're doing here and how we could move forward and that from the technology perspective, but the second part I heard was how do we get patients and the caregivers to become more educated and engaged in the process as well. I think you hit the needle on the head that there's how do we design into our standards and our work flows and our capabilities that are patient-facing to have them be an easier, more integrated part of the process, and I think some of the new technologies with FHIR APIs are really going to help us because there are a lot of products evolving in the marketplace. So, I think that there's what we're doing now that we need to continue to refine and improve with those API capabilities and the FHIR-based standards that enable that lighter, easier, touch integration and data flow to meet citizens where they're at with their phones or at the libraries when they're using the computer there to engage over portals or other platforms.

I think the other part of the question I heard from you was about the what do we do for the patients and the caregivers, and that's a tougher nut to crack. I think that when you've got complex patients – and I'm really kind of also anticipating Alexis is going to chime in a little bit here – but as you're looking at the more complex patients, what they need is different than maybe what the healthy 20-year-old might need. I think I would want to see us focus more on maybe some educational materials to help with building on what are your rights, how do you get the data, what are the questions, maybe a tutorial to help the patients on their side, but I don't know that we've really delved in enough on how do we help the patients. We've been very focused on the technology and the tools to help the data flows, and so I feel like there's an area for us to think a little bit more about for that patient engagement related recommendations. So, I'll open it up to Sheryl or other members of the task force.

Sheryl Turney
Thank you, Alix I do agree with Alix. I think Carolyn, there's a lot more to be done here relative to the patient. Because in the current landscape, a patient might go to multiple health systems; most likely those health systems, even if they are on the same EMR system, the data often cannot be brought together in one portal. So, with the interoperability rule, the patient has to the ability to share that data with a third-party app, but it falls short of saying, "Okay, well, we have a lab or some test that was done and, if that information's not brought back to the EMR system, then how is that patient to see that data in their portal and how many portals do they have to look at in order to see the data?" So, even with everything that we're looking at and what we want to do, there are challenges that have to be overcome.

And then, to what extent are patients and caregivers tolerant of all of the work that needs to be done? I mean, even in the current landscape, to get your data – and I'm not going to pick on any health record app – but if you look at the ones that currently exist, you have to go out to each system that you have. You have to put information in. Often that information isn't remembered in terms of your log-on, and so getting all your data in an app is no easy challenge for a member or caregiver either.

So, there's a lot of work here that still needs to get done. When we looked at prior authorizations, the challenge is where a patient is today, there is no line of sight that they have into anything that goes on in
the process. We know that. Today if they want to move things along, they have to make a phone call. Often they're calling the provider, then they're having to call the payer, and many times the payer doesn't even know the prior authorizations and process when you talk to the customer service person. So, it requires multiple phone calls. So, overcoming all of those challenges is not going to be something that's going to happen quickly or easily. Some of it can be resolved with some levers and incentives to make the interoperability easier, but even beyond that we can think of 100 different ways to make automation easier for a patient, but there are still some challenges as we all know that patients are going to have.

If you're a caregiver of a senior person who has dementia, first you have to get access to that person's records and that has to be established, and then once that's overcome, getting access to that information in electronic capabilities, again, you have to go through all the same challenges. So, I don't think we have yet a maturity view, if you will, maturity cycle in terms of where we need to go, but certainly we need to create one and say what are the priorities? What needs to be there as the foundational items to support the trajectory of where we are in every maybe 100 different patients or in 100 different places? So, how do we take them from where they are, and bring them so they all have the same capabilities? They may not all get there, but have they have the ability to interact the same way given the technology challenges, et cetera, et cetera. So, I do think that maybe looking at a maturity capability in some measure of working on this would be helpful.

And also, we have talked about prioritization. Which are the most important things to have first. Unfortunately, because this is a very broad subject, there are many stakeholders who have different priorities in mind. So, looking at the patient's priorities, to me that's really important. So, as we look at the broader intersection, how we can make the process easier, more transparent, and more accurate, and more predictable so the patient knows what to expect and has information so it can help guide them in the process I think are going to be very, very important. So, I think your points are very well taken and can help us as we move into this broader conversation discussion.

Carolyn Petersen
Thanks, Sheryl, and Alix both for clarifying and giving us that really very detailed look at the problem. Certainly, I think there's a real understanding within the task force of the challenges for patients, the need for awareness and education as you've noted. I say perhaps I over-spoke my question and muddied things a bit. I'm wondering what the role is that you see for patients and patient advocates in developing the technologies that are going to get us to the vision point. It's great for people to know, but there are many other interests around the table. And to be honest, within healthcare right now, there are many entities who feel that the current prior authorization system works just fine for patients. So, I'm really thinking in terms of have you thought about ways to get patients involved in standards development, in tech development? What's being done to ensure that patients' interest really continues to be a focus of this work going forward?

Alix Goss
Well, thank you for clarifying that point. That was really helpful, and I think that no, we haven't talked about getting patients involved in standards development. That might be a little bit mind-numbing from my perspective, having been in standards development since 1999, but I think that there are ways to have the end user involved in the software services, and by extension maybe those that are really interested get back into the SDO world, the standards development world. But I can see having patients almost as a
user group for user-centered design really be a part of the development of products platform. But I think that we'll take this back with the additional clarity that you provided on your question.

**Sheryl Turney**
Yeah, I agree. Thanks, Alix. I agree, Carolyn. We haven't had that discussion, but I do think it's an important aspect, and I do think that it's something that we should discuss how we can get patients more engaged.

**Carolyn Petersen**
Thank you.

**Robert Wah**
Thanks, Carolyn. I think the next hand is Arien Malec.

**Arien Malec**
Thank you very much. It's been a pleasure to participate as part of this workgroup or task force. I just wanted to go back and address maybe Clem's comment about specificity, and I think that's a line that we've been trying to walk carefully. In particular, I think if you pinned our arm behind our back we'd say well probably the logical candidate for reconciliation would be FHIR-based APIs that encompass both clinical and administrative transactions. But it's more important, I think, to establish a consistent process. So, I think people may not recognize the degree to which some of the standards evolution and lack of standards uniformity is secondary to completely different processes that are used by HHS to evolve the corresponding standards for both administrative and clinical transaction.

And in particular, I think it was the intent of the task force in the recommendations that standards advancement process that ONC has promulgated and that has been informed by a lot of the commentary of this committee as well as prior committees. And also it's consistent, I think, with the direction that NCVHS has been seeking to maybe push, prod, and pull CMS in, is the right process to follow. So, it's a process that allows for experimentation, piloting, trial use, and then broad-scale production use. And that we need to establish a roadmap for industry to follow, that there's a lot of entrenched standards that are in place around the EDI processes. As a person who runs a clearinghouse, I can tell you that there's still 4010 transactions that are kicking around. There are still print image transactions that are kicking around. So, the standards evolution is going to take some time to get right.

I think our perspective of the task force is that we need to establish a consistent and common process and establish a roadmap that leads industry towards something, and that there's a lot of work to work out in terms of what's the actual next eligibility transaction with the actual next claiming and remittance transaction, what's the actual transaction that we land on for EPA. So anyway, just as a commentary that I think we recognize how much work there is involved, how much in evolution is required, but maybe the geekiest of all comments, that it's really important to get the standards advancement process and the underlying processes used by the relevant federal agencies right up front, and that getting that right will help us evolve towards a more common process. So, thank you.

And then just doubling down on the need to incorporate the patient as a key actor, and also to incorporate the patient voice. I completely agree that having patients designing the standards, there are some
patients, and all of us are patients, and some of us have standards design processes or standards design expertise, but it's way more important to get the voice of the patient, the voice of transparency, the voice of inclusion into the requirements for the process to make sure that the output of the process ends up with standards and implementation guidance that includes patient access and patient participation as first class citizens. Thank you.

Robert Wah
Thanks, Arien. Clem, you had your hand up again.

Clem McDonald
Yes, I did. I've mastered the mute.

Robert Wah
Good.

Clem McDonald
So, I wanted to bring up this question about the patient not being able to get to their individual results without going through many portals. That's not a problem that can be solved by the vendors or by the individual institutions by themselves, because you need somebody to connect that data. Now, Apple, and now from the comments I read Chrome also has a mechanism that can do it. And two other possibilities, I've always wondered why the hospitals don't ask for a URL where the patient could push their stuff to some personal records system whenever they get seen by a clinician and it would all go together without any extra effort. The other possibility is enabling health information exchanges to also serve the patient directly as a collection site for their stuff if they don't do it already. But, I mean, we need a collection site for that data to make it be a one-stop shopping and that's sort of not gotten high attention yet. Thank you.

Robert Wah
Sheryl or Alix, I don't know if you want to comment on the issue of where individuals can… I know it's a little tangential to the prior authorization, but it is a I guess an intersection of clinical and administrative information.

Alix Goss
This is Alix. I do think that the current patient access and interoperability rule is really going to help advance the situation that Clem aptly described that patients have to get their data related to their clinicians at different portals or in different mechanisms. And as the API economy takes off and we have different products in the marketplace, we will see the ability for patients and their caregivers to get that data in their app of choice. For instance in my role within the Da Vinci Project as a consultant, hosted a community round table this past summer where we had a payer and their vendor bring together three different separate applications or platforms that enabled a patient to request their information and to receive it in their app of choice on their phone, and then being able to have all of their information in one place.

So, the app economy, meeting people where they're at is taking off and I think that this is a perfect example of how the marriage of programmatic policy and Health IT certification expectations come together to move the marketplace. And we will start to see that improve, but I think we also need to make
sure we're monitoring it and seeing how it rolls out, if it's really helping bring a better intersection of that clinical and administrative for the patient. But I think there’s also the need for us to continue to advance the other parts of the ecosystem so they're getting good timely data into those services that they may be using to help them centrally control their own health status. Sheryl, do you have any comments that?

**Sheryl Turney**
No, I think you stated it very well, Alix.

**Robert Wah**
Thank you, Alix. This is Robert again. I'll just add that there's been a discussion, that I didn't mean to quite start this deep of a discussion on the public comment side about Common Health, which is the Apple Health equivalent in Android version that Clem was talking about. The goal is in fact to make it easier and more transparent for individuals to get their information located in one place. But there's much work to be done in this area. Arien, did I miss you? Go ahead, yeah.

**Cynthia Fisher**
It's Cynthia. I'm sorry.

**Robert Wah**
Yeah, that's right. You don't have your hand up. Right. Go ahead.

**Cynthia Fisher**
Right. I can't. So, just on this topic, as we look at across the board of integrated patient information for ease of use among patients and caregivers – and I really appreciate the discussion – I would like to add that even with prior authorization as Sheryl talked about from the insurance player actor in the marketplace is as we move to more transparency both from actual things like authorization and what you get for the coverage you bought, but also as we look at price transparency and also the records. We want to be able to move systemwide, and so the patient doesn't want to be isolated to just have a prior auth from one specific provider, so that the patient could shop.

And I think the other thing for the insurers to be aware of is looking at historical claims data, Dr. Larry Van Horn at Vanderbilt found that cash prices oftentimes are in most markets from the same facility 39% to nearly 40% lower than negotiated rates. So, if a patient also wants to get authorization and compare a negotiated rate for a cash price, people should be able to have that freedom to shop and be able to have new innovative models of saving money in health care and being in control of their decisions. So, that shared information should go across insurers, across systems, across providers, not just down a portal or rabbit hole. So, I just wanted to put that out there as we move into the app economy to think of how we have a competitive market actually functional and working with transparency.

**Robert Wah**
Thanks, Cynthia.

**Sheryl Turney**
Yes. Thank you, Cynthia. Duly noted. I think that a model like the app economy that you described does require some additional impact that we would need to discuss and consider, especially regarding in-
network versus out of network providers and things like that that come into play. So, I do think that that would require a little bit bigger discussion, but certainly we'll take that back to the task force and generate some conversation around that theme.

**Robert Wah**
Great. Just a note on the time, as you all know, I'm a stickler about this public comment time so we're scheduled to a public comment period at 12:00 noon. We'll let this conversation go until that time. If we have not finished it, we'll resume the conversation on the intersection of clinical and administrative data after the public comment session. Next, Arien, did I miss your hand before? I'm sorry if I did.

**Arien Malec**
No. You got me. Thank you.

**Robert Wah**
Okay. Do you want to talk now or was that previously?

**Arien Malec**
No, I already got my comment in. Clearly it was forgettable. I'll put it down.

**Robert Wah**
Okay. I saw your hand up again. That's why I wasn't sure if I missed it. So Alexis, next.

**Lauren Richie**
Alexis, are you muted?

**Robert Wah**
Alexis Snyder, you might be muted. I see your hand up, but I don't hear your voice. I see you might be typing. Oh. So, Alexis says she's unmuted but she's not being heard.

**Operator**
Alexis, your line is open.

**Alexis Snyder**
Can you hear me now?

**Alix Goss**
Yes. Hi, Alexis.

**Alexis Snyder**
Hi. I clicked on 'unmute,' but I guess perhaps when I got cut off before and called back in, the operator put me in the wrong spot, and I didn't have the ability to talk. So, in any event, I started to say while you not being able to hear me, my mind is in many different places. I'm going to try to focus now while waiting to talk and listen to the different comments. I wanted to pull the guideline and recommendation conversation back to some of the pieces that Carolyn asked in the beginning about, 1) how patients can be more engaged, and 2) I most importantly wanted to mention some pieces that have been worked on for weeks.
and weeks and weeks within the task force. And so, one mention that the recommendations that Alix is reviewing today are only a small piece of the work that's still coming forward and the larger document that goes into much greater detail when folks are able to see it about our ideal state in reference to many areas, including the patient engagement and transparency pieces that carry over into recommendations that again are still in the working mode that you haven't necessarily seen all the work behind it.

And so to speak to that, I would just say one, as far as engaging patients pieces like this are the first step, right? So, I'm one of a few patient caregiver voice on HITAC and on the task force, and so I think by patients and caregivers being brought into processes, and there are some places in our guiding principles and recommendations where we do talk about patients being engaged in the standards process going forward. These are the first steps, because I can say that during the course of all of our work and conversations, the cases that have been brought forward for patient and caregiver are more surrounding a lot of the pieces that folks have asked about being on this educational piece that got started here. So, it's not necessarily just about being able to merge portals and be able to gather information in one place rather than several.

We have to take a step back before that that the task force has been working on for many weeks and that's getting the transparency to it to begin with. Because just because you may be on multiple portals and have information in various health systems and EHRs doesn't mean that the information that's available in all of those systems is even fully transparent and sometimes not accurate. So, when we talk about the prior authorization process, the task force has diligently been working and incorporating into our guiding principles, ideal states, and for the recommendations, pieces that engage the patient in the entire process. So, pieces like being able to self-generate information into the process that may not be coming from anywhere else.

Some of the pieces Sheryl and Alix both spoke about, to decrease the burden of being the go-between when systems aren't going right and not being able to see that information. So, increasing the transparency of the entire process where it is down the whole trajectory from where it starts to what the process is going through to get it approved or why it's being denied and what the outcome is, so that patients and caregivers can be more engaged in that process and head off problems before it leads to a straight denial. So, there's I think a lot of other pieces that in the short amount of time that Sheryl and Alix are able to run through recommendations that perhaps people aren't able to see yet. So, I just wanted to make sure that from the patient caregiver side and my voice that it has been a large part of that process, and I think that those pieces will be clearly seen in the final document.

And then I guess I would just say for the other overarching question of how patients can be involved in the future, again, I think that has been something we've talked a bit about and so perhaps as the team goes back to work we find a way to get that back into the recommendations as well. Patients and caregivers are involved in standards processes in many other places, so there is no clear reason why that shouldn't be something that happens here. And so, I want to make sure we don't lose sight of that piece as well. So, hopefully that was clear. Like I said, my thoughts were in many places after listen to the conversation, but happy to answer any questions that may have come up with what I said now.

Robert Wah
Thank you, Alexis. This has been a great conversation. As I said, I'd like to just pause the conversation here on the ICAD, and we'll come back to it after we have the opportunity for public comment. Again, we promised the public that they have an opportunity to speak at 12:00 noon, and I want to honor that promise at this point. So, I'll turn it to Lauren to go ahead and start the public comment process. Please just stay tuned for potential other comments on this task force. So, Lauren?

**Public Comment (02:28:02)**

**Lauren Richie**
Sure thing. We have the phone number up, and we'll ask the operator to open the public line

**Operator**
Yes. If you would like to make a public comment, please press *1 on your telephone keypad. The confirmation tone will indicate your line is in the queue. You may press *2 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 is from Lauren Riplinger with AHIMA. Please proceed.

**Lauren Riplinger**
Thank you. Good morning, everyone. As the operator noted, my name is Lauren Riplinger. I am Vice President of Policy and Government Affairs for the American Health Information Management Association. AHIMA represents health information professionals that work with health data of more than 1 billion patients a year. I want to say that we greatly appreciate the work of the ICAD task force thus far, and wholeheartedly agree with the goal of integrating clinical and administrative data to reduce burden for patients and providers, as well as improve care and potentially reduce costs. That said, we would like to recommend that the HITAC provide an opportunity for stakeholders to offer input on these consequential recommendations, which have only been made public today, before they are submitted to the secretary. Certainly while stakeholders have had, and we greatly appreciate the opportunity to provide general input to the task force, no one has really had an opportunity yet to provide specific input on these recommendations or to see the full narrative to describe and justify them.

For example, some of the recommendations such as the development of federal incentives and changes to existing processes for setting standards need to be considered from multiple perspectives, particularly given the range of stakeholders that they could potentially impact. I'd also note, and I know Alix touched on this during her presentation, but we do want to underscore and ask the HITAC to just provide a little more clarity as to how they envision that coordination with NCVHS as you review and approve these recommendations. So, I want to thank the committee and the task force for their work on this important topic and thank you for the opportunity to provide public comment this morning.

**Operator**
Our next comment is from Robert Tennant with Medical Group Management Association. Please proceed.

**Robert Tennant**
Thank you, yes. I'm Rob Tennant, I'm the Director of HIT Policy for MGMA, and I wanted to echo Lauren's comments. I think the work of the ICAD task force has been exemplary. I will say that MGMA members
over the last few years during surveys have identified prior authorization as the leading burden facing practices today. So, this work is absolutely critical. I wanted to also agree that we need to have more opportunities to provide public comment. I think the example here would be the NCVHS predictability roadmap, which was put out for public comment and I think was made stronger because of it.

I think we also have to know a little bit more about how NCVHS is going to interact with many of these recommendations. A lot of them require extensive federal involvement, and I think it's important for us to know a little bit more about the pathway towards those. I also wanted to raise an issue about one of the guiding principles that I don't feel made it into the recommendations, and that is transparency. We would argue that prior authorization compared to other transactions is more like a conversation between providers and health plans. And if the two parties don't speak the same language, we're going to have a problem and I think that's one of the reasons why it is such a burden for everybody.

So, I would recommend that the ICAD look at increasing transparency. And a lot of the recommendations are very complex and comprehensive. This one could be a low hanging fruit, and that is by requiring full transparency from health plans regarding whether a service or medication requires a prior authorization, how the payer supports prior authorization – for example, the 270-A, or portal, fax, or API. And finally, what clinical information does the payer require to adjudicate a prior authorization? Best case scenario would be of course the clinical template being available. That would help both providers and patient and would speed up the process. Thank you so much.

Operator
And our next comment is from Daniel Vreeman with RTI International. Please proceed.

Daniel Vreeman
Thank you. I want to commend the task force for their excellent work on this topic. I support the overall recommendations quite enthusiastically. I would like to emphasize and come back to a comment that Clem made in thinking about the language for Recommendations 3, 4, and 5. I guess I would encourage the task force to consider the verbs "converge, unify, harmonize" as you're thinking about these recommendations. They all have slightly different implications as far as the trajectory, and I recall some of the conversations in the NCVHS deliberations around this and the general principle of trying to sort of converge on or select sort of a particular terminology or code system per domain, meaning avoiding where possible the implications of mapping which becomes a sort of forever burden on everyone, as opposed to sort of consolidation.

And so, I would just ask for further consideration of that as you get towards the specificity that I think Clem was bringing up. Thank you. Overall, though, I wholeheartedly support.

Operator
There are no more comments at this time.

Robert Wah
Great. Thank you, operator. I wanted to again go back as I said before I sort of interrupted the conversation to make time for the public comment as we listed. One last time, any other comments, or
questions for the ICAD task force leaders? Seeing no hands raised, I'll go back to our chair.

Alix Goss
Robert?

Robert Wah
Yes.

Alix Goss
This is Alix. If I could just make a comment if I can. There were several comments made related to the NCVHS effort, so I think it might be helpful if I just provided a little color commentary there. Thank you to Rob for calling out the NCVHS predictability roadmap. That was an extensive and nontypical federal advisory committee approach in the NCVHS sort of standard tools in the toolbox. We undertook an effort where we had a very well-defined set of questions. There was background documentation, things that we were working on, and then 23 recommendations that we put forth that actually resulted in about three letters with a couple of recommendations each being sent to our federal audience. In this case for NCVHS, it is the secretary.

In regards to the report that'll be coming from ICAD, that report is for the audience of HITAC. So, we're a task force of HITAC. HITAC has an audience of the National Coordinator. So, that is the path that that report will take for formal submission to the primary audience, in this case ONC, Dr. Rucker. In tandem to that, because we've been working so closely with ONC and NCVHS, we wanted to make sure that we were bringing together the industry that needed to weigh in on this topic together at one point. And so, instead of reinventing the wheel and having dual hearings in the reporting efforts, we decided to use the ICAD task force as the vehicle to give insights to the convergence process in NCVHS. We won't exactly know what we need do on the NCVHS side until ICAD is finished, and the report has been advanced to HITAC.

We'll then pick up, as NCVHS, that report, continuing our collaboration with ONC along the way so that we can then determine what logically fits in our wheelhouse of authorities versus what may be advanced within the authorities of ONC. So, I think there's great questions being asked about how this is all going to advanced, and we have some general frameworks of trying to be efficient, engaging industry effectively for the feedback because this does take a village to identify the good solutions. And so, stay tuned more for that. Rich Landon is part of the task force and also my co-chair, so he'll be able to carry the baton forward very well as we move into 2021. But we're already starting to think about the input coming out of this committee.

The other thing I heard on that was feedback from both Lauren and from Rob was sort of this ability to look at the text, the full text. We appreciate the feedback. We'll take it back and discuss it, but I hope everyone understands that we've been synthesizing the work of a number of months and we're just now getting to stable initial draft text and ensuring that there's agreement, and then we're going to be building that out with the broader intersection. So, there is no official report at this point. It's pieces that are coming together and ballooning as we are refining, validating, affirming, and then extending our thinking into the broader intersection conversation.
Robert Wah
Thank you, Alix. Sheryl, I know you have your hand up. I just want to say it looks like we may have missed one of the public comments, and I certainly don't want to be accused of excluding the AMA from this conversation given my prior AMA affiliation. So, operator, we can open up the line for one more public comment.

Operator
Yes. Heather McComas from the AMA. You may proceed.

Heather McComas
Hi there. Can you hear me okay?

Lauren Richie
Hi, Heather.

Heather McComas
Hi there. Great. Thank you so much. And I'm glad they got through despite the confusion. I'm Heather McComas, Director of Administrative Simplification Initiative at the American Medical Association. I first want to echo the other commenters who have expressed their great appreciation for the task force's work over these many months. I know that in addition to the weekly calls that were visible to us, there was a lot of work going on in the background, so we really appreciate that. I also want to express AMA's thanks for being allowed to present to the task force earlier this summer, because prior authorization is such a huge priority issue for our members and also for patients.

And we also agree that it's important to integrate clinical and administrative data to reduce burden for patients and providers and prove care and we also think it has the potential to reduce cost. The comments we want to make today basically focus on process, similar to some of the comments you've heard from AHIMA and MGMA earlier in the comment period. These recommendations are wide ranging and ambitious and cover many different areas and quite complex. And they also could have many impacts on various stakeholder groups, including our member physicians but patients as well, and also standards development organizations. As others have referenced, there's things about federal incentives included in the recommendations as well as changes in the traditional standards development processes, and for this reason we think as others have mentioned that it is important to offer stakeholders the ability to offer their full feedback on the recommendations.

We just got the chance to formally see them today and we greatly appreciate the fact that the task force did have a public comment period during all of their meetings, but the recommendations themselves are newly publicly released and so we feel that it's very critical that all stakeholders be able to fully review these recommendations and provide input to HITAC before they're finalized. It's also been referenced to we think that the supporting fuller report that I know the task force is hard at work be available for public review and comment as well because that will provide the justification and the background for these recommendations. So, we urge ICAD to make that public and for HITAC to allow stakeholders to comment on the full report as well.
Finally, as others have mentioned too, we think it's really important that NCVHS and HITAC coordinate their efforts on these recommendations moving forward. I think it's been discussed some today, but I think it's not entirely clear how that's going to work. Obviously, there's been a lot of talk about harmonization and bringing things into alignment, and if at the end of the day these recommendations are taken in two different directions by two different bodies that could end up with disparate and unaligned results. In any case, we greatly appreciate all the work that both ICAD and HITAC have done on this topic and we again hope we have the ability to fully comment on the recommendations. Thank you.

Robert Wah

Thank you, Heather. On the topic of coordination between the two committees, as chair of HITAC I can certainly say I'm very comforted by the fact we've got a great person in Sheryl representing the HITAC and I'm sure the chair of NCVHS also feels the same about Alix representing the NCVHS. So, I think we do have the opportunity for coordination between the two committees as this report goes forward. But with that, Sheryl, you had your hand up. I'll let you speak on that. I think I see Arien, your hand's up as well.

Sheryl Turney

Thank you so much, Robert. And I really appreciate the comments that have come in from the public comment. I think all of those are really valid points and definitely something that within the ICAD task force we need to discuss a little bit more at length. Regarding the input into the recommendations, obviously what was presented today was just a small summary of the recommendations, and especially speaking to the comments about transparency and a couple of other things that came up today, I did want to just highlight that Recommendation 11, although it wasn't specified out in the screen, we really have included in that recommendation the information related to determining what the prior authorization requirements are for each payer, what are the orderables or requirements in order to support that prior authorization, and also the process by which that prior authorization approval will come through and then transparency into all that.

So, I apologize that it really wasn't clear based on what was presented today. Hopefully as the draft paper comes to fruition once the broader intersection information has been added with our next update, we will have that opportunity to get further input. But hopefully, that will help those that have only listened today and seen what's on the slide understand that there is a lot more depth in each of the recommendations that have come forward. So thank you, Robert.

Robert Wah

Great. Thanks, Sheryl. Thanks for your work on this. Arien, your comments?

Arien Malec

Thank you. I just wanted to address the comments on transparency of the report. So, as it's been previously noted, each of meetings of the task force is open to public comment. As we finalize and assemble the final report, I think we welcome people using the public comment period in the task force to make commentary on the report itself. That report will be issued to this group, the HITAC, which also has a public comment period, and the draft report will be made fully available via the public mechanisms, the transparency mechanisms, the publication of all the draft material, et cetera. At that point, it'll become a set of recommendations to the National Coordinator, and my assumption would be that the National
Coordinator and Secretary of HHS would either promulgate updates via rulemaking or other public coordination mechanisms which themselves have ample periods for public comment.

So, I think it's good news when folks are looking for additional feedback and commentary in the process. I think it's great to get some of that comment upfront and make sure that the final recommendations that we publish through there committee incorporate all of that feedback. Generally a sign that we're doing something that matters and has impact, but I also want to make sure that people realize that there will be multiple ample periods for public commentary and that the process itself that we're following has taken a good amount of the feedback that's already been provided both through public comment and through hearings into the draft report comment. So, I just really appreciate all of the calls for additional input into the report. Thank you.

**Robert Wah**
Thank you. And, again, thank you to our two co-chairs, Sheryl Turney and Alix Goss. We really appreciate all the work you and your workgroup have done. Clearly this has been a rich and robust discussion here today. It's apropos to mention that your next workgroup meeting is scheduled for September 15th. Clearly there's a lot of interest in this, so I'll make sure that people put that on their calendar as well. At this point, I think we'll wrap up the meeting. We're scheduled to end in just a few minutes. Again, thank you all for your time. Lauren, I'll let you do the housekeeping of other dates and other things you need to do, and I'll turn it back over to Carolyn to finish up her comments as well. But thank you all for your time and attention and talent today. I think it's been a very good conversation.

**Wrap Up and Final Remarks (02:48:22)**

**Lauren Richie**
Sure. Thanks, Robert. So, just as you mentioned, the next ICAD meeting is next week on the 15th. We'll have another opportunity for the HITAC to review the recommendations from the task force at our next meeting on October 21st. Also, also as a reminder to the HITAC members: again, if you're interested in serving as co-chair starting next year, please send me an e-mail by next week on the 16th. And again, if you just want to review the draft recommendations or any other materials from today, those are all posted on HealthIT.gov. And I believe that's all I have today, and I'll turn it over to Carolyn for any closing remarks.

**Carolyn Petersen**
Thanks, Lauren, and Robert, and also thanks to everyone on the HITAC for coming today prepared for some really on-point and relevant discussions about case reporting and the work of the ICAD. It's great to come back after several months away from this work and see the passion and the interest in keeping our work going forward. And again, thanks also to ICAD and to Steven Lane and CDC and others who were involved with the case reporting work. With that, I will let you know how much we look forward to our next meeting on October 21st and wish you a great day and a great week. Thank you.

**Robert Wah**
Thanks, everyone.

**Adjourn (02:50:10)**