HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

May 13, 2020, 9:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Magnolia Health	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
Jim Jirjis	Clinical Services Group of Hospital Corporation of America (HCA)	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Denise Webb	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative

James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Donald Rucker	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Acting Executive Director, Office of Technology
Lauren Richie	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Teresa Zayas-Cabán	Office of the National Coordinator for Health Information Technology	Presenter
Kevin Chaney	Office of the National Coordinator for Health Information Technology	Presenter
Alix Goss	Imprado Consulting, a division of DynaVet Solutions	Presenter

Operator
All lines are now bridged.

Lauren Richie
Good morning, everyone. Welcome to the May edition of our Health Information Technology Advisory Committee. I want to welcome everyone, and hope you all are well and safe, and thank you again for taking the time out of your busy schedules to be with us today. I'll take a quick roll call, and then we'll get started. Carolyn Petersen?

Carolyn Petersen
Good morning.

Lauren Richie
Robert Wah?

Robert Wah
Good morning. Present.

Lauren Richie
Michael Adcock? Maybe not yet. Christina Caraballo?

Christina Caraballo
Good morning.

Lauren Richie
Tina Esposito?

Tina Esposito
Good morning.

Lauren Richie
Cynthia Fisher?

Cynthia Fisher
Good morning.

Lauren Richie
Valerie Grey?

Valerie Grey
Good morning.

Lauren Richie
Anil Jain?

Anil Jain
Good morning.

Lauren Richie
Jim Jirjis? Not yet? John Kansky?

John Kansky
I'm here.

Lauren Richie
Ken Kawamoto?

Ken Kawamoto
Good morning.

Lauren Richie
Steven Lane?

Steven Lane
Good morning.

Lauren Richie
Les Lenert? Arien Malec?

Arien Malec
Good morning.

Lauren Richie
Clem McDonald? Aaron Miri?

Aaron Miri
Good morning.

Lauren Richie
Brett Oliver?

Brett Oliver
Good morning.

Lauren Richie
Terry O'Malley?

Terrence O'Malley
Good morning.

Lauren Richie
James Pantelas?

James Pantelas
Good morning.

Lauren Richie
Raj Ratwani?

Raj Ratwani
Good morning.

Lauren Richie
Okay. Steve Ready? Abby Sears?

Abby Sears
Good morning.

Lauren Richie
Alexis Snyder?

Alexis Snyder
Hello.

Lauren Richie
Sasha TerMaat?

Sasha TerMaat
Good morning.

Lauren Richie
Andy Truscott?

Andrew Truscott
Present. Good morning.

Lauren Richie
Sheryl Turney?

Sheryl Turney
Good morning.

Lauren Richie
And, Denise Webb?

Denise Webb
Good morning.

Lauren Richie
I know Michelle Schreiber from CMS could not be with us. Do we have Alex Mugge on the line? Okay. James Ellzy? Ram Sriram and Adi Gundlapalli both could not be with us today. Jonathan Nebeker? And, Amy Abernethy or Nina Hunter from FDA? Okay. Also, with us from ONC, we have Dr. Rucker, Steve Posnack, Elise Anthony, and Avinash Shanbhag. With that, I will turn it over to our National Coordinator, Dr. Rucker, for opening remarks.

Donald Rucker
Hey, Lauren. Thanks. Welcome, everyone. Thank you for joining. Obviously, I think all of our lives have been affected in a variety of ways with the coronavirus and the work there, and I do want to give a shout-out to all the folks who are exposing themselves on the front lines, taking care of patients and, frankly, of the public through all the supply chain work. We've been very active in a number of discussions, looking at the information flows in Cures, what can be done there – sorry, not in Cures, COVID – what can be done there and what can be augmented. Some of the health information exchanges have generated some particular opportunities.

As folks have probably heard, we are using our enforcement discretion on timelines for the Cures Act final rule, which essentially has the effect of delaying the certification parts of the program by three months on top of the month and a half that we used to get the delay out from when the rule was electronically given to the public – so, roughly four and a half months – so that's out there. There are some complementary things with CMS as well and some of the information-blocking stuff. I think Elise can talk about that a little bit later if she wishes.

We have updated COVID information on our healthit.gov website and some of the data standards there, and I think we had some good follow-ups from our COVID hearing last month, which I found personally to be very informative, and I had a number of meetings – so many, it now becomes unclear how many of them were started by that meeting, but there were quite a few. We have gotten public comments on our federal health IT strategic plan for 2020 to 2025. For folks who haven't had a chance to look at that, there are a number of things – not just about health in general, but about public health as well.

Finally, before turning it over, I'd like to thank everybody for their hard work over the last two years. Lauren and the team have put together an infographic that she can tell you about if you want to look at your work. So, with that, let me turn it back over to Carolyn and Robert, I believe. Thank you.

Carolyn Petersen
Thanks, Dr. Rucker. Good morning, everyone. It's great to see everyone back in the group. I know it's been kind of a crazy time with people dispersed and doing things they may not used to be doing, certainly working in different ways, and it's good to see us all healthy and coming together again this month. I will now hand the mic to Robert to review the agenda and approve the minutes.

Robert Wah

Thank you, Carolyn, and thank you, Dr. Rucker. Good morning, everyone. It's great to be with you all again. We're getting ourselves back on schedule with our HITAC agenda after having a couple of meetings focused on COVID. I hope all of you found that those prior meetings on COVID were useful. They've certainly provoked a lot of activity and interest, and we hope that we're able to continue to leverage health information technology to help in this important time with the COVID pandemic.

This morning, we have two major presentations. One is on the national health IT priorities for research, and the second is an update from our Intersection of Clinical and Administrative Data task force that has been meeting for over a month. So, that's our plan for today. It's a little lighter of an agenda than some meetings in the past, but we thought these were two important things for us to update, and we look forward to your review and comments on those two important topics. As always, we have a public comment period scheduled at 11:15, so we'll try to adhere to that schedule so the public knows when they can come in to comment. We've had a couple of people sign in on the public comment side, we've noted your attendance, and we'll continue to do so as people join the call.

Finally, we need to go ahead and approve our April 15th, 2020 meeting minutes. Those were sent out prior to this meeting. First of all, are there any comments, suggestions, changes, or amendments to those minutes? Hearing none, we'll go ahead and approve those minutes. All those in favor of approval of the April 15th, 2020 meeting minutes, please signify by saying "Aye."

Several Speakers
Aye.

Robert Wah
All those opposed, say "No." Any abstentions? All right, they are approved. So, with that, we've also made some time in the schedule for Elise Anthony to go ahead and give us some updates on ONC policy, so with that, Elise, if you could take us into that, I'd appreciate it.

Elise Anthony
Absolutely. Hi, Robert, and good morning, everyone. Thank you again for joining us today. I did want to echo the thanks that Don provided earlier in terms of all of the support that you have done, not just this year in terms of helping us look at things such as the COVID-19 response, but also since the inception of HITAC, and as mentioned, there is a quick look at all the work that HITAC has done, and it's available on our website. It gives you a great look at the number of task force meetings.

It's just a phenomenal amount of work: The hearing on prior authorization, more than 20 meetings of the full HITAC, 155 task force and workgroup meetings, and in terms of the recommendations that have been provided, from everything to the rules, to the Trusted Exchange Framework, to the U.S. Core Data of Interoperability – just a number of different activities that have really helped us at ONC to perform our work in the best capacity, and having that background from on-the-ground work that you're doing from the patient perspective and the developer perspective, et cetera, has been extremely helpful, so I give many thanks in that regard. I just want to make sure you guys can hear me okay. Can you hear me okay?

Carolyn Petersen
Yes.

Elise Anthony

All right, good. I was seeing that you guys could hear me. I wanted to make sure. So, the first thing I want to talk about is some of the resources that we have released and made available on our website. In regard to COVID-19 in particular, we have a page that lists tools and resources that may be helpful to the health IT as well as to the clinical community. We've also updated the interoperability standards resource that we have online to list out COVID-19 standards that are being used in the space, so I encourage folks to check that out as well, as well as the IPG – the Interoperability Proving Ground. It's also updated to reflect and provide an opportunity for folks to put in their projects related to COVID-19 interoperability. So, take a look at the Interoperability Proving Ground, but also the ISA's Interoperability Standards Advisory, and all of that is accessible on that COVID-19 response page.

In terms of questions, we've been getting a lot of great questions regarding implementation of the rule that revolves around the rule itself, but also some questions that relate to other areas of our workstream, including, for example, public health, health IT safety, certification programs, the CHPL, and we've updated the portal on our website for those inquiries, so not only is it available for inquiries, but it's also available for feedback. So, if you take a look at that page, you'll see that you are able to provide us questions or feedback on any part of the work streams there, as well as any others you can think of as well.

One thing to note is that you can submit questions or feedback anonymously. However, if you do submit questions, we won't have a way to get back to you directly unless you submit the information for contact, but you can submit questions anonymously. On that page in particular, you'll also find a way to report any information blocking complaints that folks may have, as well as to submit questions, again, on the final rule. We want to make sure that questions are coming in through that form because it allows us to see where there might be commonalities between the questions submitted, and it will help us think through opportunities for us to provide, for example, frequently asked questions and responses on our website in the future. So, I encourage you to take a look at that. I think it's a helpful resource for us as well as for stakeholders to communicate and provide us with some feedback.

We also have some updated blogs on our website, and this is a great opportunity. You can hear from our subject matter experts that are doing a lot of the work related to things such as research – and, you'll hear Teresa talk a little bit later on some of the research aspects, but there are areas regarding research and provision medicine and some of the rule provisions. There's a blog by Rob Anthony that talks about the certification side and the conditions, and how that is set up within the certification program. I encourage folks to check that out, as well as the recent one that we've released around strategic planning and how our strategic planning works with and incorporates the research agenda at ONC.

This last one is an additional plug which I always make. It's my regular public service announcement related to the rule resources. One our website, we have a number of resources that can be helpful as you are looking through and reading through the rule. Everything from webinars to fact sheets is available, and on the webinars, we also have the actual audio as well as the PowerPoints themselves. So, thank you so much for all you have done in that respect.

I want to bounce back to COVID a bit there because one of the things that I neglected to say is I wanted to just express appreciation for all of the feedback and the comments we had during the COVID hearing, as

well as for all of the folks who participated in the hearing itself. Having all of those perspectives has been very helpful to us, and we're very grateful there. In terms of next steps, what we're doing now is we are working with our federal partners to determine where a potential charge could exist based upon what we heard in the HITAC hearing and from the HITAC members. In particular, we're working with CDC to explore specific ideas for future HITAC activity, so there's more to come shortly on that as well. We will keep the HITAC updated as next steps continue. Next slide.

So, on enforcement discretion, Don summed this up pretty well, but I do want to highlight. Here's a link to a quick one-pager that lays out what exactly within the certification program side of the rule would have the enforcement discretion attached to it. Again, as a reminder, the enforcement discretion relates to the certification side – so, that's the provisions in 45 CFR Part 170. It does not relate to the information-blocking side. But, if you want to get a quick look at all of the provisions and what enforcement discretion would look like per the statement, then you can see it on this resource, but feel free – if you follow that link, it'll be there. You can also find it by going to healthit.gov/Curesrule, and it will take you there as well. Next slide.

Okay, webinars. So, upcoming webinars – this is just a plug. I encourage people to check out the webinars. We've been hearing some great feedback that they've been helpful. In addition to questions that have been submitted, we've been able to answer the ones that we could in the timeframe on the call, and then we also have those questions, and the team and I review those questions and think about, again, if there are any commonalities in the questions or areas where frequently asked questions might be helpful to stakeholders as well.

The two upcoming webinars are Compliance Timeline – so, that would be a good one to check in if you're interested in the enforcement discretion that I just talked about – and we will also have one related to the pediatric care setting provisions that are included in the rule, and that one will be on June 3rd. So, please check those out. If you are unable, no worries. They will be available online. The audio will be available as well as the slides themselves. You can see the list of the previous webinars we've had there, and again; you can check those out online. Next slide.

This is my last slide. I wanted to just highlight this. I think this came up several times in the hearing as well as in some of the feedback that HITAC provided regarding HIPAA and the updates that are included on OCR's website regarding HIPAA, privacy, security, and COVID-19. On April 24th, OCR hosted a webinar. Timothy Noonan and Marissa Gordon-Nguyen hosted a webinar that focused specifically on some of the provisions that might be of interest to health IT stakeholders. It is also available – you can access it via OCR, but you can also access it on our website on that COVID-19 resource page that I mentioned earlier. It was a really great webinar, and I think it provided a lot of clarity and helpful information for folks who wanted to understand what the statements and updates have been from OCR. So, hopefully, that's helpful to stakeholders and helpful to the HITAC as well, and I think that's all I have for right now. Thank you, Lauren.

Carolyn Petersen
Thanks, Elise, for all those updates, and particularly for the information about where to find things on the healthit.gov website. Just a clarification: We will be doing the public comment period at 11:45, and with that, we will move to the first presentation. That is a presentation on the National Health IT Priorities for Research from Teresa Zayas-Cabán and Kevin Chaney. I'll pass the mic now. Thank you.

Teresa Zayas-Cabán

Thank you, Lauren. Good morning, and thank you for the opportunity to be here. As Lauren said, my name is Teresa Zayas-Cabán. I am chief scientist for the Office of the National Coordinator for Health Information Technology. I'm joined by my colleague Kevin Chaney, who is the senior program manager with the chief scientist division, and we'll be discussing the policy and development agenda, but before we do, I wanted to provide a bit of background on the chief scientist division and some recent updates. Next slide, please.

So, we see our work in our division as sitting at the intersection of research and care delivery. ONC traditionally doesn't fund research per se, but we see our role as leveraging the health IT infrastructure and the investment this country has made in health IT to support the biomedical and health services research enterprise. We direct projects that help advance the research agenda and have a robust portfolio of projects under the Precision Medicine Initiative patient-centered outcomes research. We've been collaborating with the Office of Technology with the Leading Edge Acceleration Project in Health IT funding opportunity. We recently launched an effort focused on workflow automation policy development through the use of health IT. We've been leading studies in artificial intelligence and continue to be engaged in conversation with regards to use of machine learning and AI and health and healthcare, and broadly focus on accelerating innovation in health IT.

Aside from projects, we also coordinate with key biomedical and health services research supporters such as colleagues at the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Assistant Secretary for Planning and Evaluation, and others outside of the department as well.

As you all know, 21st Century Cures Act prioritized interoperability, which will be critical for research so the policies, and regulations, and technology that ONC is advancing broadly have great applicability and are critical to be able to advance discovery. The Cures Act and the implementation will be catalyst for innovation both by making available data that can be presented in novel ways to providers and patients and caregivers alike, and also supporting novel care delivery models as well as enabling scientific discovery with regard to diagnosis and treatments and new ways of delivering care. Next slide, please.

I wanted to highlight a couple of recent activities. In particular, as you may be aware, ONC released its most recent special emphasis notice under our LEAP in Health IT funding opportunity. This funding opportunity was published initially in 2018 with the goal of addressing well-documented and emerging challenges inhibiting the development, use, or advancement of interoperable health IT at scale across healthcare systems. The most recent special emphasis notice had three areas of interest, and our division is leading one, focused on cutting-edge health IT tools for scaling health research, and this actually builds on one of the recommendations in the priorities and the agenda we're discussing this morning.

As you may be aware from my previous presentation to the HITAC, ONC has been involved with the Precision Medicine Initiative that was launched a few years ago since prior to its launch. As Elise noted, we've recently been providing updates regarding this work through a blog post series, with the final one due to be published next week. We recently released a final report from the second phase of the Sync for Genes Project, which has been focused on getting genomic information in standardized ways to the points of care and for research, along with a companion publication in the *Applied Health Informatics* journal.

As I mentioned earlier, we also have a robust portfolio of patient-centered outcomes research projects. We released a final report from one of them, which was developed in collaboration with AHRQ, and it focused on sharing patient-reported outcomes through health IT. We also redid the webpage, so I encourage you to take a look, with updated descriptions of the project and outputs from each. Please be on the lookout for additional reports on two of the projects that have concluded, focused on coordinated registry network for women's health technology and privacy and security later this spring and into the summer. Next slide, please.

What our work in this portfolio project and our collaborations with federal agencies as well as private sector stakeholders have demonstrated is how instrumental health IT to the research enterprise. Making usable electronic health information and as many other data types as possible readily available and easily transferable for patients, providers, and researchers is fundamental for some of the critical activities that are undertaken in research and discovery, including successfully assembling research cohorts, effectively analyzing collecting data, and recent interests across different research programs returning results to participants. Next slide, please.

In particular, the increased availability of electronic health data and the investment in the health IT infrastructure have created an unprecedented opportunity for biomedical clinical health services and public health research. However, challenges remain with regard to data quality, access, and management, and unfortunately, this sometimes results in research being inhibited and advances in discovery potentially being delayed. We saw an opportunity to examine those gaps and challenges more closely and develop key priorities and related actions to enable effective and efficient use of those data, as well as the existing health IT infrastructure, to advance research and discovery. We're very fortunate to do so collaboratively with stakeholders along the way and are very happy to discuss the results with you in a little bit more depth today. I'll now turn to my colleague Kevin Chaney to discuss the resulting agenda.

Kevin Chaney
Good morning, everyone. Thanks, Teresa. So, today, I have the pleasure to walk you through our National Health IT Priorities for Research, a policy and development agenda which articulates a vision of a health information ecosystem supporting research and advancing scientific discovery. Next slide. So, how did we go about doing this? It obviously required a lot of input. So, first, we started with an extensive background report to better understand the federal and non-federal activities to advance the national health IT infrastructure in support of biomedical and health services research, as well as what were the large research initiatives under way or anticipated. That will be driving our national health IT infrastructure requirements. We also held discussions with key informants – so, those who are experts on EHR interoperability and usability as well as the health IT architecture requirements needed to support research, and this helped us identify six key gap areas in the health IT infrastructure to support research, and I'll go over those in just a little bit.

We took these gap areas, and they provided the framing for an in-person workshop, which is where we had about 30 federal and private industry stakeholders, and we asked them to further explore those gap areas as well as thinking about what stakeholders and activities would be necessary to improve scientific discovery and application, and we then took these discussions and distilled them further into seven cross-cutting challenges that we saw across the initial six gap areas that needed further validation. And then,

ultimately, we took those through some additional validations, spoke with some of our key informants again, and this led us to a series of priority areas, and we took these initial priority areas and presented them to the American Medical Informatics Association conference at two different panels. And then, based on attendee feedback, we reached back out to initial key informants and distilled them even further into what became our final nine priority areas.

But, before we get there, I want to take a quick look at the gaps and the challenges that we identified for this process. Next slide, please. So, taken together, the background report and our key informant interviews pointed to the following six gap areas in the health IT infrastructure that needed to be addressed. The first was the adaptability of the health IT infrastructure. So, when we think about health IT, it can be incrementally adapted to address new scientific discoveries. We think about operational and workflow needs that incrementally get adapted. We're thinking of the evolving business and clinical priorities, or even organizational shifts, and the things that we do to update some of our health IT. This is done less when we think about research.

The second gap was the ability to produce high-quality data for research. So, systems do not consistently perform data collection in ways that would better support research consistently, identify the data captured, its timing, the level of granularity that's needed, how it was captured, and the context during collection. The third gap area, health IT functionality needed for research, looks at the growing need for health IT to support functions that easily incorporate research evidence into practice through decision support triggers and rules, whether that's making an application for granting interfaces or APIs with third-party functions and IT-driven challenges in the workflow.

The next gap area is data aggregation across multiple platforms, which is obviously no surprise to everyone here on the call. This has been a constant challenge, both for us in the clinical space as well as in the research ecosystem. The fifth challenge was the advancement of patient engagement in research, which, again, we need to have a diverse patient engagement strategy to be able to reach those who are typically underrepresented in research and figure out better ways to engage, as well as keep them engaged as a part of research. And then, the sixth and final is realizing a transparent and scalable architecture. So, the division of research informing practice and then practice generating data back again for research means that developers need to deploy tools on a large scale that request and manage data, but also, we must utilize a systems architecture that simplifies the process of obtaining data for research and for incorporating research findings into practice.

So, those were the six gap areas, and we took those gap areas and presented them at our in-person workshop. Next slide. We discussed those areas over the course of two days, and what came out of that was a series of seven challenges that were cutting across those gap areas, and this really started to create the foundation of what would become our priority areas. So, the first one was the transparent and interoperable health risk-related data. The second was tools that allow use, interaction with, and sharing of standardized EHR data. The third was solutions to enable aggregation across multiple non-EHR-based data sources. The fourth was functional solutions for patient matching and identity management. The fifth was consent management necessary for data-sharing and research. The sixth was research opportunity for those who have traditionally been underserved or underutilized in research participation. The seventh was opportunities to encourage dialogue and education on the use of health IT infrastructure for research.

Lauren Richie
Pardon me, Kevin. I'd like to ask everyone to please mute their lines. Thank you.

Kevin Chaney
Next slide. So, taken together, we now have the background report, our key informant interviews, and the workshop, and it informed a vision for a health IT infrastructure that supports alignment of the clinical and research ecosystems where research happens faster, better, and easier, and new knowledge available at the point of care to improve outcomes. Researchers would be able to easily access high-quality data in standardized formats with the necessary metadata to understand where, why, how, and by whom data were collected. The health IT infrastructure would also support widespread access to the tools and services needed for more effective and efficient research, including the ability to match data across multiple sources and aggregate those data for faster analysis. The health IT infrastructure-enabled tools would facilitate patient-centered communications and mechanisms to recruit participants across a wide spectrum of organizations and settings, improving interest and engagement. Next slide.

So, what does the agenda look like? The agenda is supported by two goals. The first one is to leverage high-quality electronic health data for research, and the second is to advance the health IT infrastructure to support research. Within each goal is a set of priorities, and those priorities include one or more supporting strategies or tactics, which then identifies a specific need that currently exists within the research ecosystem. Each action underneath these priorities is broken into something – again, hence the name "policy or development agenda" – something that's either a policy-oriented lever or development-focused lever. So, policies could be anything from additional collaboration across our stakeholders or perhaps informing the utilization, such as NIH did, with requesting more use of FHIR standards as a part of their processes, to more development work, which would be like a demonstration project or pilot study that's looking at the actual development of a standard or the application or development of a tool to support research.

Some of our stakeholders across these obviously include our other federal colleagues, but also include research foundations, healthcare provider organizations, health IT developers, the IT sector at large – so, your Googles, your Amazons – patient advocacy groups, obviously, as we will not be able increase participants and their education and ability to participate in research, payers, researchers, as well as funding entities that fund research, and especially standards development organizations as well as any other relevant stakeholders. So, it will be key to identify the current work and the appropriate stakeholders to promote efficiency and avoid duplication of effort, so we try to do that across the policy and development agendas to ensure that we're aligning and coordinating with the right folks.

So, I'm going to take a deeper dive now into each of the priority areas and their supporting strategies. Next slide. So, the first priority is to improve data quality at the point of capture, and this really gets at how our research is only as good as the data that we have, and unfortunately, health data are not always captured in standard formats or with the corresponding metadata needed to ensure the integrity and fidelity of the data. Individual data points need to be captured seamlessly, completely, accurately, consistently, and in a standardized format to improve the use of electronic health data for research.

For use in research, data must be accurate and precise. Metadata are particularly important here, so the quality of the data must be balanced against the needs of users who generate the data, and strategies

needed include coordination of a multi-stakeholder effort to identify high-priority metadata elements, the development of metadata standards, and the adoption and use of data and metadata standards. I would like to say that one of the important aspects, for instance, that ONC is doing currently is working on this aspect right here, which is trying to identify emerging high-priority data standards and metadata standards that are needed for both research as well as care. Next slide.

The Priority Area 2 is to increase data harmonization to enable research uses. Common data models allow for analysis of differing data sets by converting them into a common format, yet harmonizing these models remains a challenge, and so, for health data to be used efficiently for research, they must be extracted and aggregated in a seamless manner that allows for harmonization across different organizations, and also to be available for reuse for future research inquiries in accordance with established privacy and security safeguards.

Border-cross agencies that fund biomedical and health services research need to create incentives for researchers to use and share common data models, as well as institute mechanisms to communicate updated information about new and emerging data models to study section reviewers and to researchers. One of the other tactics underneath this is to investigate funding a large-scale – think of a national or centralized – research workbench platform, which would allow researchers to share data elements, crowdsource, and converge on data models, share tools for data extraction and cleaning, and a place to promote existing services, or perhaps provide peer-to-peer support – an area to disseminate ideas related to analysis of methods and predictive models used to support research.

A single common data model that maps clinical data elements across various EHR systems would be a large-scale project, but it's possible given the examples already developed and used in research settings. Again, we're thinking of networks such as Sentinel, Core Net, and others that have established common data models. Again, the challenge is that each model is developed for the fit purpose of that organization or network's research needs, which can sometimes make interoperability a challenge. We see FHIR serving as an important avenue here. Next slide.

The third priority is to improve access to interoperable electronic health data. In addition to being captured in standard formats, data must be accessible through standardized extraction and transmission mechanisms available to all authorized users within an infrastructure, so this includes the availability of reference documentation to support the identification and extraction of the specific data needed to answer the research question.

Experience with public **[inaudible] [00:36:55]** will drive incremental improvement of API standards, and while this trend will enable data-sharing for a variety of end users and purposes, documentation regarding the schema and technical specifications underlining the health IT systems may be needed for researchers to understand, integrate, and analyze the data from these open APIs, so we're specifically calling out specific requirements for certified systems to make sure that their technical specifications are publicly available so researchers can understand how the data points are represented, and also to encourage health IT developers to make available APIs and accompanying specifications and design EHR systems to enable access by other systems. And then, ultimately, through a lot of pilot work, we can test the effectiveness of the schema publication and API expansion toward small and midsize health IT developers. Next slide.

So, moving into the fourth priority, which is to improve services for efficient data storage and discovery, research data are often inaccessible due to localized source. Supporting standards that ensure data are both interoperable and identifiable will allow access to data in new ways, increasing the breadth of information available for research. In addition, centralized solutions to data storage may be needed to encourage those who have collected data for research purposes to maintain and make data available for future research. Next slide.

Priority 5: Integrate emerging health and health-related data sources. Integrating data collected outside the care delivery process that may affect health outcomes such as social determinants of health, patient-generated health data, and environmental exposure is critical to improving clinical care and research, Work is needed to support receiving, processing, and integrating these external health-related data streams and health IT systems in a standardized way as appropriate. Therefore, health IT systems should support an infrastructure and underlying standard that can integrate and link to these novel data elements. Next slide.

Priority 6: Improve methods and tools to support data aggregation. Presently, many steps involved in aggregating data from multiple sources are often done manually by researchers, and this curation is not standardized or replicable at scale or across multiple institutions. Future areas to focus to achieve advanced aggregation functionality include patient matching, data use agreement management, data curation, and more convenient analytic methods and tools. Advanced data functions are needed to improve the ability to aggregate data across various sources in both the clinical and research ecosystems. Again, these include functions to effectively and efficiently support matching and linking data, honoring data use agreements, looking at identifying redundant data, and managing updates to the data and the metadata, and working with varying data formats. Next slide.

Priority 7: Develop tools and functions to support research. Current resources are not optimized to facilitate critical research activities. Advanced functions will support consent management of personal data for research and improve processes such as recruitment, enrollment, randomization, and data deidentification. Tools are needed to more efficiently search, index, and query systems to identify patient cohorts or extract data about research participants. Additional functionality could be developed to more efficiently randomize participants to treatment and control groups in the trial, and tools that support robust deidentification and the use of deidentified databases to increase confidence and security and manage risk are also needed. Next slide.

Priority 8: Leverage health IT systems to increase education and participation. Potential participants are not involved in the research due to barriers such as lack of awareness of available studies, effort required to participate, or sometimes the lack of trust in the research community. Approaches that support better education, engagement, and participation about or in research are coming into use, but further work is needed to pursue infrastructure improvements enabling and incenting participation from a diverse patient population.

Patients and their providers may lack clear incentives to participation or encourage participation in research, so therefore, tools and interfaces embedded within the health IT system could be used to more effectively recruit and enroll participants by providing education materials regarding research participation and providing information back to those individuals who participate in research to ensure that we can increase

their interaction and sustained engagement. The health IT infrastructure should reduce barriers to participating in research to encourage inclusion and representation of all populations. Next slide.

So, Priority 9: Accelerate integration of knowledge at the point of care. Gaps between new knowledge and its integration at the point of care are widespread. The rate at which new knowledge is expected to be generated, both by traditional research and new care delivery approaches such as precision medicine, will continue to outpace its integration and use if infrastructure and capabilities are not harnessed properly. Ongoing digitization of evidence needs to be complemented by integration and implementation of this information back into clinical care – for instance, using Clinical Decision Hooks or API tools. Advanced methods and solutions are needed to support these findings within the health IT infrastructure, and as these systems improve, they can be used to accelerate the rigorous but lengthy process used to integrate evidence at the point of care. Teresa, I'll hand it back over to you.

Teresa Zayas-Cabán

Thank you, Kevin, and thank you for reviewing the priority and actions outlined in the agenda. Next slide, please. So, essentially, what we tried to articulate is that solutions are needed to enable the research community to more quickly and efficiently benefit from the available electronic health data and to leverage the existing health IT infrastructure. Collaboration across public and private entities will be necessary to realize the vision we articulated in the agenda. The current pandemic has illustrated in real time some of the gaps and challenges that we identify in the agenda and our need for a highly adaptable, transparent, and scalable health IT infrastructure that has the ability to capture high-quality data and aggregate those data across multiple platforms, the goal being that data can be analyzed for quick insight and shared back with the broader community, including providers and researchers as well as patients and their families. Next slide, please.

So, to be able to advance some of the agenda, I wanted to briefly talk through some of what ONC will be doing or continuing to do, as well as our collaboration with our federal colleagues. We will continue to be focused on coordination, advancing standards, and infrastructure work, and working to implement actions across several of the priority areas through programs and policies in collaborations with stakeholders, as we've been doing all along. As Kevin noted, we've been collaborating with NIH's All of Us research program and standards development organizations to pilot and advanced standardized data-sharing – I mentioned the Sync for Genes project, for example, and that continues and has moved on to Phase 3. I've already mentioned the LEAP in Health IT program announcements and the current awardees. We're in our third round of funding for that funding opportunity. We're furthering progress on some of the key actions across several priorities in the agenda.

We expect to continue standards development activities to address areas of high priority, not just for clinical care, but also for research, and we'll work collaboratively across the department in doing so. And, something I wanted to highlight is that the priorities that we outlined here also align with some of the needs and infrastructure priorities across federal agencies, and some of that is illustrated in how the agenda supports the goals in the federal health IT strategic plan. And, while we develop this with a primary focus on research, many of the priorities outlined in the agenda are relevant to other use cases such as post-marking surveillance, bio-surveillance, and public health. Next slide – oh, sorry.

And then, I did want to outline briefly how this aligned with some of the work that other federal colleagues are doing. In particular, for example, we were able to collaborate with Food and Drug Administration, which, as some of you have heard, is undergoing an IT modernization effort. FDA is supported by significant IT infrastructure and received and manages large quantities of data, and to be successful, they require access to efficiently collected and high-quality data, which would be advanced by the priorities in the agenda. They will also require improved data storage services, which I know they're working on, and new tools for aggregation of data for research, and they are also looking to incorporate real-world data and real-world evidence into decision-making and develop novel IT tools for regulatory purposes.

Similarly, we work very closely with the Veterans Health Administration, which is the largest integrated healthcare system in the U.S., and the VHA research enterprise is supported by four major lines of research, three of which depend heavily on clinical data to conduct studies, which is derived from over 20 years of nationwide electronic health data. They also have two major research initiatives that also depend on electronic health data: The VA Informatics and Computing Health Infrastructure as well as the Million Veterans Program, which you may have heard is part of the Precision Medicine Initiative. All of these initiatives are dependent not just on electronic health data, but robust infrastructure to be able to do analysis, and also feed findings back into clinical care as appropriate.

We've been working also very closely with the National Institutes of Health, and they have been focused most recently in data science and open science, and the researchers need access not just to high-quality electronic data to do their research, but also robust research data infrastructure and tools. They have been emphasizing the need for access to data that are fair, accessible, interoperable, and reusable, and standards are needed to be able to advance that goal. They've been funding the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability initiative, or STRIDES, which is providing cloud storage and computing support for high-value datasets. They also published a notice last year encouraging researchers to use the same FHIR API that is in final ONC and CMS Cures Act regulations, and we've been working very closely with them to implement related activities.

The All of Us research program will require ongoing advances in data aggregation and analysis, and NCI, for example – the National Cancer Institute – also needs access to robust health data infrastructure to aggregate and harmonize health data. So, with that, I think we wanted to leave some time for questions. Thank you.

Carolyn Petersen
Great. Thanks, Teresa and Kevin. HITAC members, if you have a question, please raise your hand in the Adobe Connect tool, and I'll call on you in the order in which you raise your hand. So, let's start with Arien Malec.

Arien Malec
Thank you. Very good presentation. Two questions. First, I don't see anything here on the legal framework for research, and in particular, how to address more ubiquitous use of real-world evidence pulled from EHRs with the requirements for protection of human subjects and IRB approvals. If we're going to be using data more broadly, we may need to consider additional mechanisms to protect the rights of human subjects, particularly with regard to use of deidentified data or other kinds of research needs. So, as a point in case, I've heard – at least anecdotally – as we're looking at risk factors for COVID-19 and other kinds of real-

world evidence related to COVID-19, at least some of the issues regarding pooling data are caused by the need to get specific IRB approval for each of the research needs as opposed to being able to pool data and do a variety of cohort analyses.

The second question is – maybe I have too many, so I'll just confine it to – how do we address the 90/10 split with regard to clinical trials data? In my experience having previously done drug development and data management, there's a good chunk of the data that is common in between a variety of clinical trials – things like lab data, demographic data, adverse event reporting data, and the like. And then, there's a wider variation around very deep areas that are specific to therapeutic area, drug class, et cetera that require data that may well not be in the EHR. So, the data that's in the 90% is very likely in the EHR; the data in the 10% is very likely in case notes – unstructured data and other sources of data that might not be structured – so I wondered about the proposal for addressing some of the inherent variation particularly in outcomes data, endpoint data, and some aspects of specific safety data that tend to have wide degrees of variation. Thank you.

Teresa Zayas-Cabán

Arien, thank you for the questions. So, in terms of some of the issues you addressed with regard to informed consent, IRB approval, and data sharing, what I'll say is that we focus on advancing some of the infrastructure functionality that would enable data sharing with attention to informed consent, and with the necessary privacy and security provisions in place, so there's some recommendations and actions around codifying data use agreements, and also developing out existing standards and things of that nature to be able to ensure that appropriate privacy and security protections are in place. Under the LEAP in Health IT funding opportunity, ONC made out awards to focus on, for example, further developing out the FHIR consent resource, which will include consent for research, and we're also advancing some of that in collaboration with NIH, for example, which are very much focused on some of these issues.

With regard to the fact that some data are fairly consistent across clinical trials and others are not and may not be in the EHR, again, we'll be collaborating with NIH on SCN multiple fronts. As I said, we will continue to focus on advancing relevant standards, and we'll be working with our sister agency to identify what are the high-priority use cases, and we are looking to try to make sure that we identify needs that are relevant across use cases, programs, and agencies to be able to work collaboratively. In addition, the agenda does speak to working to integrate relevant data from other sources and finding ways to do so effectively and efficiently without adding burden to healthcare providers in doing so. Kevin, I wasn't sure if there was anything you wanted to add.

Arien Malec

Thank you very much.

Carolyn Petersen

Let's go to Ken Kawamoto.

Ken Kawamoto

Hey, thanks. So, my question is historically, the research committees had a data model or competing data models that are different from what's used in the clinical domain. Do you see any reason why, for example, with NIH recommending the convergence on FHIR and the fact that there is an established clinical domain

approach to try to gain consensus there, mainly through the U.S. Core Data for Interoperability, that the research data model issue cannot be solved by converging on a common USCDI-based set of FHIR profiles that span both clinical and research?

Teresa Zayas-Cabán

Thank you, Ken. That's a very timely question, and it's something that we're working through collaboratively with and within NIH. I am currently on a temporary reassignment to NIH, and have been working with Dr. Mark Donald, who I know is on the line. I'm coordinating FHIR activities pursuant to the notice that NIH issued last year, and this is something that has come up and that we are going to be exploring further, whether there's an issue of better harmonizing those common data models with FHIR or converging on FHIR as the data model to be used, and ways to do so effectively, and bringing the research community along with us.

Ken Kawamoto

That's great. I would just try also to keep it convergent at the profile level because there have been fits and starts in HL7 already of competing FHIR profiles, at which point even though you can say everyone's using FHIR, they still don't talk with each other, so I would still encourage focusing on not creating a research-specific set of profiles that are similar, but different from the clinical set of profiles.

Teresa Zayas-Cabán

Thank you.

Carolyn Petersen

Thank you. Let's go to Sheryl Turney.

Sheryl Turney

Thank you so much. I want to thank you for this presentation today. I think it's very important. As folks in this group know, I am a huge supporter of research. My family has participated as a result of many different types of medical issues. One comment I wanted to add to what Arien said about the privacy is that it's a little bit concerning that more and more deidentified data is really not deidentified. So, are there any efforts that you are pursuing to ensure that patients are educated to know that there is a risk, however small it might be?

I know there have been various reports that I have seen and read that have talked about even the state APCDs, which are the all-payer claims data. In many cases, when that data is combined with newspaper, it can actually reidentify individuals when you look at things like accidents, births, and certain situations like that. So, in terms of aggregating data, I think there are valid concerns, especially in light of all the use of AI and other types of techniques that are being used to analyze the data, and of course, if everyone's interest was altruistic, that wouldn't be an issue, but we know that's not the case. So, can you talk a little bit about that?

Teresa Zayas-Cabán

Yes, and what I will say is that I agree with you; it's an issue that has increased recognition. We have been working collaboratively with Sage Bionetworks for a few years, and what I will say is that I think the critical piece is to be very clear with individuals as they enroll to participate in research studies and use the model

that Sage has developed in terms of education and teach-back methodology, to put it simply, to make sure that not only are they provided the information at a level that is understandable, but you also ensure the risks and stay in clear contact and communication throughout the lifetime of the research study. I'll say that all of this is breaking new ground on many different fronts, one of them being returning results back to participants and keeping them engaged throughout the lifetime of the study, so I think that may serve as a good model that others can emulate, and we'll have a lot of lessons learned in terms of how to do this best.

Kevin Chaney

Teresa, this is Kevin. I would also add on that for the last several years, the All of Us research program has had specific workgroups targeted around certain groups of interest – so, pediatrics or certain focus groups like Native Americans, et cetera – about thinking through all the considerations when it comes to privacy and security, not just for everybody, but especially for certain individuals and sectors of the population.

Carolyn Petersen

Great, thanks. Let's go to Les Lenert.

Leslie Lenert

Hi. I want to thank you for a great presentation. I really think you covered a lot of the key issues. The specific comments that I had were two. First, we always face a tension with privacy versus the quality of the data. As we move toward patient-controlled levels of disclosure-specific fields, for data to be useful for research, we have to be able to mark that data as not missing, but intentionally suppressed, or some other approach like that. If we're really going to allow patients to have control of their data at a field level, the standards need to reflect this notion of the difference between missing and intentionally withheld.

Second, I'd like to call out the success of the All of Us project, and particularly the rise of patient-driven approaches to research through Sync for Science with that, and the role that personal health records can have in research, and that it'll be important for our standards to really facilitate this as patients can download their records through 21st Century Cures Act, standards to personal health record apps for studies. They can also upload them to scientific projects, and we need to think through the patient-oriented approaches for research through personal health records.

Elise Anthony

Thank you, Les, for the comment. Just to add to your last comment first, as I said, the blog post on Sync for Science and the work we've done so far in collaboration with NIH should be coming out next week, and I agree that we need to continue to develop patient-controlled participation in research and other activities as a way of making sure that they're engaged and they're involved, and in the agenda, we prioritized or made recommendations around merging the infrastructure for continued patient engagement and research activity. So, your comment is right in line with one of our priorities.

In terms of privacy and data-sharing and some of the issues you bring up, it's something that's been mentioned previously, and certainly something we can look to in terms of what the standards can support. I think there's also possibly an entire research agenda around what happens as people start sharing part of their record and not other parts, and what's usable and useful for a particular research study, so thank you for that.

Carolyn Petersen

Do we have other questions from the HITAC members? If so, please, raise your hand on the Adobe tool, or let me know verbally if you're just on the phone. Okay, it looks like we don't have any further questions. I want to thank Teresa and Kevin for coming to speak to the committee. We'll now move to the next presentation, which is an update from the Intersection of Clinical and Administrative Data task force. I'll turn the mic over to Sheryl Turney and Alix Goss.

Sheryl Turney

Thank you so much, Carolyn. I appreciate it. Can we go to the next slide? Great. So, today, we're going to talk to you a little bit about the Intersection of Clinical and Administrative Data task force. We're just going to go over our progress to date and next steps, and hopefully have a fruitful discussion. Can we go to the next slide? This is the membership of our task force. I'm not going to read everybody's name out, but I wanted to say thank you so much to all of the people who are participating. Our membership has changed a little bit from the beginning, and those updates are made here. We also have a number of industry experts who have come to participate who are not regular task force members, and so, the meetings have been extremely enriched through their efforts. I think we can go to the next slide.

I wanted to remind the group as we get started today what our charge was for the Intersection of Clinical and Administrative Data task force, and it was to design and conduct research on emerging industry innovations to validate and extend the landscape analysis and opportunities, invite industry to present both established and emerging end-to-end solutions for accomplishing medical and pharmacy prior authorizations that support effective care delivery, reduce burden, and promote efficiencies, and then identify patient- and process-focused solutions that remove roadblocks to efficient medical and pharmacy electronic prior authorizations and promote clinical and administrative data and standards convergence.

We want to produce recommendations and related roadmap considerations for submission to HITAC and their action, and these deliverables will be shared with NCVHS to help inform its convergence and prior authorization activities, and also to make a public summary of our findings, hopefully no later than September of 2020. We established a vision for this overarching charge, and that was to support the convergence of clinical and administrative data, to improve data interoperability, to support clinical care, reduce burden, improve efficiency, and further implementation of "record once and reuse," and that's really the vision that we are trying to develop. In fact, the workgroup has begun working on an ideal state, if you will, to see how we might reimagine the work and not necessarily be constrained by the existing EMR systems that everybody is currently using, and trying to take it up another level, if you will. We can go to the next slide.

So, in essence, this open approach that we utilized was to create a compendium of the industry artifacts and the other federal work products and source documents that had been created and presented, and we utilized all the assets that had been brought to HITAC and ONC throughout the last year, and also, materials that various industry groups like WEDI, the Da Vinci Project, HL7, and Carin – all of those groups that have been participating – and, there are many. I'm not listing them all because I don't want to leave anyone out. Essentially, there are many aspects that we have created in this compendium as a resource for the workgroup participants.

And then, we tried to focus a small group to really give the group something to start with and created a clinical workflow. That quickly became drilled down as we were discussing it based on different individuals and their EMR systems, and we really didn't want to focus on the EMR process as much as the process for burden and really take it out of one single type of system and try to look at it in more of a model way, if you will. So, what we did is pivoted a little bit, and we started working on a workbook that tried to bring it up a level to data classes, actors, and some of the considerations and guiding principles that we have in order to scope out what our final paper would include.

The ICAD workgroup then transformed that workflow, if you will – into that workflow. We looked at these efforts and tried to define some connection to the work that HITAC had been reviewing over the last year. So, one of the things we wanted to make sure of is that all of the groups that have come and spoken and presented materials to HITAC would be considered, so between the compendium and also the work that we're putting in the background in our workbook, we made sure that all of the considerations and recommendations that have been made by third parties to HITAC were incorporated into the work that we are processing so that we're not basically leaving out any group or third party that has an interest in our work. We can go to the next slide.

So, in terms of our progress to date, just to remind this group, we do meet weekly on Tuesdays from 3:00 to 4:30 Eastern. You're always welcome to join us in addition to the workgroup that we have. Subgroups do meet throughout the week, and we have two or three of those going. As I mentioned, one is focusing on the ideal state and guiding principles. We have another one that's been focusing on data classes, and we soon will hope to be pivoting to what the goals for our paper would be and our priorities, as well as what our recommendations will look like. We've had demonstrations by third parties. Surescripts and CoverMyMeds came on March 28th, and then we had Regence – or, Cambia – and Humana come and make presentations on May 5th, and then, this week, we had a great discussion that was led by American Medical Association, and there may be additional presentations made in the future. We had one more planned that was postponed, but we'll have to see how that goes. And now, Alix is going to take you through our next steps. Alix?

<u>Alix Goss</u>
Thank you, Sheryl. Hopefully, you can all hear me. I appreciate you setting us up with the foundation of what the task force is about and the substantial progress that we've been making as we've been creating a framework of thinking that will lead us toward our work product of a report. So, on this slide, I'm going to talk about the next steps, and then we'd like to have some discussion time with the committee. We've got it queued up on the next slide. So, for the next steps specifically, we're going to continue with the framework of our weekly meetings, which are scheduled through September. We're going to continue to have workbook elaboration, meaning our small workgroups that are focused on the data classes, guiding principles, and the ideal state. We'll continue to elaborate their work, and from the perspective of guiding principles and ideal states, we've identified the opportunity to take a deeper dive with the privacy and security aspects, so we'll be working on that small working group in a deep dive over the next couple of weeks.

As Sheryl noted, the result of those small workgroups will really help us create the framework or fodder that will enable us to define the recommendations that we need to craft for the full HITAC's review. As a part of the recommendations work that we're doing – at least, I know from the guiding principles and ideal state

workgroup that we've already taken a look at the third-party recommendations to HITAC, and are factoring that into the foundational effort, so we'll round that out with our subsequent small working group efforts.

One of the challenges in front of us is to take the very focused conversation around prior authorization and extend that or extrapolate it to the larger intersection of clinical and administrative data. This is going to provide us with a really important step that gives us the opportunity to provide different types of recommendations to HITAC: Prior-authorization-specific and the larger framework aspects of our ecosystem needing to converge clinical and administrative data types, standard frameworks, and policy adoption. We seek to produce our draft recommendations mid-summer, with the final ones targeted by September, but I believe we'll have touchpoints along the way, so this gives us a nice framework for the work that we need to complete over the next two months to achieve that September goal. I'd like to move to the next slide, please.

As an opportunity to give you an update, we wanted to leverage it to solicit some input and have some dialogue with you that will help advance our task force efforts. So, we created a framework of four questions that we'd like to throw out there today to start some discussion in addition to other questions that may have been generated from the update that we've delivered. So, we are looking to generally get some feedback on the broader intersection of clinical and administrative data. We've been thinking a lot about prior auth, so we'd appreciate input from you on goal areas that we should be covering on questions we should be answering in regard to the broader convergence conversation.

We've had several areas that have been bubbling up as repeating themes within the task force, such as coordination of benefit complexities, prior authorization, goals related to cost transparency for patients at points of care related to prior auth, the lack of attachment requirements, and what that means in the role not only of prior auth, but in other functions within the information exchange between payers and providers, and also some considerations about what should be the timeliness level that we're all achieving when we request a prior authorization and we receive a response or a pending response. So, we'd appreciate hearing from you on any key considerations related to those or other topics you may have that are similar to that list I just covered.

Third, we've been thinking about the aspects of piloting and how that might reveal opportunities and barriers within the EMR system. This really helps to get at the workflow dynamics that are at the crux of data capture, and transparency, and keeping the whole care team – patient and their team – engaged as we move forward with trying to improve prior authorization specifically. So, we're interested in any piloting activities that might be able to help us get at the crux of those barriers and challenges.

The fourth question is we're looking to see if there's any way to standardize the data requirements across payers which clinical decisions are based upon, even if the prior-authorization-type decisions differ by payer, plan, and product. And, as we noted, the USCDI has been a part of our thinking in regard to the data classes, so we'd like to open up some discussion around how USCDI fits into the model. These are just some general questions to get us started, but at this point, I think we want to open it up, Lauren, for questions from the committee.

Carolyn Petersen

Great, thank you. HITAC members, if you could signify that you have questions by raising your hand in Adobe, that would be great, and we'll start with Ken Kawamoto.

Ken Kawamoto
Great. Thank you for this work. I was hoping that as you use the administrative data or go into it that you could advocate for the claims data to be available through USCDI and that process. Perhaps you could comment – I'm thinking in particular, for example – when it comes to procedures that are done in our health system, there is oftentimes great CPT coding that's available, but oftentimes, the actual procedures through the procedure interfaces that are available don't have any standardized coding associated with them, and I think it could help for other purposes, like making sure that users are aware that this exam has already been done, and therefore it shouldn't be done again because there's a good chance it's going to be duplicative and waste resources. So, I just wanted to ask whether you've considered getting claims data through this effort included through USCDI.

Alix Goss
I think that's a really great question. Sorry, Sheryl. That's a great launch-off point for us to take back into the broader conversation. We've been very focused on prior authorization, and I think the idea of claims data is a far bigger scope of consideration which gets us to the next phase of our work with broader considerations, so I really think it's a great idea for us to put that on the table. Sheryl?

Sheryl Turney
Yeah, I absolutely agree that that's a great point of discussion, and obviously, there are systems where payers exchange data with EMRs today, but what we've been told is most of that claims data then gets put into a separate database that's not available through the EMR. So, you're really looking at how we can make that data available through the EMR, and I think that is a really valid point we need to talk about, so thank you for that.

Alix Goss
Thanks.

Carolyn Petersen
Thanks. Let's go to Clem McDonald.

Clem McDonald
This question is narrowly targeted for this group, and I couldn't ask at the last one because I didn't get connected, but for many things with prior authorization, we'd like to know the values of tests and results, and in that case, we'd probably like to get at some of the status codes that aren't claims codes, they're medical record codes like LOINC and RxNorm. And, in that context what I've found in general – a lot of the systems by ONC are able to deliver the test results to the outside through a messaging system with the appropriate codes, but people inside the institutions have a heck of a time finding them because almost never within large systems are they actually stored with, say, the test results.

There's some mapping data somewhere, and I don't know if it's the same with the drug data, but it's a problem, especially for researchers within the organization trying to find this stuff, so it might be worth thinking in some future world of requiring that the primary codes in USCDI be stored in the records with the

specific test results, drug descriptions, or the conditions, so if you've got a condition record, it would carry the similar codes. Now, I don't know if all of them suffer from the same problem, but I do know it's a big problem with LOINC in lab testing, that this is really not for your committee specifically, but you probably would like to get at this stuff too, going in the other direction from what Ken Kawamoto suggested.

Alix Goss
Just so I'm clear on what you're recommending, Clem, what you're recommending is that the test results and those indicators and codes be stored with the test results.

Clem McDonald
Yeah, I think it generalizes to the other cases, but I don't know if they are not already there. So, if you've got a prescription record, the standard code should be stored as the primary field in a prescription record, and if you've got a test result, the standard code should be stored – the truth is the researchers are having a heck of a time finding these codes in the systems, which are quite complex systems. They probably are there somewhere, but they're in some mapping table somewhere.

Alix Goss
Okay, I think I understand.

Clem McDonald
Thank you.

Carolyn Petersen
Thanks. Let's now go to Christina Caraballo.

Christina Caraballo
Hi, thanks. Thank you for the presentation. I just wanted to chime in on how this would fit into the USCDI model. I think that when we are looking at USCDI, we need to make it kind of fundamental in how we're looking at any type of data element that we're trying to get to USCDI. We've really defined a process, and when we're going through anything that we're evaluating, I think we should look at the criteria that ONC has put into place with feedback from both our committee and the industry. I think it's important that as a first step toward readiness, we submit the data through the submission form that is hopefully going to be launched soon and continue to monitor the process from submission to Level 1 to Level 2 to USCDI.

When I think about the promotion model that we have put into place collectively, we really thought through industry readiness and need and have started to define that criteria to move through the process, and it gives really good boxes to check to help get data elements and data classes through the process in general, so I think just using that as the template will help us guide our work and enable us to better position the new things that we're working on for ONC not only to evaluate for USCDI, but also just for the industry to better understand if things are ready for national adoption even if they aren't put into USCDI at this stage. Thank you.

Alix Goss
Thank you, Christina. USCDI is foundational to our thinking and leveraging the work that the other committees have done, so we want to build upon those earlier recommendations early on in this small

working group, and Sheryl, you may want to speak to this as you've been more intimately involved with that small working group. They've really worked to harmonize the way we're thinking about data flow, data classes, and data elements, all within the context of the USCDI work.

Sheryl Turney
Christina, I understand what you're asking for as well because having been on that USCDI working group, I do think that a great maturity process was adopted, and I do think that up until now, always for various reasons, claims data has been kept separate from the clinical data, and it's our opportunity to bring those together through this effort, and I think that claims data often is already set up in a good way because it is already exchanged electronically, so although not all of the data may be present in an EMR system – and, that aspect of it would need to be handled – as the data comes to a payer through an electronic transaction in most cases and is returned, obviously, it's probably more ready for consideration in the USCDI model than some of the other aspects, but how that data needs to be used and the piloting of those opportunities to bring that data together are some of the ways that can demonstrate the value of bringing that data together – I think there are some Da Vinci pilots going on right now that demonstrate the collaboration between providers and payers in terms of reducing gaps in care and things like that where having the claims and clinical data brought together is definitely making a difference. So, I appreciate that recommendation. I think it's a good one.

Carolyn Petersen
Thanks. Let's now go to Ken Kawamoto.

Ken Kawamoto
Thanks. My question is around your thinking on the frameworks for getting prior auth versus standardizing on the discrete data level requirements, and this comes from my review in particular of Da Vinci and HL7. In reviewing those kinds of standards, the overall interaction frameworks and the use of CDS Hooks, FHIR, et cetera all look quite good. The place where I think it starts falling apart is like many projects, it doesn't really deal with the granular data that needs to be exchanged. So, for example, let's say to check on certain prescriptions, you need to know what the patient's LDL cholesterol level is. There still needs to be a process to say, "Well, if there is a cholesterol level, what's the process that ensures that that's actually going to be mapped to LOINC?"

So, that's a prototypical example of something where it seems like the standards have already been existing to fix it, but in reality, a lot of that data might not actually be available in standard form. Something more complex might be, say, trying to prescribe home oxygen, and you need to know what the patient's oxygen saturation is both on room air and on whatever liters of oxygen, and most current systems may only just give you the oxygen saturation from the pulse ox without actually telling you if it was on room air or two liters of oxygen, et cetera. A similar kind of thing is lung cancer screening, where CMS requires that you report the patient's number of pack years that they've smoked, and that might be in the EHR, but there's no actual interface to pull that data. So, I guess my question is around what your thinking is on how you're going to deal with that issue. Even if the framework is available, in the end, you need that discrete data level standard – that data in standard form, whether it requires mapping or data that's currently not being pulled at all to be pulled. What's your thinking on that?

Alix Goss

Ken, let me just make sure I got your question right. Really, what you're talking about is it's one thing to have a framework, but another thing to be able to know that there is discrete data that is available that the intersection with the policies of the payers can be pulled back into the PA process, and whether that data is actually within the EMR or an ancillary application so that we make sure that we have the right specific elements needed for whatever medical necessity determination is being performed.

Ken Kawamoto
Yeah, that's right. So, if you take the home oxygen requirements, it's one thing to say, "Hey, I can detect that you're about to place a home oxygen order," and that's sort of a separate issue where those orders themselves need to be standard-encoded, where oftentimes, it's not, but let's say you detect that you are actually trying to place a home oxygen order. Then, with a lot of these models, I think the payer would say, "Well, here's the information I need." If we're simply going to stop at "Now you have to fill out if the patient has an oxygen saturation less than 88% when you're on room air" and you expect the user to just look it up and fill it out, that's one thing, but I think a lot of these are expecting that if the data exists in the system, it will pull it back.

You run into issues there, for example, where I don't think any of the EHR systems right now append the liters of oxygen that the patient is on to oxygen saturation when they return it. So, those are the kinds of things where what I would imagine you would need to do is say, "Well, we're going to push this through the USCDI process to expand the vital signs component of the USCDI data elements to say we are also going to have this standard way where whether the patient is on room air or however many liters of oxygen when this oxygen saturation was measured, it will be part of what gets transmitted." Because then, you can answer that question. Without it, you would be filling it out with incorrect information or you would be asking the user to go ahead and do it themselves.

Alix Goss
Yeah, this – go ahead.

Sheryl Turney
Go ahead.

Alix Goss
Thinking about your question, it really about… It really presents an interesting dynamic on top of the workflow considerations that we've already been discussing in that there's the data capture dynamics that happen with – did it actually get – can it be – is it captured during the interaction between the patient and the provider, and then put into the EHR? And then, there's the second aspect which relates to the use case related to burden reduction where we say, "Hey, payer, I want to do a prior authorization for Suzy Q," and we go through this coverage requirements discovery, the document templates, and then the prior authorization.

So, we've been thinking about the ability for how you use the 278-type prior authorization transaction scope of content, but to be able to look at API interfaces that can leverage the content out of the EHRs to get us more automation reducing human intervention, but when you couple the frameworks of those use cases in FHIR along with the way the data's captured… I think you've identified a longstanding challenge that we're going to have, which is stuff is always going to be discovered as a new data element that might be needed,

and how do we make sure that that data element is not only supported in the foundational standards, but how does that then traverse all the way from that point into the USCDI frameworks and the EMR solutions that are certified? So, it's a complex issue, and I'm glad you brought it up. I think it's something we're going to have to tackle. Those are my initial thoughts. Sheryl, do you have other thoughts on that?

Sheryl Turney
I agree with you, and I think that this is why we're looking at different subjects like what the data requirements are for different types of prior authorizations and whether that data is even available in the EMR, which is the point that you're trying to make. It is likely that there are going to be different types of prior auth that every payer looks for, but as you point out, that data may be available in some EMRs, and maybe not in others. So, what would our recommendations be in those cases? I think that this is a big problem, not a small one, but maybe the right solution here is to have a framework put in place so that like the USCDI and the maturity of that framework, this framework can be matured over time as well, tackling one data group at a time, if you will, for prior authorization. And, if the oxygen requests are one, and we need something else – somebody else was bringing up something for medical devices – there are going to be specific data needs for each of these, and all of the data may not be in the EMR that needs to be transmitted and then needs to come back.

So, to me, by looking at it as an ideal state, I want to pretend that at the end of the day, if this was an integrated system that we could revisit, what is it that we would want to have happen, and how do we try to make that happen over this cross-section of vendor tools, both at the payer side and at the provider side? Because we have to deal with both, and then the communications back and forth. I think what HL7 is doing – and, in other aspects, WEDI and Carin – they're all focusing on the transmission of that data, and what we need to focus on is not only that, but also the receipt, storage, and use of that data because as I said before, having claims data available in some system off to the side that's not connected to a patient isn't going to be helpful when you're looking for those procedure codes related to that patient. So, we need to somehow have recommendations that allow the integration, and that is not going to happen overnight. So, I think we're most likely going to try to focus on some framework to allow that interaction to occur over time through a maturity process.

Alix Goss
I think there's also a tie-in there with that maturity framework idea, Sheryl, that ties to some of the payer-related processes we've been discussing and trying to make sure that the prior authorization requirements are periodically reviewed and refreshed, and that over time, what we need prior authorizations on will change, and we need to have a method for that, but we also need to have a tie-in related to evidence-based medicine, and that all starts to then get back to the discrete data captures and back to your point about the storage access and use downstream within the USCDI and the products. So, it's a very multifaceted item that you bring up, Ken.

Ken Kawamoto
Yeah. I would just note that in almost every project like this that I've encountered, this particular issue is identified as a challenging issue, and the can is kicked. I brought this up specifically with Da Vinci as a comment in the balloting stage, and they kicked the can on this one as well – at least, at that point. I understand why because trying to solve it completely is completely daunting. At the same time, I think if we don't have this, you'll just end up having forms that get presented to clinicians that they just have to fill out

a bunch of by hand, wondering why it's in the EHR, and if it is, whether they will have to reenter this, which defeats the purpose of the burden reduction to a great extent. So, I would just encourage that it be kept in scope, acknowledging that this project is not going to solve the entire process, but like you said, you could identify approaches with specific examples and say when the next thing comes up – and, it inevitably will, and there will be a lot of them – this is the process that it shall go through in the future.

Sheryl Turney

Yeah, I absolutely agree, and I do think that this is an item where there need to be some recommendations related to how to provide more than just the data exchange, but also, maybe there's an opportunity – and, I've mentioned this before – where the EMR system may need to open up certain aspects that provide more open-source-type solutions that allow for the integration of payer and provider data more greatly, and maybe that needs to be in some cloud space somewhere or whatever in order to provide the solution, but at the end of the day, there are probably going to be a lot of these hoops that need to be integrated, and the only way to tell them would be to start piloting something. So, hopefully, we can come out of this group with some recommendations for pilots, and this might be a great one to start with.

Carolyn Petersen

Great, thank you. Let's go to John Kansky now.

John Kansky

Thank you. I had a comment related to the observation of the need to combine clinical and claims data together, and for the awareness of the task force, I wanted to make sure you were aware that an increasing number of state-based and community-based health information exchanges have participation from both payers and providers, which manifests itself in a couple of different ways. One is that in some cases, there are both clinical data and claims data that are matched around patients and populations that can be used for various constructive purposes – for example…the consideration of whether health information exchanges can serve as a source to help with completing or providing prior authorization data as an example. The bad news, obviously, is that this situation exists in a minority of states and regions, but I just wanted to mention that.

Alix Goss

Thank you. It is a good assessment of perspective from a health information exchange, which – I used to lead the Pennsylvania statewide health information exchange network, so I appreciate the variability aspects. It is wide.

Carolyn Petersen

Great, thanks. Let's go to Arien Malec.

Arien Malec

Thank you. I just wanted to respond to Ken's comment, which I completely agree with. I do think it's important to recognize that the current state is paper, fax, portal – a heavily inconvenienced, unacceptable state. So, advancing the current state, even if we don't get to full automation with all this great information, is beneficial, but we need a model that lets us get toward a fully real-time system, and I think some of the work that we've been doing in terms of articulating the happy path and the end state while being pragmatic about how we model through it does get us there, and it will likely require a multiphase step where the first

step is "Hey, we see that you're doing a home oxygen ordering" – again, really appropriate comments on the need to be able to identify that we're doing a home oxygen order – and a mix of discrete data and data that exists through attachment or data collection toward a need where some of that data is actually captured in an upstream source in the EHR.

I guess the last thing is just an observation that there is administrative complexity and clinician complexity to collect the data upstream in the EHR, and so, it may sometimes be better to burden clinicians at the time of PA than at the time of data entry, so maybe the room air O2 saturation is a bad example; you might be able to get some good decision support or be able to automate some of that directly off of the instruments in the hospital. But, if we're asking every clinician to enter the O2 mix every time you collect the O2 saturation, you can actually drive burden upstream, and it may actually be better to concentrate some of that burden at the time of the PA. So, again, those are really good comments articulating the need for a progressive and incremental approach to reducing administrative complexity and noting that sometimes, pushing administrative complexity upstream actually increases data entry burden for clinicians, so we need to be mindful of both ends of that. Thank you.

Carolyn Petersen
Great. Thanks, Arien. Are there any other questions from HITAC members who are on the Adobe Connect? If so, please raise your hand. And, are there any questions from HITAC members who are on the phone?

Clem McDonald
This is Clem. If I may, I just have a follow-up on Ken's question.

Carolyn Petersen
Go ahead, Clem.

Clem McDonald
So, I think he's absolutely right. Oxygen measurements have no meaning if you don't know how much oxygen they're on, although mostly, they're not on any. I think one fix for this would be that the vital sign specification in neither ONC nor FHIR include that. I don't know if I'm wrong, but I think that would be an easy fix.

Carolyn Petersen
Okay, then if we have no more questions from any of the HITAC members, I will say thanks to Sheryl and Alix for coming and presenting to us today and holding this discussion. I believe Robert wanted to circle back to a discussion from earlier, so I will pass the mic to Robert.

Robert Wah
Thanks, Carolyn, and thanks to Sheryl and Alix, and also note that it's great having Alix here on our task force – I guess it's a joint task force – and she's from the NCVHS, and as we talked about earlier on, we're always looking for ways in which our two federal advisory committees – the NCVHS and the HITAC – can work together, and I think coming together on this issue of prior authorization is a perfect example of this. So, anyway, I did want to say that we appreciated Elise giving us an update on where ONC policy is right now, and I particularly wanted to see if we had any further comments from the HITAC about her presentation on where some of the policy is, and specifically any follow-up from our COVID-19 hearing or other

discussions that we've had, so I wanted to make sure that the committee had a chance to bring that up again.

So, I just want to ask the HITAC – I know it's out of sequence now because Elise's presentation was at the beginning of this, but if there are any other comments you have about the COVID-19 follow-up or other policy issues that Elise had in her presentation. I thought it would be appropriate to have an opportunity for the committee to discuss that. And, we also want to make sure anybody who's on the phone that is not on the Adobe application and can't raise their hand also has the chance to participate at this point. Okay. I guess I also wanted to give Elise a chance to add anything else that she didn't have time for in her presentation because we had to limit her comments as well.

Elise Anthony
Sure. No, I think I covered most of the items. I just want to make sure folks have the latest information on where they can find some resources regarding some of the different initiatives that we're doing. I definitely want to encourage folks to sign up for the listserv as well because that gives you a great look at the current things that are coming through as they're coming through, such as the blogs, the updates to the inquiry portal, et cetera.

Robert Wah
All right, great. Well, if there aren't any other comments or questions from the committee, I think we'll proceed a little bit early to the public comment period, and I'll turn that back over to Lauren for that.

Lauren Richie
Great. Thanks so much, Robert. We do have the phone number pulled up on the screen here for the public members who would like to provide a comment. Operator, can you open it in public line?

Operator
Yes. If you would like to make a comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. If you would like to remove your comment from the queue, please press *2. For participants using speaker equipment, it may be necessary to pick up your handset before pressing *. We will pause for a brief moment to pull for comments. Our first comment is from Lauren Riplinger with AHIMA. Please proceed.

Lauren Riplinger
Thank you. Good morning, everyone. My name is Lauren Riplinger. I'm the vice president of policy and government affairs for the American Health Information Management Association. AHIMA represents health information professionals that work with health data for more than 1 billion patients a year, and we recently brought together a group of our members who are really actively focused on this important topic of integrating clinical and administrative data, and the committee and the task force's really current focus on prior authorization is incredibly important, but we believe that it's just as important to focus on additional administrative processes that require data exchange between clinicians and payers such as inpatient authorization and medical necessity reviews.

Some key areas of interest that we've acquired from our members include the need to improve processes for both patients and clinicians, thereby removing barriers and delays to care for patients as well as reducing

administrative burden for clinicians. We're also very focused on addressing factors beyond automation, including more standardization of business processes and other factors that will help facilitate trust between clinicians and payers. It's also important to consider on-the-ground operations, including how information flows throughout the healthcare system and really, the crucial role health information professionals play in translating that clinical information for administrative purposes, including, obviously, the revenue cycle.

Another key area of interest we believe is important is addressing the coding accuracy and ensuring there's really a clear understanding of how those code sets are used for both clinical and administrative purposes, and of course, the need to prioritize privacy and security, including assurances that only the minimum necessary information is shared and used for the specific transaction in question. We just really want to thank the committee and the task force for their work on this important topic thus far and, of course, welcome the opportunity to serve as a resource for the committee and the task force going forward. So, thank you for the opportunity to allow me to comment this morning.

Lauren Richie
Thank you. Operator, do we have any additional comments?

Operator
There are no more comments at this time.

Lauren Richie
Okay, then I will turn it back over to Robert and Carolyn for any closing remarks.

Carolyn Petersen
Thanks, Lauren. I just wanted to share my appreciation with our presenters today – Teresa, Kevin, Sheryl, and Alix – for making time in this very busy season, and to let you know I'll be looking forward to next month's meeting in June, which we will also do virtually. Go ahead, Robert.

Robert Wah
Thanks, Carolyn, and again, we're very appreciative of everyone committing their time and talent to this effort. These monthly meetings are very important, and I think we get a lot covered. Again, I recommend you look at the summary graphics of all that we've accomplished as a committee. When you stand back from it, it's quite impressive. I also want to make sure that as always, if you have comments, suggestions, or ways to improve the process for this committee, please let Carolyn and me know, either through email or other means. We look forward to making this the best possible and effective committee for you. As was noted, we have our next meeting scheduled in June, and I'll turn it over to Lauren to give all the details of that and some of the other housekeeping issues, but I look forward to seeing you all in a month. Thanks.

Lauren Richie
Thanks, Robert. Yes, June 17th is our next virtual meeting, and as Alix and Sheryl mentioned, our ICAD task force meetings are weekly on Tuesday, so the next one coming up is on the 19th. At this time, I will see if there are any other closing remarks from Dr. Rucker, Steve, or Elise.

Donald Rucker

I just want to thank everybody for all of their comments and leave it at that. I wish everybody safety and good health.

Lauren Richie
Okay. Well, thank you, everyone, and with that, we will adjourn, and we look forward to touching base again next month. Thank you all. Have a great day.