

Transcript
October 17, 2018
Virtual Meeting

Operator

All lines are now bridged.

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

Good morning, everyone, and welcome to the October edition of the Health Information Technology Advisory Committee here at ONC. Coming on the heels of our September meetings, we have made some significant progress on some areas, and so we have a good number of updates for the committee as well as anticipating some deeper discussions around our standards work. With that, we will officially call the meeting to order starting with roll call. Carolyn Peterson?

Carolyn Petersen, Co-Chair, Individual

I'm here.

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

Robert Wah?

Robert Wah, Co-Chair, DXC Technology

Present.

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

Michael Adcock? No Michael yet? Okay, Christina Caraballo?

Christina Caraballo, Member, Kizmet Health

Present.

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

Tina Esposito? Cynthia Fisher?

Cynthia A. Fisher, Member, WaterRev, LLC

Here, good morning.

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

Good morning. Brad Gescheider?

Brad Gescheider, Member, PatientsLikeMe

Here. Good morning.

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

Good morning. Valerie Grey?

Valerie Grey, Member, New York eHealth Collaborative

Good morning.

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

Good morning. Anil Jain? Not yet. John Kansky indicated that he would be absent. Ken Kawamoto?

Kensaku Kawamoto, Member, University of Utah Health

I'm here.

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

Steven Lane?

Steven Lane, Member, Sutter Health

Good morning.

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

Leslie Lenert also said he will be absent. Arien Malec? Sorry, was that Arien? That's okay, we'll circle back. Dennie McColm? Not yet? Clem McDonald?

Clem McDonald, Member, National Library of Medicine

I'm here, but I have to apologize. I'll have to leave in about two hours because I got some family obligations.

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

Thank you, Clem. Aaron Miri?

Aaron Miri, Member, Imprivata

Good Morning.

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

Brett Oliver?

Brett Oliver, Member, Baptist Health

Here.

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

Terry O'Malley?

Terrence O'Malley, Member, Massachusetts General Hospital

Here.

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

Ratwani? I think I heard Raj dial in.

Raj Ratwani, Member, MedStar Health

Yeah, Raj is here.

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

Steve Ready?

Steve L. Ready, Member, Norton Healthcare

Present.

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

Patrick Soon-Shiong? Not yet. Sasha TerMaat?

Sasha TerMaat, Member, Epic

Here.

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

Andrew Truscott?

Andrew Truscott, Member, Accenture

Present.

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

Sheryl Turney?

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

Present.

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

Federal Officer

Denise Webb?

Denise Webb, Member, Marshfield Clinic Health System

Present.

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

Kate Goodrich said she would be absent today. Chesley Richards? Not yet. Ram Shiram?

Ram Sriram, Federal Representative, National Institute of Standards and Technology I'm here.

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

Lauren Thompson said she would be absent today, as well. Here at ONC, this is Lauren Ritchie. I am joined by Cassandra Hadley, Seth Pazinski, and Executive Director of Policy Elise Sweeney Anthony. With that, I will turn it over to Elise for a few welcome remarks.

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health

Thanks, Lauren, and welcome, everyone. I hope everyone is having a wonderful day today. We have a great agenda laid out. I wanted to first thank everyone for joining, but also to send regrets on behalf of Dr. Rucker who could not join us today. He has, however, taken a look at the work that's under development, particularly with the Standards Priorities Task Force and the Annual Report Workgroup, and he's very excited by the progress that you are making, and he appreciates your work. I also wanted to note a couple of things that are on the move at ONC, so we'll highlight some of those as part of the remarks, but first, I also wanted to welcome National Committee for Vital and Health Statistics, as well, who will be sharing with us a little bit about their work.

In terms of upcoming HITAC work, I've been busy, and as you might have noticed, there is more work to come. First, many thanks to the Interoperability Standards Priority Task Force and the Annual Report Workgroup for the work that they're doing to move forward their objectives and charges. Also, in terms of what you might have noticed, you might have noticed that, on OMB, ONC's rule is now under consideration by OMB. We look forward to, obviously, working with our partners at OMB and release of the rule in the near term. Once that happens, as we stated before, we look forward to the HITAC reviewing the rule and engaging with us to provide feedback.

A couple of additional things, the EHR reporting program, so today is a big day for two reasons. Not only is the HITAC having its meeting, but comments are due today. The EHR reporting program request for information has been out for some time. We've shared with you a little bit in terms of what the goal of the EHR reporting program is and the focus of the request for information. We're now looking forward to hearing from the public. Comments are due today by 5:00 pm. For all of the public that's listening in, please do take the opportunity to comment, and as we discussed before, once the comments are in, we'll be sure to bring back the criteria work to the committee for consideration, as well. We look forward to your feedback and we will definitely share with you a summary of the comments we receive once we've had a chance to analyze them and bring them together.

Other updates, on behalf of Steve Posnack, let me just give a plug to his blog that he released, I believe

it was last week or the week after, focusing on FHIR and where FHIR is located around the country. I encourage folks to take a look at that. It's a great resource. Also, the security risk assessment tool has been updated. Information is available on our website. We hope that that continues to be a resource for providers and others as they're implementing EHR systems across the country.

Other fun news is our annual meeting. Our annual meeting is coming up on November 29th to 30th. It will be in Washington, DC, a two-day meeting where we have an opportunity to hear from our partners in terms of the work that they're doing. There'll be a combination of plenaries as well as breakout sessions. Registration is currently open, but we do encourage you to register as soon as possible. We'll be sharing more information about the agenda as we get closer to the annual meeting. Overall, obviously a number of things are going on and a number of pieces yet to come. As always, we thank you for the work that you do. We know you do this as a volunteer, in a volunteer capacity, and we really appreciate it. It helps us to do our work here at ONC and to make sure that we're hearing from diverse stakeholders.

Thank you, again. Let me transition over to Carolyn and Robert to start us off with the agenda.

Carolyn Petersen, Co-Chair, Individual

Thanks, Elise. Good morning, everyone. It's great to see us all on the call this morning. We have an agenda that was sent out a couple of times in the last few days. In brief, we will be doing an overview of the Heat Wave ONC blog post on FHIR by Wes Barker. We'll have a presentation by the National Committee on Vital and Health Statistics with Bill Stead, Rich Landen, and Rebecca Hines. We'll then have a presentation on the Interoperability Standards Priorities Task Force draft recommendations with Ken Kawamoto, Steve Lane, and Dan Vreeman. Then Aaron Miri and I will present an update on the HITAC Annual Report Workgroup's work. We'll have a period for public comment and then closing remarks and adjournment.

I think at this point we need to approve the September meeting minutes, which were sent out in a couple of the packets earlier in the last few days. Could someone please make a motion to approve those minutes?

Male Speaker:

So moved.

Carolyn Petersen, Co-Chair, Individual

Could we have a second?

Male Speaker:

Second.

Carolyn Petersen, Co-Chair, Individual

All those who approve the meeting minutes, would you please respond by saying aye?

All Committee Members

Aye.

Carolyn Petersen, Co-Chair, Individual

All those who do not approve the meeting minutes, would you respond by saying no? All those who abstain, would you please announce by abstain? Okay, I think we have the September meeting minutes

approved. Did you have any comments, Robert?

Robert Wah, Co-Chair, DXC Technology

No, thank you, Carolyn. I'm dialing in from Beijing, so I'm having a little trouble remaining connected. I'm probably not gonna be as active on this call as before.

Carolyn Petersen, Co-Chair, Individual

Okay. Well, we're glad you're able to be with us today and we'll keep the meeting moving. Please do let us know over the chat if you have any concerns. Then, let's go right into the presentation on the Heat Wave ONC blog post. I will turn the post over to Wes Barker, analyst with the Office of Technology.

Wes Barker:

Yes, thank you so much. As Elise mentioned, Steve Posnack and I co-authored a blog called Heat Wave; The U.S. is Poised to Catch FHIR in 2019. This presentation will focus on the underlying analysis that went into calculating a lot of the numbers that go into the blog. Next slide, please. The objective of the analysis and the blog was to estimate the availability of FHIR across EHRs currently used by hospitals, and obviously it's practiced nationwide. We brought together a couple different data sets in order to accomplish this task. The first data that we looked at was the API documentation provided for all 2015 Edition products that are certified to the G8 Application Access - Data Category Request.

Certified criteria, one of the requirements for these criteria is that developers submit the URL to a publicly available API documentation on their public website. What we did is we analyzed the chapel data to identify all certified products that had certified G8 and pulled that URL. Then we reviewed all the documentation available through those URLs to determine the syntax of that certified API. For purposes of the blog, we took a look to see whether or not APIs were certified to use FHIR, release two or three, a non-FHIR certified API or another API. That provided the data for us to understand what products, what developers are certifying 2015 Edition APIs using any set of standards, particularly where they're focused on fire.

For the market element of the analysis, we used Medicare EHR Incentive Program attestation data to approximate developer market share. This is publicly available data that ONC had public for many years. It essentially aggregates all hospital and eligible professional attestations to the Medicare EHR Incentive Program. That attestation data includes the certified products used by those healthcare providers, and so we essentially match the 2015 Edition API data to those program attestations and the certified products that are used by hospitals and the clinicians.

The data remerged and the measurement that we're about to go through and take a look at sort of approximate FHIR availability if healthcare providers were to upgrade their certified technology to 2015 Edition. It's not a – this is currently what is being used by hospitals and office space practices. It's more, if those entities were to adopt the 2015 edition software, this would be the market coverage of FHIR. Next Slide, please.

The results, first off, 32% of Health IT developers certified to G8 published that they are using FHIR Release 2, and then nearly 51% of developers are using a version of FHIR combined with OAuth 2.0. Now, we say a version of fire. As I said, we looked at release two as well as to see if they certified using release three, but there was also some documentation that was unclear which version of FHIR that they had used. In that case, we would have noted in the data a version of FHIR. Without complete accuracy, we can't say everyone uses release two or release three unless they specifically say that in their

documentation. Essentially, a third of developers had said that they specifically use FHIR Release 2. The market impact is much greater than those numbers. 87 percent of hospitals and 69 percent of clinicians are served but health IT developers with products certified to any fire version. When you look at the developers with the largest market share, that coverage is 82 percent of hospitals and 54 percent of in that documentation.

Although a third of developers and about a half – use FHIR Release 2 and about half said a version of FHIR, the market impact is much greater than those numbers. Approximately 87% of hospitals and 69% of clinicians are served by Health IT developers with products certified to any FHIR version. When you look at the top, the 10 developers with the largest market share, that coverage is 82% of hospitals and 54% of clinicians. You can see the impact this just those 10 largest developers have on the market as a whole. Next slide, please.

This table, which is in the blog, shows what I was talking about regarding the 10 developers with the largest market share and the API standards referenced in the API documentation. As you can see here, for these 10 developers, they've all used FHIR in their certified APIs. All of them released two except for one, eClinicalWorks who uses release three. You can see the different market shares for these 10 developers. Some have market share in both clinicians and for hospitals, and some more just in the clinician market. Either way, just looking at these 10 developers on their own, you see their movement towards the adoption of FHIR in their certified APIs and the overall market impact of those APIs. Next slide, please.

All right, this map in the following slide is another map. These are also included in the blog post. These maps show – they take the overall data and visualize it geographically. For those who may not be familiar, we're using hospital referral regions, known also as HRRs. Hospital referral regions are a boundary line for healthcare, and it's commonly used in healthcare literature to show healthcare referrals, patient sharing, healthcare coverage, etcetera, and it gives a nice boundary line that county or state lines don't provide, which are more political boundaries and not healthcare boundaries. This is a nice way of visualizing healthcare data.

As you can see here just for looking at the APIs, for all of these HRRs, we calculated the percent of hospitals that had a 2015 Edition API enabled with FHIR. Again, not all of these hospitals have the 2015 Edition system with FHIR enabled at the hospital location itself, but if they were to upgrade to 2015 Edition, this is what we approximate this market share of FHIR would be. As you can see, there's a number of HRRs where 100% of hospitals would be enabled with FHIR and a vast number of other HRRs are 75-90%. As you can see, only about two HRRs have hospitals where less than half of them would be enabled to put FHIR. This is wide coverage of FHIR just looking at the hospital data. Next slide, please.

Here's the same depiction using the clinician data, same calculations looking at, if clinicians were to upgrade their software to 2015 Edition, this would be the market coverage of FHIR in these areas. As you can see, a few more referral regions that are 50%, but as you can see, most of the country, over half of clinicians and in the HRRs would have a certified EHR enabled with FHIR. Next slide.

For those who haven't read it, this is a link to the blog post, Heat Wave, and for the data used for this analysis, the API documentation for 2015 Edition products is available at this URL on the Chapel. This lists all the products that have the G8 certified criteria certified in their 2015 Edition products, so you can scroll through all of the API documentation for those products. The API documentation is also available with machine-readable data, as is all the chapel data through downloads, as well as through

the OpenAPI available on the chapel. Then, the Medicare EHR Incentive Program attestation data is available on Health IT dashboard through our data page. That's a direct link to that data and its documentation, as well. That's the presentation.

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

Okay, thanks so much, Wes. We do have time for one or two quick questions from the committee. Any questions for Wes?

Arien Malec, Member, Change Healthcare

This is Arien.

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

Arien, go ahead.

Arien Malec, Member, Change Healthcare

First of all, this is fantastic data. I just really applaud ONC for doing the survey. I just wanted to give a little bit of a history lesson. We have seen, I think, the fastest adoption of FHIR in a standards-based way than any other standards-based development that we've seen in the EHR certification program. Part of that is because we have a higher penetration, EHR is deployed across the country, but part of that is based on the mechanisms that we used to get FHIR out in the country. I just want to provide maybe just a little primmer. I'm gonna retweet my Twitter thread on this as soon as I can find it, but when we were looking at certification criteria for stage three or for what became both the QPS and the promoting interoperability program, we were a little bit stymied because FHIR was one of the standards that was emerging, wasn't quite yet – had all the edges roughed down or all the rough edges ground down, so it wasn't quite ready to name in standards. If you named it in certification criteria, it would've gotten locked in. At the same time, we didn't want to promote an API specification that was known to be old or not mention API criteria at all.

The result of just thinking through that, and the standards committee had been thinking through this problem for quite a while, was that a number of us met at the Argos restaurant in DC after a standards committee meeting, I think, in November of 2015, if my memory serves right. Again, I'll find my history lesson and retweet it out. We agreed on forming a public-private consortium to drive FHIR-based standards evolution. We got together many of the leading provider organizations as well as the leading HIT developer organizations, created a pass-the-hat-around, so self-funded the thing, and created a program led by Micky Tripathi to drive standards-based FHIR APIs using OAuth, ably assisted by Josh Mandell and Graham Green – Graham Grieve, rather, not the author. The result – and then, at the same time, ONC enabled this program and this approach by putting together certification criteria that were functional in nature as opposed certification criteria that named particular standards.

As a result, this combination of functional certification and a well-formed public private consortium that consisted of the leading HIT developers and leading provider organizations in conjunction with standards organizations like HL7 with a funding model that drove voluntary adoption and a permissive set of certification criteria that was thoughtful about the stage of evolution that we had. Standards development led to the situation that we are seeing now on the ground, which I think everyone would agree is fantastic. That's leading to secondary evolution for things like Apple Healthkit or the Apple health app being connected to many of those EHRs that are mentioned on the ground leading to greater

personal autonomy and ability to import data into people's health records. I think it's just a moment to reflect on what a successful policy framework looks like. I want to thank the administration at the time in ONC for putting together that certification program, certification criteria, and I think this is a model for good standards-based evolution in the country, a successful model to look at and pattern off of because it has led to, as I said, the most rapid evolution of standards and availability that we have seen in this country. Again, I just want to applaud ONC for putting together the data, but more so, I want to applaud ONC for putting together a policy framework that helped us get to the state that we're sitting in. Thanks, all.

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

Thanks, Arien, for the additional thoughts and comments. Any other quick questions before we move on? Hearing none, at this point, we would like to welcome the NCVHS for an update. I will first turn it over to Bill Stead.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Good morning. I'm Bill Stead from Vanderbilt University and chair of the national committee, and I have with me on the line, Rich Landen, who is a member of the full committee and of the subcommittee on standards, and Rebecca Hines who is our executive secretary and designated federal official. Rich and Rebecca, will you say hello so people know your voice?

Rich Landen

Good morning, this is Rich.

Rebecca Hines

Good morning, Rebecca.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Thank you. First slide, please. What we hope to do this morning is briefly review our mandate, talk a bit about the opportunity for collaboration between HITAC and NCVHS, share the parts of our 2018 workplan that intersect with HITAC, and then come to what we view as the key question that the two FACAs might be able to address together. We're gonna try to keep the presentation brief so that we'll have at least 10 minutes at the end for discussions. Next slide, please.

This is our mandate, basically, to advise the secretary on health data statistics, privacy, and national information policy, and the strategy to address those issues. We also have an explicit responsibility to advise the department around the implementation of the administrative simplification provisions of HIPAA and as reiterated in the legislation in Section 1104 of the ACA. In addition, we're explicitly chartered to inform decision-making about data policy at the state, local level, and in the private sector. Our emphasis throughout this is really on health information and data policy. The IT components are enablers to that. Next slide.

We have 18 members with very diverse demographics, scientific backgrounds, and scopes of practice, if you will, a nice mixture of people that are left brain and right brain. Next slide. In terms of the opportunity for coordination, it is first founded in the legislation of 21st Century Cures Act that asks the national coordinator to consider that the relevant and available recommendations and comments from NCVHS be included in the development of policies. From our perch, there is a real opportunity for us to work together, at the minimum, to avoid conflict in the things we are recommending, but ideally, to

identify opportunities for convergence and coordination of activities and deliverables. We both have much more on our plates than we have the bandwidth to deal with, and the more we can coordinate that, we think it will be helpful both to ourselves and to each other, and to the industry. Next slide.

I won't read this. I'll let you read it, but this is a key point from public comment that we recently received, and it reflects many comments we've heard from many parties over the last 18 months of our work. There is a real hunger from all stakeholders, as best we can tell, to figure out how to move from the siloed world of administrative and clinical standards to have a more harmonized set that both gives the opportunity to reduce redundancy and development, and probably equally or more important, redundancy in terms of uptake and various workflows. It captures a lot of what we think the opportunity is. Next slide.

These are the six major items on our 2018 workplan that is obviously now coming to closure. We're gonna give some high-level updates on the first three, the predictability roadmap, our work on health terminology and vocabulary, and the work on health information and privacy beyond HIPAA. Then, obviously, the whole purpose of this call is the last bullet around coordination between the FACAs. Next slide, please.

At high-level, the NCVHS predictability roadmap is guided by a vision that covered entities and business associates would be able to use up-to-date HIPAA standards consistently garnering increased value from the standards by avoiding one-offs, workarounds, and reliably know when updated versions would need to be dealt with and time to prepare systems, resources, and business processes. This is now a project that has been underway for about 18 months in which we have been collaborating with industry stakeholders to understand the challenges and the possible ways that we might find a path forward to be both more predictable and more flexible and adaptable. Next slide, please, and throughout this, Rich, interrupt me if you feel color commentary will be helpful because you're the specialist and I'm the generalist in this

Rich Landen

I shall, my general.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Thank you. Throughout the course of 2017, we engaged with a number of key groups in information gathering efforts. In the middle of that, we had an initial versioning workshop that identified five key themes that have stood the course of the subsequent year around governance, the update process, the regulatory process, data harmonization, and the challenges of third-parties that are not currently covered entities. Next slide. In May, the standard subcommittee held a chief information and innovation officer's forum to really bring together groups from a variety of perspectives to test ideas. In July, the subcommittee compiled the findings into three major outcome goals and to drafts of recommendations, which we have sent you a narrative document that includes those, and over the course of the rest of this fall, we are hoping to complete the outreach process leading up to a hearing in December to obtain another round of feedback on the draft recommendations allowing us to write a letter to the secretary early in calendar 2019.

Rich Landen

Bill, let me – may I add? This is Rich. Let me add a color commentary on the CIO forum. The innovation and information officers that Bill mentioned were there, but more generally the people invited, the individuals invited were in the executive level of organizations, sometimes provider organizations,

sometimes standards groups, sometimes health exchanges and health developers, Health IT developers, but it was an executive level of the people who were not individually down at the detailed technical level of implementing the standards, but they were the group that were the policy and budgetary visionaries for their organizations and who owned the responsibility for positioning those organizations for how those organizations would employ these standards in both currently and in coming years, and particularly in budget cycles. What we were trying to get at there was actual sense of those who were charged with implementing any upgrades to the standards. I just wanted to paint that picture of the background of who those folks were and why the standard subcommittee and NCVHS felt is so important to get a very good feel of the pulse of that particular segment. Thanks, Bill.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Thanks, Rich. That was helpful. Next slide, please. The areas of emphasis of the draft recommendation are three, improvement in the federal processes, improvement in the standards development organization processes, and improvement in the oversight and governance in the form of stewardship, specifically more visible enforcement of existing regulations, more frequent guidance, and outreach to the industry, and improve responsiveness to the NCVH recommendations and others regarding the timeliness of regulatory activities. Trying to work with the standards development organization to increase the diversity of industry participation in both the standards and the operating rule workgroups, increased timeliness, and improve the various workgroup processes for productivity. Underlying it all, increasing the transparency in a way that allows better matching of industry needs and values. Next slide.

This summarizes the outcomes that we hope will come from the roadmap and the relationships of those outcomes to the five themes that emerged in the August 27 workshop. Next slide. Finally, on this block, we would encourage the members of HITAC, probably as individuals, much the way that NCVHS has responded to some of the input that HITAC has needed, to participate in the current open public comment on the roadmap recommendations. We are really asking people to think carefully whether they would improve predictability of the process, whether we're missing key recommendations, and whether the – specifics about the value proposition that people see in one or another recommendation, and equally important, potentially unintended consequences because these recommendations are basically suggesting a sea change in how we go about this work. We're hoping, if you have time, that you will provide that input because it will flow into the hearing, which is going to be December 12th, 13th of this year.

Rebecca Hines

Bill, this is Rebecca. If we can have those comments by November 20th, then they can truly be included in the thinking that goes into that hearing.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

That's a brief run through of the predictability roadmap. If we could have the next slide, NCVHS has not taken a serious look at health terminologies and vocabularies since early in the 2000s and we've stepped back in the course of the last 12 to 18 months in collaboration with the National Library of Medicine to take a fresh look to see how the environment has changed and the problems that we're experiencing, both from the perspective of the organizations that are maintaining the terminology and vocabulary systems and from the perspective of the people that are trying to use them with the hope that we can develop actionable recommendations for HHS. Next slide.

Through this process, we have begun to get our heads around three types of opportunities, a few that

are near-term that are changes that we think can be framed in a letter to the secretary that would be approved hopefully at our February 2019 meeting, another set that are more midterm, such as really getting our head around the explicit pathway for convergence of clinical and administrative data standards that will require a significant private-public cooperation, and then, finally, longer-term, technology and research development opportunities that would, in essence, change the playing field. Next slide.

This summarizes the three near-term opportunities, first, to update the principles that are used to guide adoption of health terminology and vocabularies. Those principles have not been updated since 1998 and there was clear agreement at the workshop that we held back in the summer that we needed to have each of the terminologies have explicit statements of their purpose, their boundaries, and guideline for use. We needed to build into the principles and adoption the importance of communities of practice in defining the scope of a content area and we needed to build a valuation of how well the terminology was performing against its stated purpose, its usability, currency, and cost benefit into the adoption process, and that we needed an adoption process and timing that would be suitable for a relatively constantly changing landscape around terminology and vocabulary. Next slide.

I might say one more about the third bullet. In the early years of the evaluation of ICD-10 and how to go about ICD-10, NCVHS held a number of hearings around the value of different approaches. Given that we currently appear to be on a journey with ICD-11 that would be as lengthy and complicated as the journey that we went through with ICD-10, we think that it would be timely to really evaluate the value of different approaches, in particular, really, the question of whether it makes sense to have a U.S. modified version such as the current 10-CM or the current 10-PCS, or whether there might be other approaches that might be more flexible and adaptable. Next slide.

This is the basically the timeline that's designed to lead up. It shows the work we've done to date leading up to an initial letter to the secretary in February, and then we will then have to decide if we have the bandwidth to deal with follow on projects such as the one I just mentioned it. Next slide. The third thing we wanted to briefly review was the work we've been doing around health information and security beyond HIPAA, trying to identify whether there are additional levers that might work alongside HIPAA to deal with the very different world we have today than that that we had when that legislation was passed in 1996. Next Slide.

This is the framework that has evolved as we talked about it or thinking about this problem, in that you have the current legislation, which is focused on [audio cuts out] [00:45:59] and their business associates and most of the rules and work are built around managing compliance risk, the exposure to penalties and corrective action when a covered organization fails to act. A lot of the health information today and probably lends itself to a very different type of protection that's surrounding use and disclosure risk. How do we protect consumers from misuse? There needs to be a mechanism for that that currently really does not exist. We've got that spectrum. This slide depicts which part of that spectrum might be handled with regulatory compliance, which parts involved improved data stewardship, and which parts might involve new data protection such as the European Union and California have been partaking. We're also trying to explore which parts make sense from a public perspective and which parts should be handled by the private parties. Next slide.

This is just a high-level view of one of our use cases, how that may work out for the case of health data registries. Next slide. This just lays out where we are in this work. We're fairly early in the journey. We hope to be in a position to frame potential approaches to the model we just depicted in a way that we

could have a hearing toward the end of the first quarter of calendar 2019. Next slide. This just shows it's been a busy year. We've produced six reports, which in essence are, establish the landscape that policy questions exist in, and then three letters, two the secretary, one to ONC with actionable recommendations. Next slide.

This brings us to what we think is the essential question. At least it's one question and we think it's probably the essential question that we need to explore on the pathway to harmonization. It's really whether it's in the best interest of our patients, the healthcare business community, the health statistics, and research community to maintain really separate HL-7, CDA, FHIR XML systems for clinical, interoperability, and X-12, NCPDP, EDI systems for administrative and payment simplification. We don't think there's a right or wrong answer at this time. In theory, requiring some participants to maintain two systems is hugely inefficient. However, the two systems do exist, and it'll be disruptive to change them, but we think that it would behoove both FACAs looking forward to considering, what's the best available path? We'd like the feedback on whether this is a key question from your perch, and if so, any thoughts you may have how our FACAs might coordinate our activities to advance the ball. I believe you've been sent, as a pre-read, a scoping document we developed about the opportunity for collaboration and we would appreciate you engaging and suggesting how to work that document in a way that would help us work together to the best degree possible. Thank you.

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Bill, this is Elise. I just wanted to take a minute and thank you, as well as Rich and Rebecca, for all the work that you do in this space. We have a long history between ONC and NCVHS of working together and sharing the work of the FACAs and I look forward to that continuing. I know the work streams are focused on different areas, but the impact on Health IT, I think, is something we can always think about how we can collaborate and work together.

<u>William Stead – Vanderbilt University Medical Center – Chair of National Committee</u> Thank you, Elise.

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

We do have time for, perhaps, maybe one or two quick questions before we transition. Any thoughts or questions from the committee members?

Steven Lane, Member, Sutter Health

This is Steven Lane. I'll chime in. I raised my hand, but we may not be using that. I want to just respond to your key question at the end regarding whether or not we should look at harmonization of the clinical and administrative standards, and as a practicing clinician who works in a large healthcare organization, I will certainly say that we, in the trenches, are challenged by all the different standards and the various ways we need to implement and support our systems so as to meet the different standards. I just think, at a very high level, the answer is yes, that simplification and harmonization make as much sense as it could, and I think the real key question is, what is the path forward? Obviously, each of these standards is developed in its own domain to address very real means as they arose across our ecosystem. I think now the challenge is looking for those opportunities and I do hope sincerely that our FACAs will work together and find those opportunities, and when you hear our next presentation, we may in fact identify some.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Very good.

Arien Malec, Member, Change Healthcare

Hey, this is Arien.

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

Go ahead, Arien.

Arien Malec, Member, Change Healthcare

Again, I just want to, first of all, thank you, Bill, for the presentation and thank NCVHS for the work that you've done. As Steven mentioned, I completely agree that the administrative inefficiency that we have by split systems is a drag on overall industry. Just to take a particular example that I think is one of those drags on efficiency, ACOs and MA plans that receive risk-adjusted funds often require reconciliation with clinical record and the administrative and claiming record in order to justify risk adjustment because the risk adjustment is based on the administrative data and not on the clinical data that's collected in HER. A more efficient process would allow for better methods for risk adjustment at lower overall efficiency. However, the amount of deployed system on the administrative side, primarily the backend adjudication and the frontend claiming payment chargemaster, etcetera, infrastructure that has been built up around, to a lesser extent, EDI standards, and to a greater extent, ICD-10 and the administrative code sets, CPT, and others is pretty significant. This ends up being a timeframe question. If we start to think about what it would take for, for example, CMS to change its backend adjudication system and its backend risk adjustment, clinical quality measurement, and other systems, you can see the magnitude of the problem. A way to potentially frame this problem is to think about the timeframe, think about the strategic direction and think about the timeframe over which we'd undertake this journey and acknowledge that it will be a long, arduous, and complex journey, but one that we cannot complete if we do not start.

<u>William Stead – Vanderbilt University Medical Center – Chair of National Committee</u> Well said.

Rebecca Hines

Arien, if you look at the recommendations and the narrative report that hopefully you have a copy of, you will see they are laid out in three time block phases to reflect your comment, near-term, what has to happen on all fronts, middle term, and then down the road.

Arien Malec, Member, Change Healthcare

Awesome, thank you.

Rebecca Hines

Yeah, the committee is thinking just that way.

<u>Clem McDonald, Member, National Library of Medicine</u>

This is Clem. I can't put my hand up because I'm not on the web, but I wondered if I could ask a question.

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

Sure, go ahead, Clem.

<u>Clem McDonald, Member, National Library of Medicine</u>

At the committee meeting, one of the real strong points at your workshop back in September, late August, there was a real strong point about having only one code per usage. I didn't hear that come up again. Secondly, the NCPDP I don't think have mentioned a list of important standards because they're doing all the e-prescribing. The third one is to emphasize the vocabulary and I think coding systems are the same thing. That is, they fit in the same kind of slots. We shouldn't forget them.

William Stead - Vanderbilt University Medical Center - Chair of National Committee

Thanks, Clem, and the near-term opportunity to clarify purpose and scope of each of the terminologies, to try to make sure that we don't have two competing terminologies with the same purpose. Scope can overlap if the purpose is different. You're quite correct, that's part of what we think can be in the near-term recommendations.

Clem McDonald, Member, National Library of Medicine

Thank you.

Christina Caraballo, Member, Kizmet Health

This is Christina. Bill, Rich, and Rebecca, thank you so much for the presentation. One thing I wanted to point out and agreeing with the earlier comments, this does look like an area that we want to take a deeper look at harmonizing. Even though it might be difficult, I think this is somewhere where we can add a section in our annual report to bring up the topics. Based on the slide you brought up on the public comment, you stated that there was a very widespread desire to move away from having different approaches for, what you say, bulking on billing to clinical, so I do think that this is an area that we can possibly add to our annual report and look at as an opportunity for ONC to dive into further, as well as potentially the HITAC with your group.

<u>William Stead – Vanderbilt University Medical Center – Chair of National Committee</u> Very good.

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

Okay, well, not seeing any additional hand raised, I think I want to, again, thank the NCVHS team for presenting today. It sounds like we will have a few follow up actions. At this time, I would like to welcome our ISP Task Force cochairs, Ken and Steven, to share their progress on draft recommendations. Steven or Ken?

Steven Lane, Member, Sutter Health

Thank you so much, Lauren. I appreciate it. We're gonna go ahead. I'm gonna start off and then Ken will pick it up part way through. Thank you so much for the opportunity to, again, present the work of our very active and engaged task force. We presented back in September about our plans to proceed with an initial focus on orders and results. We have largely completed that work and are coming back to provide a report back, and we will be joined by Dan Vreeman from Regenstrief Institute who helps to lead the work that they do there on LOINC, and he'll be providing some comments on the great collaboration that we've had with them so far. Next slide.

As mentioned, we've held a number of meetings focusing on the priority domain of orders and results as

part of fulfilling the task of our task force. We met with Brett Andriesen and reviewed the contents of the ISA as they pertain to this domain. We had presentations by a number of the subject matter experts who are listed here, and we went through and identified two main areas where we thought we could make recommendations related to orders and results. We're gonna be going through those in some detail. Next slide.

The two areas that we identified had to do with the ordering and results themselves, as well as some general standardization that we thought would be helpful to support this general workflow. We will be going through these in more detail, but at a high level, our first recommendation having to do with the orders was that there should be consistent encoding of all orders and their results as they are placed by providers, as they work through the system of resulting agencies, and are returned to clinicians and other stakeholders, and very importantly, to the patient. We felt that the results needed to be sent back to providers with full codification that would allow them to be ingested and fully utilized by the receiving systems. There was a lot of discussion about the importance of making results directly available to patients and their proxies in the way they can effectively receive and make use of those results. We felt that it was also important to standardize the orderable tests themselves so that both clinicians and patients had the ability to compare and contrast and understand what has been ordered and how to proceed with those.

In terms of supporting standardization, we felt there needed to be standards to integrate external decision support for stakeholders at various points in the ordering workflow and to meet a number of important needs, including, but certainly not limited to, needs related to prior authorizations. We're gonna go through these in a little bit more detail and drilling and drilling down into them one by one.

The next slide, the first priority recommendation relating to the consistent encoding of test orders and results, specifically to results in this case, and what we felt in the task force was that it was critical that all results came back with mapped coding to standardize vocabularies, specifically to LOINC and SNOMED CT, and LOINC is typically used to identify the result components and then the individual observations are codified with SNOMED CT. We spent some time understanding and appreciating this difference, and really understanding the key role that each of these code sets play in getting this data to providers. We felt that obviously this couldn't all be tackled at the same moment and that it was going to be important to identify and prioritize the most commonly used results of each of the typical order types, so we're including laboratory imaging and other order types that are common in clinical medicine, and we talked a lot about how to enforce the use of information models and terminology standards really across the full spectrum of test orders and results, that there is a lot of variability in that area today. We felt that the mapped codes should be included when the results are maintained in and exchanged between Health IT systems, the idea that you wouldn't simply send the result, that the result would always come with its metadata, and that that would be maintained by the receiving systems and then be available when that data is subsequently exchanged with other systems.

While we feel that it's important that the mapping be done as high up in the process as possible, ideally at the level of the actual resulting system, sometimes that system is an EHR where a test could be resulted by a clinician in the clinical context, so those systems also need to be able to support the coding of the results, but certainly, many results are generated by laboratory information systems, radiology information systems, etcetera, and all of those systems need to have functionality that will support this coding, ideally at the source, but later on down the line if that's necessary. Then, we felt that it was important that there be support, probably initially by CLIA, to ensure this coding is being done and maintained along the way, that there are a number of regulatory levers that could be pulled, and we'll

go through some of those in detail.

On the next slide, we're talking through what we identified as the various regulatory levers that are available, and a real thanks to Arien Malec for helping us to understand this area. I don't know that we need to go through these line by line, but I will point out some highlights. Specifically, we felt that there is a lot of data available today in the EHRs that we can look at to see where this coding is being performed effectively and maintained in the system, and where it is missing, so using available data to highlight the opportunities for additional work. A lot of work has been done by industry stakeholders and should be continued, especially around the standardized laboratory results interface, but we feel that there needs to be a companion guide to link that to HL-7's medical document management. It is clear that some results contain textual information that's maintained in documents and that needs to be managed with as much standardization as the numeric results that are typically found across laboratory result interfaces.

There is work ongoing by the ONC with CMS, CDC, the AMA, a lot of this around the support of electronic mobile quality measures, all of which should continue, but really with an increased emphasis on the utilization and maintenance of these codified results. Then, similarly, our work is ongoing with the FDA and the NLM, and Clem McDonald really provided a lot of great input here from the NLM perspective, but here, there is a need for continued mapping between the output of analytic devices and the terms that are maintained in LOINC so that all those results can be codified. Next slide.

Beyond the ONC, there are opportunities for the FDA and for CMS to help to support this direction, promoting the use of LOINC in the FDA oversight of laboratory devices would be critical. Then, CMS, we had a number of specific recommendations related to how CMS could help promote the use of this standardized data and support its integration into the systems. This would include working with NIST to develop a testing program to assure compliance with these coding standards, and we specifically felt that this could be supported ideally through CLIA certification, but if this was not completely effective, it would not be unreasonable for CMS to require this coding as a condition of payment for services provided and paid for by CMS. Next slide.

The next priority had to do with the sending of these results to clinicians in a codified format with the associated standard codes. Here, we've had great partnership with Terry O'Malley from the USCDI Task Force who's been very much involved in our work, and we really feel that there's an opportunity to continue to collaborate and utilize the USCDI to ensure that the prioritized results are interoperable via the various transport mechanisms that are used to move them around. This should be transport agnostic, whether the results are being sent via HL-7, V2, B3, FHIR, you name it, future standards, as well, that this notion of codification and the maintenance of the metadata should work in all of the systems, as I mentioned earlier, prioritizing the coding upstream in the system at the point the data is being generated as opposed to relying on receiving providers or others to code it after the fact, and again, maintaining that data, as we said, that metadata as the information is transported between systems. Here, we're talking about not only the resulting agency systems, the recipient provider systems, but downstream into the personal health records when it goes to HIE's, payers, public health, and other stakeholders, that the metadata should just always be kept together with the result data.

Moving on to the next slide, here, again, we made specific recommendations for potential policy actions that would support this. A lot of the same players here looking at the role of HL-7 in supporting this. There are opportunities for ONC to support the requirement and maintenance to send the discrete data and maintain it through the pathway. CMS, we felt, could establish guidelines promoting the use of

these standards with certified H-IT and making that required in their reporting standards. There are opportunities to include these requirements as the data is transmitted back for APM requirements, the MFFP program, etcetera. We spent some time discussing the fact that electronic laboratory receipts had been removed.

It was felt to be a topped-out measure in the merit-based incentive payment system program and we really questioned whether that was optimal, that we felt that should probably be maintained as a requirement in that system, and in fact, expanded to address the structure, content, and terminology associated with that laboratory result receipt. We specifically felt that this should be reintroduced, so that we can maintain a focus on this. Again, looking to NIST as a possible organization to develop a testing program to assure compliance with the recommendations, and there were certainly opportunities for other federal agencies to also require the use of standards-based laboratory recording and receipt. Go on to the next slide.

The next priority area that we focus in on was the need for these results to be available to patients and their proxies in a way that they could effectively view them, receive them, and download them and then utilize them for their own needs. Here we focused on requiring that ordering providers who receive results make those results available to patients in a timely manner. We identified the fact that states have varying laws which impact the ability of providers to make these results available, and we really did feel that those laws needed to be harmonized. We needed to look for opportunities to remove that variability so that both providers and patients could have a common expectation of how these results would be made available. We felt here, again, that there is some progress being made making these results available via APIs, but we felt that should be done whether or not the results have been encoded.

There's a lot of information sitting in electronic health records which is not being made readily and conveniently available to patients who we felt that this should not await the coding piece before patients are given access. We felt that it was important that patients have patient friendly result display names that are consistent and standardized across systems so that if they're receiving similar results from multiple sources that those not only can flow together in a logical way at the data level but also at the human readable level. The patients can understand the results and we felt the standards development organizations, specifically LOINC is doing work in this area and we felt that should be continued and required.

Here again, there was discussion about how we could assure that this will be done. That the results will be made available to patients and that we would again recommend starting with making this required by CLIA regulation, but if necessary, looking at this as a condition of payment for the resulting agencies. As mentioned, there's real work that needs to be done to align state and federal policies to assure consistent and predictable data access and interoperability from the patient's perspective. Next slide.

Here again, we looked for potential policy levers that could be pulled. Certainly, CMS can make patient data access a requirement for relevant programs. That access should be available both via APIs as well as other mechanisms such as document-based exchange using C-CDA. We felt that CMS should continue to promote patient access as a condition for certification for health information technology. ONC, we felt should continue to facilitate the maturation of LOINC and we'll be hearing from Dan a little bit about the work that has gone on to date. It's very much in a direction that supports these recommendations, but that work needs to continue especially if this is going to be required for all results, and we mentioned the patient friendly terms making that a requirement, as well.

Next slide talks about the second priority within our first category. Making sure that the orderable tests are standardized between systems. This is really similar to what we've been saying about the idea of requiring catalogs of orderable tests. This is focusing on the tests that are ordered as opposed to the results that are generated, but these should be standardized across systems, so patients know when similar or a different test has been ordered by different providers so that providers are in the position to be able to compare and contrast orders that either are being considered or perhaps have already been placed for a patient. We felt that there was need for a consensus development project – process to develop sort of the standard orderables.

Some of this work has already been done, again, by LOINC which has really anticipated a lot of the recommendations that we've included here about the idea of having standard orders, standard order panels that have codification system behind them so those can be utilized. There are good methodologies for distributing these orders and order panels between systems, but needing to require that, we felt, is important. The next slide begins the second priority area and Ken is gonna take it from here.

Kensaku Kawamoto, Member, University of Utah Health

Okay, thanks, Steven. We just have a few more slides on other recommendations that we worked on. These are noted as secondary pretty intentionally. The notion is that we wanted to identify the other items at the core that we wanted initial focus on and here are items that we think still should be worked on, but something that didn't quite rise to the level of the other ones. These, by nature, have a little bit less detail to them, but I'll go through and explain these two. We focused a lot on how the orderables and results are transmitted or should be transmitted using standard forms. There was a lot of thought that in addition to the actual data you want interpretation and decision support on top of them. Two of the recommendations the group had —

[Crosstalk]

Aaron Miri, Member, Imprivata

Hi, this is Aaron Miri. I just received a phone call regarding order refill. I guess I goofed a number on the form.

Kensaku Kawamoto, Member, University of Utah Health

Is somebody unmuted unintentionally? Okay. The first is to not take advantage of the growing efforts in the CDS hook standard which currently has –

Aaron Miri, Member, Imprivata

Sorry.

Kensaku Kawamoto, Member, University of Utah Health

Is starting to get support around the patient view hook which is when a patient's chart is opened, and to leverage and advance it for areas that are important for orderables, for example, for when reviewing results and also when placing orders as well. One specific area where this notion of external decision support was in the area of net patient information, so basically, the actual payment that, for example, a patient would be expected to make for when a lab is done, or where imaging is done etcetera and for — this information's relevant to relevant stakeholders to be available, this is something that we felt will probably will be — I guess both of these would be likely worked on as a component of one of the other

priorities we had discussed, which was around cost transparency and care value, so probably something we'll revert back to later on in this task force. Next slide, please.

Again, related to this notion of supporting and providing systems support, another area that we identified as being really important was the notion of prior authorizations. This is the area where, in many types of orders, before you can place the order, you need to get prior authorization from the payer. This is an appropriate order to be placed for the patient. This is a source of a lot of inefficiencies and phone calls, faxes, that kind of thing. This is an area that there's a lot of existing efforts underway such as for Da Vinci, NCPDP and CMS. The recommendation here is to harmonize these into a consistent approach. I think the good news is, it's obviously a pain point and it's being worked on and our recommendation is to foster those, but also harmonize them. Okay, next slide, please.

That wraps up our summary of the recommendations. As an update, again, for how the task force is intended to work, we decided we'll continue to just tackle new topics that were identified and that continue to be identified as being important. The next one the task force will work on is closed loop referrals in care coordination. We have a meeting scheduled currently for the next three biweekly meetings to address this topic and that's where we are with that. Next slide, please. I think at this point we were gonna see if we could get some feedback on this from Dan and the committee. Dan, would you like to comment on your thoughts?

Daniel Vreeman

Sure, can you hear me?

Kensaku Kawamoto, Member, University of Utah Health

Yes.

Daniel Vreeman

Okay. First of all, thanks for the opportunity to participate in this discussion. I must apologize because I seem to be losing my voice a bit, which I wish it was due to something exciting like cheering for a sporting event or concert, but unfortunately, I think it's due to something more academically mundane, which is teaching too long in a big classroom without a PA system. Don't take that for a lack of support for the priorities and recommendations of this task force. From my perspective, as Director of LOINC, I want to applaud the task force for this great work and I really believe that it's an important direction, and you've identified some really key areas. To tie back to some of the comments from NVCHS update, LOINC is specifically focused on creating identifiers – standard identifiers for tests, observations, and documents. This area is something near and dear to our hearts that we want to encourage.

First of all, I also want to underscore just a couple of things, maybe elaborate on a few points. One is that the consistent standardized identification of orders and results really facilitates the development and use of the other priorities you mentioned such as CDS or quality management frameworks etcetera, it's really a facilitator of those bigger goals. It's important to build on that to accomplish those other aims. In addition, building on the more general recommendations from CLIA which has an overall encouragement of using LOINC and HL7 2.51 for lab data exchange is a good start, but I think, as the task force outlined rationing that encouragement up to additional requirements and support will help move the ball forward.

The other point I wanted to make is the theme of prioritization across the major categories of tests and results can be helpful both in thinking about the laboratory side and other kinds of clinical tests. On the

lab side we've looked relatively closely at the patterns of results and also the patterns of orders.

Now, our empiric data from the lab result side is a little bit dated, but in that work, we highlighted how a small number of test account for a very large portion of the volume. Roughly 500 tests or so accounts for 99 percent of the volume. The downside is that across institutions that core or common set varies more than you might expect, but it does highlight the fact that you can achieve significant benefit even if not everything is done. To that end, I'd point out, the other interesting finding was that we found that 99 percent of patients had all of their data in that common set, which means that, certainly for some patients, there will be esoteric things that might not get coded right away, but we can still achieve broad based benefit by thinking about that prioritization.

On the order side, we worked closely with the SNI framework group back around 2015 to look at a common order set, and from that work a couple things. One is, we struggle to get empiric data that was nationally representative, and so, at the end, we ended up with more of a consensus-based list of those orders than a truly empiric one, but nevertheless, that work was important. We continue to publish that common order list as part of the LOINC distribution, that we know it needs some additional refreshment and input, but out of that, we also developed a set of business rules and logic to help explain, how might I think about mapping my local order panel with a standard one? What are the criteria that I should use to decide that this is the same or different?

In addition, I wanted to highlight that while there is a very strong quartet of implementation guide standards from HL7 around data coming in and out of the lab that's version two based, thinking about this context of the actual semantic standards and how that relates to the syntax standards or exchange standards is important as we think about other pathways and mechanisms for exchange such as GDA or FIHR. We want to ensure that the semantic representation works across all those models and I think the recommendations to that effect are good and noteworthy.

Also, want to highlight the interest in the – from the FDA in encouraging standardized coding of test results as far upstream as we can get it, namely, involvement from the IPC and test vendor community. That activity is ongoing and we're starting to see some real momentum. It will have a cascading effect, meaning that'll make it easier for the laboratories themselves to implement these coding standards, and that direction, that work should be encouraged.

And then, last, I would say, some of you might sort of be worrying or wondering about whether there's gonna be a flood of new requests for concepts. We want to request that these recommendations go forward. This isn't the first time that concern has been raised and I think it's definitely one worth considering and being aware of. I want to make a couple comments about that. First is, beginning in October, we entered into a cooperative agreement with ONC that specifically provides some additional funding for LOINC content development and technical improvements, specifically around the data classes as describe in the USCDI, and that will provide some additional support in this realm.

In addition, we'll continue to monitor, for example, the policy decisions around development of order panels and so forth. There may be cases as we go through where we need to build additional flexibility to allow reuse in certain context. We will certainly be paying attention to that and be taking input from the community as we move forward with that. I'll note that a number of large reference tasks are already underway in the process of mapping their order catalogs, order codes to LOINC codes as well.

And then, I guess, the last closing comment that I make is just to circle back on that order catalog piece

to note that the American Clinical Lab Association did do a study that demonstrated pretty significant cost savings for implementing those electronic test compendiums or, as they call them, electronic directory of services, and that information was forwarded to ONC that I think is a useful starting point for thinking about, what is the overall value that might be realized by moving in this direction? Again, apologies for my voice, but thank you for the opportunity to share a few thoughts.

Steven Lane, Member, Sutter Health

Thank you so much, Dan. This is Steven Lane again, and I just wanted to add a couple of additional thoughts before we open to discussion and that is that we really see these as interim recommendations that we're sharing with the HITAC today. You'll recall that the ISP taskforce has rather a long timeline and we anticipate bringing back a final report and recommendation to the HITAC in the September 2019 timeframe. Between now and then, we have quite a bit of time laid out to continue to review standards and priority uses and to develop our findings and a recommendations letter. You will recall that we identified a number of priority-uses, including the orders and results. You heard from Ken that we're gonna be moving on to look at referrals and care coordination next, which was another one of our priority uses, but the others include medication and pharmacy data, evidence-based care for common chronic conditions, social determinants of health, and the key issue of cross-transparency. We anticipate that as we work through these areas that what we learn in looking at one will inform our thinking about the other, and that we will continue to refine these recommendations over the coming months and then bring back a final recommendation.

Carolyn Petersen, Co-Chair, Individual

Steven, this is Carolyn. Do you have any further comments or things to add before we start the discussion?

Steven Lane, Member, Sutter Health

I think we are ready to hear your feedback and input.

Carolyn Petersen, Co-Chair, Individual

Okay. Well, if the members of the committee would raise your hands using the functionality in the adobe connect, I will recognize you in the order that you pop up and we'll start the discussion.

Clem McDonald, Member, National Library of Medicine

Is that – no hands have come up, I can't make my hand go up and if there's no one else with their hand up I would like to make a comment. This is Clem.

Carolyn Petersen, Co-Chair, Individual

Go ahead Clem.

Clem McDonald, Member, National Library of Medicine

The issue of the statement, and I may not have heard it exactly right about getting the data to the patients, whether or not it is coded, I'm in favor of getting everything to the patients, so don't get me wrong, but if there isn't a code on the name of the test, I do not think you can ever get the names to line up as you also suggested. I'm not sure if I misunderstood, but I think having coded values of the test, that is what the test result came out as, versus having a coded thing to say what the test measured what it was or different and, again, I may have misunderstood.

Steven Lane, Member, Sutter Health

No, I think you're right, Clem, that our desire is to have both of those, both standardized and codified, but they are parallel processes. The standardization of the test names the patient friendly display name of both of the test names and the result components we believe and of course, you contributed to the development of these recommendations, we believe that all of those should be standardized and that standardization should be required by all the appropriate agencies. I will add that even in preparing for today's presentation. There was additional feedback from members of the task force, David McCallie in particular pointed out the fact that we don't have standards for the timing of release of results to patients, and that in addition to looking for harmonization across the country of what results can be released, looking for standards of when results are released because of course, we're looking at recommending that both ordering providers make the results available to patients, but also that the resulting agencies themselves make those results available.

We will certainly need to harmonize that timing across the different places where the patients may choose to go to get their information. I think again, we will be continuing to see additional feedback like what Clem just shared and we'll incorporate that into our final recommendations next year.

Cynthia A. Fisher, Member, WaterRev, LLC

This is Cynthia Fisher, just raising my hand here as well supporting this good work for adding those codes and having this harmonization and the release of the information as soon as it's digitally available to the patient would be fantastic. I would also add that when we get into trying to also provide the data that is actually both the billing data in pricing, net pricing transparency, which is inevitable as we move toward consumerism in healthcare, it will be ever more important for the standardization of the codes so that the patient can actually have a voice if there is an error or in reporting, but also to be able to compare apples to apples in their pricing.

Carolyn Petersen, Co-Chair, Individual

Thank you. Are there other people who have questions? Okay I don't see any other questions from HITAC members, either through raising hands or by acknowledgment in a phone line. Did you have any other comments Steve, or Ken, or Dan?

Steven Lane, Member, Sutter Health

I'll just add that we are looking forward to moving ahead with our work on referrals. We have already set up a number of subject matter experts to come in and educate the group. We see referrals as a great opportunity to again, focus on an area where some standardization work has been done and is in process that we can really leverage and encourage, and then also look to future needs knowing that patients and clinicians are all very much engaged in the referral process and anything that we can do to make that more efficient and effective in moving information between providers and other clinicians, members of the care team as well as the patient and their proxies will certainly benefit everyone in the process. Hopefully, we'll have a chance to come back at a future HITAC meeting and report on that work and continue to keep you updated as we look through our priority uses.

Carolyn Petersen, Co-Chair, Individual

Okay thanks Steven. Lauren, unless you have any other questions or follow-up on that presentation. I think we are probably ready to move onto the next one.

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

None for me. I agree.

Carolyn Petersen, Co-Chair, Individual

Okay. For the next presentation Aaron Miri and I will review what the annual report workgroup has been doing, and hopefully have some good discussion with HITAC members about what to be included in that report. We have some – again, we'll review our scope of the work group and the schedule we've been working under. We will go through the structure, review the landscape analysis, talk about the opportunities, and concerns we've identified in the gap analysis, and then present the initial recommendation. Steve and I agreed that I would start working up through the gap analysis, and then he will present the recommendations, and we'll begin the discussion. I'm going to move fairly quickly through the material that you have already seen in previous updates so that we can maximize our time for discussion, but definitely, if you have any questions we'll be happy to answer those at the end of the presentation. If we could have the next slide, please.

Here is the membership and the ONC staff who are working on this project, seen this before. Next slide please. Our overarching scope is to inform, contribute to, and review, draft and final versions of the annual report that will be going to HHS and congress. We'll also be helping to track ongoing HITAC progress. Specifically, we need to provide feedback on the content of the report with regard to the things that are called out in the 21st Century Cures Act. That would be analysis of HITAC progress related to the priority target areas, assessment of health I.T. infrastructure and advancements in those priority target areas, analysis of existing gaps in policies and resources for the priority target areas, and then some ideas for potential HITAC activities to address the gaps that are identified. Next slide, please.

These target priority areas, again are interoperability, privacy and security, patient access, and then anything else that HITAC feels should be a priority target area. Next slide, please. The meeting schedule for our work group, we've had four meetings so far, we will have another one tomorrow which you all are welcome to attend as that's a public meeting we will also be meeting in November and December, and then continuing to wrap things up through winter and spring before we start on the 2019 report. Next slide, please. We've met and spoken with this group in June and September. We are reviewing the landscape analysis and gap analysis today. Then we'll be presenting again in November and additional as needed in the new year. Next slide, please. Here's the basic structure that we talked about at the last meeting and that seemed to be agreed upon by the HITAC.

Our executive summary overview progress that we made in fiscal year of 2018 a landscape analysis, a gap analysis, some recommendations for addressing the infrastructure gap, suggestions for future HITAC initiatives, and then conclusion and some appendices that have information that would be supporting what's in the report, and also helping people find resources to further their education about these issues. Next slide, please.

Let's start into the landscape analysis. Next slide. In essence, we've got the legislative requirements and the current ONC and HITAC priorities. For each priority target area, we will be including some background and the current state where we'll look at recent advancements in various topics and also provide some examples that are related to stakeholder groups. Next slide, please. For interoperability, the current state in advancements, we've got existing exchange efforts, including things like direct trust, exchanges, vendor networks and C-CDA. We have ONC's proposed regulation covering open APIs information blocking and other health I.T. topics. There is the draft trusted exchange framework, and then standards in implementation specifications to support priority uses. That would be things like the CDI, the interoperability standards, priorities, and fire. The next slide, please.

Coming to privacy and security. Current state topics and advancements get us to the OAuth 2.0 security profiles for authentication, privacy, and security protections for PGHD remote monitoring data and telehealth data, have user controlled mental health and behavioral health information sharing. It can be things like interoperability framework like care quality, I.T. activities that address the opioid epidemic and social determinants of health, OCR, consumer, and provider guidance for mental health the behavioral health and SAMSA guidance for 42 CFR part two. The next slide please.

In addition, privacy and security concerns arising from increased health information sharing for research. This could be things like the Apple ResearchKit, 23andMe, NIH's All of Us, and other initiatives that are currently in development. There's a concern about improved patient matching and verification. Some things there with the HHS, PCOR, patient matching the PNL project and other things as well. Then, there's disaster planning for health I.T, the HIPPA security risk assessment tool. Next slide, please. Coming to patient access to information. Some of these current state topics include the blue button initiative. That would be things like my healthy data at CMF, data collection using mobile and wearable devices. A relevant concern here would be the FDA precertification program and the use and sharing of PGHD. Here we come to things like ONCs, PCOR, PGHD policy, White Paper, the practical guide, and the patient engagement playbook, and then changes to CPT code sets to support telehealth. Next slide, please.

Then, also, the use and sharing of social determinants of health data. At first the standardized data capture using LOINC and efforts to address health inequities. Finally, we have emerging platforms for data sharing by patients and caregivers. That could be things like the Apple HealthKit and open note. Next slide, please. Now, we'll come to the gap analysis and in each of these target priority areas we're going to go with the gaps identified and then some opportunities identified. This will take us more into what we hope will be the meat of our discussion. Next slide, please. With regard to interoperability, the gaps identified by the work group include these ongoing efforts regarding open APIs, information blocking, the tests, and standards and implementation specializations. A lack of knowledge about user experience of health information exchange that would help us understand better what's needed and what needs to be improved, unmet needs of additional care settings and stakeholder groups.

This could involve things like long-term care and perhaps some community-based initiatives that extent healthcare services and offer people support. There's a delay in the timeliness between issuance of guidelines and development of technology. There's the need to increase the level of interoperability. Of course, we've been talking a lot about that. The need to improve data quality providence and usefulness, and infrastructure needs of stakeholder groups, particularly as that regards broad access. The next slide, please.

Some opportunities that the work group has identified include establishing usability metrics for health information exchange, an expansion of priority use cases to meet the needs of these additional care settings and stakeholder groups, addressed alignments of the timeliness of guidelines and the development of technology, and incentives for change across stakeholder groups to improve the level of interoperability and data quality, and support for increased broadband access across stakeholder groups, particularly among underserved populations. The next slide, please. Further opportunities should continue to improve patient matching when sharing data and address the reality gap between the perception of what certification requires and what actually happens in the field. For example, continued mapping of C-CDA and Fire standards required when integrating networks and sharing data amongst smaller providers who may lack resources.

Let's move on to privacy and security. Some of the gaps identified by the work group include variability of information sharing policies across the states. We know California recently implemented a new law with the consumer privacy act, but other states are looking at other things and we could see significant variability as other states bring their policies online. A lack of knowledge about HIPAA and the confidentiality of substance use disorder patient records regulation implications, a lack of user control to share and disclose information, implications of the European Union's general data protection regulation and privacy shield. There is variability in adoption of cyber security framework. For example, healthcare organizations may be concerned about being held liable for breach of data at a vendor. There is a lack of user awareness and education about policy and security settings and implications of emergence of the Internet of things.

We haven't really talked a lot about that at HITAC this year, I think we've been focused on other things, but from the patient perspective, as people have the opportunity to use additional devices that are connected to help them manage their care is become — may become more of an issue. Next slide, please.

Now, let's look at the opportunities that are identified by the work group. There is increased uniformity of information sharing policies across states, education about HIPAA and confidentiality of substance use disorder patient record, regulation implication, granular levels of consent to share and disclose information, the opportunity to address the implications of the GDPR and privacy shield, the port for widespread adaption of cyber security frameworks, education of technology users about privacy and security settings particularly with regard to social media and mobile health tools, the opportunity to consider what needs to be regulated with regard to the Internet of things, and the opportunity to continue to improve patient matching when sharing data. Next slide, please.

Then, coming to patient access to information. Some gaps that the work group has identified include the lack of patient and caregiver access to patient data, the use and sharing of PGHD and other data from mobile devices, the need to improve alignment of timing of planning activities with operational impact of tech development, potential for a lack of net neutrality due to market forces, unmet infrastructure need or underserved populations, accessibility and usability of patient portals and other patient facing technologies, patient awareness and education about health I.T. resources. Next slide, please.

Then, some opportunities in this area include the supportive use of APIs to improve access to patient data, consider workflow and technology improvements to increase use of sharing of PGHD and health data. For example, an impact clinical grade data collected by patients on testing costs, to better align the timing of planning activities with operational impacts, considering implications of varying experiences with net neutrality at the national, state, and local level, support infrastructure needs for underserved populations, including exchange costs prevalence of electronic equipment, internet access, and availability of pharmacy services in telehealth. Next slide, please.

Then, a few more improvements to accessibility and usability of patient portals and other patient technologies. Encouraging patient and caregiver education about health I.T. resources and address the reality gap between the perception of what's been certified for a system and what actually happens in the field. The next slide, please. Now Aaron's gonna take over with recommendation ideas.

Aaron Miri, Member, Imprivata

Yep, thank you Carolyn. Can everybody hear me okay? Hello? Can you hear me?

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

Yeah, we can hear you.

Aaron Miri, Member, Imprivata

Perfect, all right. Perfect, okay. First of all, I wanna thank the committee and thank the HITAC for listening to these recommendations. I do, before we go into it, wanna stretch, these are initial recommendations and ideas. Obviously, it is our requirement to bring this back to you all, the larger group to think through and as I say, marinate on these items and ideas and come up with other ones because we very much want this to be a two-way street where you helped to inform us from all of your expert perspectives on items that may be haven't floated to the top or recommendations.

Our goal here isn't to lament and say, oh, woe is me, we have all these issues in health I.T. The goal is to really find tangible items that the HITAC can request to work on to start knocking some of these out of the park and then start measuring that effectively. With that, let me go into the way this works here. For each priority target area, we'll obviously show you the recommendations that we have come up with on our first pass and then at the end of all this, we'll talk through this and have a discussion around the HITAC for what we presented and other items can come to mind. Next slide, please.

All right, around the opportunity for addressing the reality gap between a perception of what has been certified and what is truly inoperable. An example that's out there commonly is the continued mapping of the C-CDA and Fire standards are required with integrated networks and sharing data among smaller providers who may lack the resources to upgrade their systems. Being maybe on a 2015 version and somebody else is on a 2014 version, or some vendor is not using Fire. I have this problem here in my health system where a lot of our smaller interface systems don't accept Fire. Even if I wanted to go to Fire standard I can't. A HITAV, activity idea for us – again, these are ideas, maybe further measure, whether systems are truly interoperable at both a content and transport levels after implementation, especially among those smaller providers. We can begin to really see on a granular basis what is going on out there. What's really interoperable and what is not and what is the reason why? Next slide.

All right, another item here. Increased uniformity of information strength policies across the states. There's implications when you have the California Consumer Privacy Act and other numerous privacy and security regulations that differ state to state. HITAC activity idea consider the federal role in setting guidelines for exchange of data across states and really try to sort of raise the watermark here so that folks at a state level can understand how to match what the federal watermark is and so that we can get conformity across all the different states. Another opportunity is support for widespread adoption of cyber security framework, really consider whether a nationwide cyber security framework should be adopted, and this really speaks towards really setting that minimum bar. What are the speed limits for which the data on the highway needs to travel at? Today it's sort of a voluntary speed limit.

Well, that's not how we really worked on — when you actually drive a car, it's pretty mandatory and you get pulled over by a cop if you blow it. To the degree of it, should we consider that? Should we consider those types of, what is that that nationwide cyber security framework. Another activity idea around this and delineate — is to delineate cyber security accountability for data by role. This speaks towards what Carolyn spoke to a little earlier which is, covered entities constantly been holding the bag because of a lack of diligence by maybe BAs or other people that they're exchanging data with. Is that appropriate, is it not, should we look at and say, as a HITAC give recommendations back to how to further strengthen that and give clarity back to where accountability belongs actually, so that we can actually begin to

progress and move the ball forward on parts of the sector that maybe are lacking than others, maybe. Next slide.

Another opportunity is supporting the use of APIs to improve access to patient data. I think ONC and CMS are doing a phenomenal job, but maybe there's more things that we can do. Maybe there's other ways to continue to further and strengthen the use of APIs. Another opportunity, support infrastructure needs for underserved populations including those exchange costs and prevalence of electronic equipment, internet access, pharmacy services, use of telehealth services. As an activity idea here, it's kind of measure that impact of monetization of exchange of data. Brett on our committee really had some great examples of his health system of where this has been impactful from a pharmacy side and trying to place meds out there in the community and where this is now costing the smaller rural pharmacies out there, money just to receive that order electronically. I mean, there's things like that out there that are a hinderance and almost – you could almost coin an information blocking, but it's really just business practice.

How do we begin to measure that impact? How do we actually quantify this, so we can tell this is an issue or this is something that's in practice very sparsely. Next slide. Another opportunity is to consider improvements to accessibility and usability of patient portals and other patient facing technology. For our HITAC activity ideas, maybe measure the length of time a portal has been online and working properly. Patient engagement or patient understanding of data. There is, I think so much literature out there, particularly recently about patients just not knowing how to interact with their provider. How do we begin to really start measuring that? How does the HITAC – how do we start looking at this and saying, is this the right vehicle and modality to interface with our patient population? Are there other better ways and how do we measure that?

Another opportunity, encouraging patient and caregiver education about health I.T. resources. From a HITAC activity idea sort of identifying use cases, demonstrating the value of patient's data to the patient. I think we have seen a lot of other literature about patients not realizing just how important it is to take oneself and really empower themselves with that information about their own health data and really make them part of their own care plans. How do we further encourage that? I think ONC did a phenomenal job with the playbook, how do we take that to the next level, should we look at that, is that an item for the HITAC to consider? Next slide.

All right, so this is about the part where we invite questions. I will kind of throw this up in three parts for anybody who has questions on the HITAC. Lauren, I think maybe we should use the hand raising feature for this one since I'm sure there's some great ideas. Is that appropriate?

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

Yes, that'll work fine. Thanks, Aaron.

Aaron Miri, Member, Imprivata

Perfect, all right. I will pose to you all, HITAC, please, be brutal, be honest, be up front, and let us know your thoughts on some of the recommendations, add to those recommendations, add to those landscapes, and, again, I want to stress that this is a work in progress. We have many more meetings before we present to you our final recommendations. I definitely look forward to your initial feedback so with that please raise of hands.

Carolyn Petersen, Co-Chair, Individual

Let's not be shy folks, it's your opportunity to really help us show ONC and congress what HITAC as concerns and what we think needs to happen.

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

Yeah, and if you're not on Adobe, just feel free to pipe up on the phone.

Terrence O'Malley, Member, Massachusetts General Hospital

Hi, this is -

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

I think someone with the letter T hand raised, I'm not sure if that is a HITAC member or not.

Terrence O'Malley, Member, Massachusetts General Hospital

This is Terry O'Malley. I put my hand up, I think.

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

Okay, thanks, Terry.

Terrence O'Malley, Member, Massachusetts General Hospital

Just to comment on one of the issues about sort of alternate service providers and provider sites. In particular, a home and community based service providers, I think that's a really excellent place to be looking for areas that overlap between the NC NSCBS and the HITAC, and you've got home and community based providers who are central to the long-term management of really complicated, medically complex, functionally impaired, particularly elders at home who need these services and yet, these are entities that are not under HIPAA and yet, there's a critical need to share HIPAA information with this group. I think this would be a great use case to really flag and flesh out because it's got tremendous clinical relevance and policy relevance and certainly H-IT and standards relevance. Thanks.

Aaron Miri, Member, Imprivata

That's good feedback, thank you

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

And Sasha.

Sasha TerMaat, Member, Epic

Thanks. This is Sasha, just trying to kind of understand how this will work from a logistics perspective if the idea that the annual report group is proposing areas that we might undertake to form new task forces. In the future, and then I guess I'm just trying to wrap my mind around the timeframe of how we might be engaging on these areas. Would they follow some of the upcoming work that we have already discussed?

Aaron Miri, Member, Imprivata

Great question. Carolyn do you want to take the first stab?

Carolyn Petersen, Co-Chair, Individual

Sure. As the work of this group is defined through the 21st century cures, it's kind of a review of what we've done this year, and then an identification of things that HITAC should be looking at in the future. I think what we have to do – the workgroup is doing is to try to identify some of these new priority areas and new things that the HITAC and the full committee should be looking at in the coming year, then assuming as a group we agree upon those, we then have some freedom to decide if we want to deal with that through more groups or task forces or work with ONC to identify other structures or ways of addressing those concerns. We do have some latitude.

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Yes, hi and this is Elise. Yeah, I think Carolyn is right in terms of not only looking at where things are currently, but also future opportunities for engagement not only when the report goes to congress, but it also would be shared with Dr. Rucker and ONC and would be an opportunity for us to help identify additional charges that could be reviewed and considered in the future.

Sasha TerMaat, Member, Epic

And then just so I understand, this is Sasha again, is this just the new areas for consideration? Because I would certainly of course also prioritize other areas that we have previously focused on. For example, revisiting the trusted exchange framework which was a project from earlier this year when we have more information about that. Do we need to be prioritizing the ongoing work of the standard prioritization workgroup in this same list or revisiting the trusted exchange framework when the next draft comes or are those pre-prioritized on a different list and this is just what net new things we should do?

Carolyn Petersen, Co-Chair, Individual

This is Carolyn. I have not seen anything in any of the materials that suggests that it needs to be one way or the other. I would think that certainly the trusted exchange framework is something that would be revisited periodically in the future, particularly as work is underway. That would just be within our purview, because it's one of the items that's called out specifically by 21st century cures.

[Crosstalk]

Sasha TerMaat, Member, Epic

I think it might be helpful as we are gathering feedback to keep those items on the same list too, so we have a sense of kind of ongoing work that we want to prioritize for 2019 next to new work, and then we can make appropriate judgment calls about – if new work would preempt ongoing work and take over our focus or supplement it and replace it etcetera.

Carolyn Petersen, Co-Chair, Individual

And that's good feedback for ONC I think, in terms of how they work with us to structure work of the task force of HITAC in general.

Aaron Miri, Member, Imprivata

Yeah, and I would also add, I think, Sasha what's also maybe confusing here, at least it was to me for a little bit was, we're trying to do two things in one. One, we are trying to establish the report card essentially for the work that's ongoing like the test and everything else. You'll have that list of, where

are we with our deliverables are we red, yellow, green, how are we doing against what we decided to measure against? And then, you'll have the net new items, that the HITAC has asked to do and then Dr. Rucker and team have done their process to get approval or not get approval, depending on the topic or whatever. Then, that report card then, in my opinion, is a living document, where as we go forward, you're always adding new things or completing items that you've been working on for a while. We're just missing that first stab at it and I think that's what's confusing is, we're trying to do both in one. I totally take note of what you are saying. I agree with it.

Carolyn Petersen, Co-Chair, Individual

Elise or Lauren, do you have any perspective to share on how the new items that we come up with relate to the priorities that the HITAC has worked on this year like the trusted exchange?

Seth:

Hi, this is Seth Pazinski. I'm with ONC and I would agree with Christina's point, that you wanna keep the current work that the committee has done over the past year if there's additional work within those topics, and I would recommend keeping those on the list in addition with any new topic areas that are being proposed.

Carolyn Petersen, Co-Chair, Individual

Okay. Steven Lane had his hand up. Do you want to go ahead, Steve?

Steven Lane, Member, Sutter Health

Yeah, I'm curious, we had a great presentation from NCVHS earlier in our meeting with a real request to collaborate and align our work, and I'm curious if the task force has given any thought to specifically what opportunities we may have to do that and where we might want to start down that path.

Carolyn Petersen, Co-Chair, Individual

We had not seen the presentation prior to this meeting, so it hasn't been something that we've discussed previously, but it certainly is something we can talk about tomorrow at the next meeting of the annual report workgroup.

Steven Lane, Member, Sutter Health

Yeah, as I mentioned, I think there may be opportunities for us to align the work of the ISP task force with NCVHS and I think perhaps we might want to even have a separate meeting with the leadership of each group to discuss those opportunities, but I think approaching that from the HITAC perspective, and I think it's great if you guys have a meeting coming up please let us know, the ISP task force chairs, what you come up with and whether you feel that there is an opportunity for us to collaborate with them.

Carolyn Petersen, Co-Chair, Individual

Thanks. Denise, your hand is up. Do you want to share your comments?

Denise Webb, Member, Marshfield Clinic Health System

Sure, just building on what Sasha said, I have to admit that I was – I mean, looking at slide eight that gives the outline for the report, I was kind of getting lost on the differentiation between our current work and future work given the current landscape and what the gaps are. So just as an outside looking in trying to predict what the reports gonna look like and reading that report, I mean I just wanted to chime in on what Sasha said because I think the HITAC progress, the progress of our committee, I think what you all are saying is, it's gonna be sprinkled throughout each of those areas or is it going to be a

separate section? I guess I'm just a little bit lost in this too.

Carolyn Petersen, Co-Chair, Individual

There is a lot of information to organize, that's absolutely true and I know certainly, when we were initially discussing what should be included in trying to think about how to structure that, we could see that sometimes there was overlap, and it just seemed a bit amorphous. On one –

[Crosstalk]

Denise Webb, Member, Marshfield Clinic Health System

I was just gonna say we definitely don't wanna lose sight of the work we've been doing and make the distinction between, here's what we are doing, what we need to continue working on and here are new things. I think there has to be a clear distinction so there's an acknowledgment in the report of the work we've done and that it's not finished in many respects, but there's more to do.

Carolyn Petersen, Co-Chair, Individual

And we do anticipate acknowledging what we have done to date, and of course recognizing the ongoing aspects of that work. As well as bringing out the new things. Are there other questions by the HITAC or from HITAC members on the phone?

Aaron Miri, Member, Imprivata

Again, I would just stress the HITAC to please take some time, think about it. Look at our current progress, look at the things that we haven't touched upon. There was some great discussion in the last face-to-face HITAC, so we would really appreciate more comments like that. We really took those to heart and ran with them, so the more you can feed us back of items, good or bad, ugly, great, the better.

Christina Caraballo, Member, Kizmet Health

This is Christina. Just chiming in as part of the work group. We didn't actually dive into what we've done for progress to date. It's just kind of a marker in the slide deck, but if you're trying to digest the report, if you look at the main heading going to slide eight with the landscape, the gap analysis and addressing the infrastructure gaps, the way we've laid it out is that under each of those main headings we've got a subsection with each of the four priority areas. So, that's kind of the structure we're looking at and I do think the recommendation to add what we've done to date that needs to be ongoing, would be really valuable as well. I just want to agree with that comment from Denise and Sasha on that and kind of offer some insight to digest this deck of the layout.

Carolyn Petersen, Co-Chair, Individual

It's true. One of the challenges for us in talking about what we've done so far is that when we started meeting it was in August and we, at that point, didn't know or weren't able to state pretty thoroughly what HITAC would have accomplished in the calendar year because we knew we still had quite a bit to go with ISP. For example, with the definition of information blocking, with whatever further activity there would be regarding the trusted exchange framework. It is true that we have not framed all that out yet, but as we are getting closer to the end of the year we'll be in a better position to summarize that and including notes about things that still need to be continued or will be ongoing for some period of years, but we appreciate the feedback and that lets us know that this is of importance to the HITAC. Are there any other questions from HITAC members? I'm looking at the list and I don't see any hands raised. Please do raise your hand or let us know if you are on the phone.

Aaron Miri, Member, Imprivata

All right. Do we want to – should we move to the next section or should we – what do we suggest?

Carolyn Petersen, Co-Chair, Individual

Let's keep going.

Aaron Miri, Member, Imprivata

Okay, I think next slide. I guess that's the end of it then, right?

Carolyn Petersen, Co-Chair, Individual

That's the end of the slide deck, but of course if any of the HITAC members have other comments or questions, this is the time to discuss.

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

Carolyn, this is Lauren. Should we proceed to public comment at this time?

Carolyn Petersen, Co-Chair, Individual

I think if we can do that, that would be a good idea, Lauren.

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

Okay, operator can you please open the public line for comments?

Operator

Yes, thank you. If you like to make a public comment, please press *1 on your telephone keypad and a confirmation tone, indicate your line is in the question queue. You may press *2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key.

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

Thank you, and while we are waiting for public members to dial in, I just wanna circle back to the attendance. I know we were joined late by Michael Adcock, Tina Esposito, Arien Malec, but I also wanna check to see, have any other members joined since role call at the beginning of the call that I missed? I think we captured everyone. Operator, do we have any comments on the phone?

Operator

No comments at this time.

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

Okay. We'll then close the public comment period now. I will turn it back over to Carolyn and Robert for any additional just closing remarks before we adjourn.

Carolyn Petersen, Co-Chair, Individual

Okay, this is Carolyn. We do have some time. I'm wondering if there are any comments from HITAC members related to any of the updates we've had today or any other questions that you feel would be

relevant to bring forward at this point.

Steven Lane, Member, Sutter Health

Carolyn, this is Steven. The only thing I would ask is if the NCVHS folks have hung in there with us and are still on the line, whether they may have identified opportunities in listening to our further discussion for ongoing collaboration.

Carolyn Petersen, Co-Chair, Individual

That's an excellent point. Bill or Rich or Rebecca, did you have any further comment or other things about opportunities having followed on with the rest of the discussion?

Steven Lane, Member, Sutter Health

It sounds like we may need to schedule a follow-up meeting to get the answer.

Carolyn Petersen, Co-Chair, Individual

Okay that's fine.

[Crosstalk]

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

On adobe, they may have dropped off already.

Terrence O'Malley, Member, Massachusetts General Hospital

Hi, this is Terry O'Malley, just a follow up on Steve's question. In ONC, is there sort of an overview map of the areas of responsibility for these two FACAs and a sense of where the overlap is, and where they are more independent, and where areas of potential collaboration are essential, and where they would be nice to have? Do we have a sense of how these two FACAs connect?

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Hi, this is Elise. Within tiers, there is a specific list of areas that Congress has asked that the HITAC look at. I think we can coordinate with, in particular, Rebecca Hines who's the DFO or Lauren's counterpart over at NCVHS and see if we can pull their list as well and share it with the full committee. Then we can identify where there might be synergies or opportunities for collaboration.

Terrence O'Malley, Member, Massachusetts General Hospital

Yeah, I think that would be really helpful. Thank you so much.

<u>Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health</u> Absolutely.

Carolyn Petersen, Co-Chair, Individual

Any other last thoughts or comments, questions? I think we've concluded all of our business for today, Lauren.

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

Okay. Thanks, Carolyn. Just as a reminder, our next meeting is on the 14th of November. It looks like we

will have some additional progress to share by then, and just as a public reminder that all the information from today's meeting can be found on HealthIT.gov on the HITAC pages. If there is nothing else, then we will go ahead and adjourn for today. Thank you, everyone, for your time.

Male Speaker

Thank you.

Male Speaker

Thank you.

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

Thank you. Goodbye.