The Office of the National Coordinator for Health Information Technology

# Transcript

## HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

June 17, 2020, 9:30 a.m. – 12:30 p.m. ET

VIRTUAL

# Speakers

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

| | | |
|---|---|---|
| James Ellzy | Defense Health Agency, Department of Defense | Federal Representative |
| Adi V. Gundlapalli | Centers for Disease Control and Prevention | Federal Representative |
| Jonathan Nebeker | Department of Veterans Health Affairs | Federal Representative |
| Michelle Schreiber | Centers for Medicare and Medicaid Services | Federal Representative |
| Ram Sriram | National Institute of Standards and Technology | Federal Representative |
| Donald Rucker | Office of the National Coordinator for Health Information Technology | National Coordinator |
| Steve Posnack | Office of the National Coordinator for Health Information Technology | Deputy National Coordinator |
| Elise Anthony | Office of the National Coordinator for Health Information Technology | Executive Director, Office of Policy |
| Avinash Shanbhag | Office of the National Coordinator for Health Information Technology | Acting Executive Director, Office of Technology |
| Andrew Gettinger | Office of the National Coordinator for Health Information Technology | Chief Clinical Officer |
| Lauren Richie | Office of the National Coordinator for Health Information Technology | Designated Federal Officer |
| Al Taylor | Office of the National Coordinator for Health Information Technology | Presenter |
| Brett Andriesen | Office of the National Coordinator for Health Information Technology | Presenter |
| Seth Pazinski | Office of the National Coordinator for Health Information Technology | Presenter |
| Christal Ramos | Urban Institute | Presenter |
| Gary Ozanich | HealthTech Solutions | Presenter |
| Kathy Frye | HealthTech Solutions | Presenter |
| Fredric Balvin | Urban Institute | Presenter |
| Emily Johnston | Urban Institute | Presenter |
| Anthony Gray | Urban Institute | Presenter |

## Call to Order/Roll Call (00:00:01)

**Operator**
All lines are now bridged.

**Lauren Richie**
Good morning, everyone. Thank you, again, for taking the time to be with us today. I hope everyone is well and enjoying the start of their summer as much as you can. With that, I will call the meeting to order and get started with official roll call. Carolyn Petersen.

**Carolyn Petersen**
Good morning.

**Lauren Richie**
Robert Wah.

**Robert Wah**
Good morning. Present.

**Lauren Richie**
Michael Adcock. Not yet, okay. Christina Caraballo.

**Christina Caraballo**
Good morning.

**Lauren Richie**
Tina Esposito. Not yet, okay. Cynthia Fisher.

**Cynthia Fisher**
Good morning.

**Lauren Richie**
Valerie Grey.

**Valerie Grey**
Good morning.

**Lauren Richie**
Anil Jain.

**Anil Jain**
Good morning.

**Lauren Richie**
Jim Jirjis. Not yet. John Kansky.

**John Kansky**
Good morning.

**Lauren Richie**
Ken Kawamoto.

**Ken Kawamoto**
Good morning.

**Lauren Richie**
Steven Lane.

**Steven Lane**
Hello.

**Lauren Richie**
Les Lenert. Arien Malec.

**Arien Malec**
Good morning.

**Lauren Richie**
Good morning, Arien. Clem McDonald. Aaron Miri.

**Aaron Miri**
Good morning.

**Lauren Richie**
Brett Oliver.

**Brett Oliver**
Good morning.

**Lauren Richie**
Terry O'Malley.

**Terrence O'Malley**
Good morning.

**Lauren Richie**
James Pantelas.

**James Pantelas**
Good morning.

**Lauren Richie**
Raj Ratwani.

**Raj Ratwani**
Good morning.

**Lauren Richie**
Steve Ready.

**Steve Ready**
Good morning.

**Lauren Richie**
Abby Sears. Alexis Snyder.

**Alexis Snyder**
Good morning.

**Lauren Richie**
Sasha TerMaat.

**Sasha TerMaat**
Good morning.

**Lauren Richie**
Andy Truscott. Sheryl Turney.

**Sheryl Turney**
Good morning.

**Lauren Richie**
Denise Webb.

**Denise Webb**
Good morning.

**Lauren Richie**
Michelle Schreiber.

**Michelle Schreiber**
Good morning.

**Lauren Richie**
James Ellzy. Not yet. Ram Sriram.

**Ram Sriram**
Good morning.

**Lauren Richie**
Adi Gundlapalli is not able to be with us. I do believe we have a representative from CDC on the line. Jonathan Nebeker or Elaine Hall.

**Adi Gundlapalli**
Actually, Adi is also on the line. I'll join for a little bit. Sorry. Yeah, thank you.

**Lauren Richie**
Great. Good morning, Adi. And Jonathan or Elaine. And Amy Abernethy. Nina Hunter. Okay. With that, Also from ONC, we have our National Coordinator, Dr. Rucker; our Deputy National Coordinator, Steve Posnack; Director of Policy, Elise Anthony; Acting Director of Technology, Avinash Shanbhag; Chief Clinical Officer, Andy Gettinger; and Seth Pazinski, our Division Director of Strategic Planning and Coordination. And with that, I will turn it over to Dr. Rucker for opening remarks.

## Welcome Remarks (00:03:06)

**Dr. Rucker**
Okay. Thanks, Lauren. Welcome, everybody. Thank you all for joining. Obviously, Covid-19 still is front and center in all of our activities. We are engaged in lots of ways with HHS and some various parts of HHS on how ONC can support their activities in fighting Covid, getting more data on any number of critical clinical questions there. You may have seen HHS posted some lab reporting requirements last week to get a richer set of data on race and ethnicity. We have been working with a number of the HIEs who are in a very good position and able to provide that and merge results from other data sources to provide some of these richer data sets, number of activities going on there. We have a Covid web page that you can check out if you have questions there. We're going to be talking today about the draft voluntary user criteria for the EHR reporting program, which, as you remember, was a requirement in the 21st Century Cures Act. So, not fully funded so we've been using some of our general money for that.

And so, more to follow there. We have our 2020 ONC we're calling it tech form, our interoperability form. Registration for that is now live. So, you can see that. I don't know if there are limits on virtual attendance. We've bumped up against physical attendance limits in the prior three years we've done that. It's always been a pretty exciting, high yield activity. So, hopefully, in the virtualized way, it will be that. We have some pretty interesting virtualization software that we're going to use for this. On the management front, I guess, I want to congratulate Steven Lane and Jim Jirjis for their reappointments to HITAC for another three years. Both have been very helpful. Steven has done an amazing job with many things. And Jim, certainly, we've had a number of thoughtful conversations with him as well. And we just want to thank everybody. We, obviously, are in a funny state where the things we do are more important than ever because people realize that there are vast IT issues in figuring out the diagnostic work of Covid.

We still, ultimately, don't really know how it's transmitted, what its latency is, what its disease patterns are, on the one hand and then, obviously, the entire tele health virtualization on the other hand. So, with that, let me turn it over to our chairs, Carolyn and Robert.

## Review of Agenda and Approval of May 13, 2020 Meeting Minutes (00:06:43)

**Carolyn Petersen**
Thanks, Dr. Rucker. Good morning, everyone. It's great to see everyone back at the meeting again. And I appreciate everyone's flexibility in transitioning from the regular in person meeting we, typically, have in June to this virtual format. We have today four presentations. We will start with a review of our 2020 work plan by Lauren Richie. Then, Al Taylor and Brett Andriesen from ONC will give us some updates on the standards recommendations. Aaron Miri and I will report in on the work of the annual report work group. And then, Seth Pazinski and Christal Ramos will lead a discussion on the EHR reporting program draft user criteria. We'll have a public comment period and then, wrap up just a little bit after that. So, with that, I think we'll start by approving the minutes from the May 13 meeting. All of those in favor of approving those minutes, signify by saying aye.

**Group**
Aye.

**Carolyn Petersen**
And all of those who oppose approving the minutes, please signify by saying nay. And are there any abstentions? All right. We have approved the minutes from the May 13 meeting. I'll pass the mic to Robert for his welcome.

**Robert Wah**
Thank you, Carolyn. And let me just add my welcome to everyone else who is here. I did want to follow on to Don's comment about the HHS guidelines for lab reporting. Obviously, this is something that I thought was important for the committee to hear based on our conversations about where technology can help in the Covid-19 epidemic. I think we talk a lot about the value of lab information but the need for richer metadata around the lab results, such as demographics and individual. So, I thought that was an important part to share. I'll also say that many of you have heard me talk about the Commons Project that I work for and am on the board of. We also are very interested in finding ways to use lab data as it becomes more important for movement. I know there has been a lot of controversy about the value of individual lab results in terms of passporting or allowing people to move into countries or venues. But there is a need for better flow of lab information, particularly in this epidemic.

And so, we're working with people like Microsoft, Google, and others to figure out if there is a standardized FHIR endpoint protocol that can be used to distribute lab results so that everyone knows how to get those lab results easily into their systems. And so, I think that's an important piece of work. We also launched the Common Health, the Apple Health equivalent, in Android. And so, now we're able to inject lab results into both Apple Health and Common Health. And that will lead to people being able to display their status based on the lab results. So, I think these are activities that we had all talked about during our Covid discussions. And I hope to see more activity to add more fluidity with data as we need in this important fight against the Covid-19 epidemic. So, with that, I'll turn it back over to Lauren to describe the HITAC 2020 work plan.

## HITAC 2020 Work Plan (00:10:27)

**Lauren Richie**

Great. Thanks, Robert. So, now that we are about halfway through the year, I just want to take a little bit of time to talk about our plans for the remainder of the calendar year. So, if you recall back in January, we presented a work plan that really just went through the summer/fall timeframe. And so, we just wanted to pick up where we left off. So, really kind of a continuation of what we presented back in January and, again, focusing our remaining plans and activities around our three priority target areas as interoperability, privacy and security, and patient access. So, this represents input we received from the prior year. We also presented this list back in January. This covers conversations that we've had either at the task force level or control committee level or topics from the annual report or other ONC priorities. But, essentially, many of these topics have been under consideration and help to feed into the plans for the balance of the calendar year.

This is just a quick snapshot of where we are to date and what's coming down the pike. So, again, thanks to your recommendations, obviously, we've completed and released the ONC Cures final act, review of the CMS interoperability and patient rule, and completed your feedback on the federal health IT strategic plan. Obviously, today we're going to have our official committee level roll out of the fiscal year '20 HITAC annual report and starting that conversation. Also, today, obviously, looking at draft criteria for the EHR reporting program. Last month, we heard from the ICAD task force. And we'll plan to hear from them again in the fall. And then, obviously, we're still exploring options for additional Covid-19 follow up activity for the committee. Looking ahead, we identified innovating and using received data as a priority topic, which may or may not be kind of folded into the ISP activity looking at the trusted exchange framework and final common agreement. And then, perhaps, taking a more focused look and discussion around patient access.

So, again, just a timeline view of some of the things I just mentioned. So, those items in blue being confirmed for the end report, the EHR reporting program today and the ICAD task force. I just wanted to highlight two activities we're planning for the fall. And that is around the interoperability standards priorities. So, if you recall from the Cures Act, it requires us to take a revisit or review the standard priorities that were identified from the baseline report set of recommendations that we received from the ISP task force last fall. And then, also possibly looking at the ONC EHR contract guide that we are anticipating presenting to you for feedback in the October/November timeframe. And then, just a note. In September, we will hold additional administrative meetings to talk through a number of items but, more importantly, looking ahead to 2021 and starting to get your input for plans for next calendar year.

So, that was it. So, I just wanted to give you a snapshot of what's to come. Obviously, as we have additional thoughts and conversations, feel free to send those my way. And then, we will plan to have more dedicated time in the fall for additional planning activities. With that, I'll pause to see if there are any questions on this so far. All right. So, again, feel free to reach out at any time if you have any thoughts or questions. So, with that, I will turn it back over to our co-chairs.

**Carolyn Petersen**

Thanks, Lauren. We will now have some updates from Al Taylor and Brett Andriesen with ONC. Go ahead, please.

## HITAC Standards Recommendations Updates (00:15:48)

**Al Taylor**

Thank you very much. I'm Al Taylor from ONC standards division. I'm joined by Meyers parrot, Merlin. He'll be chiming in occasionally in the background. Sorry about that. We all know that the ONC published the USCDI Version 1 in March of this year. And even before we published it, in fact, the second half of last year, we've been working on the next version of USCDI by developing the criteria for evaluation of new data elements that are proposed for addition to the USCDI in future versions. The HITAC, especially the USCDI task force, developed these criteria to determine what are the minimum entry requirements for the different levels of data elements and the levels of maturity and levels of development and use in interoperability that are designated as either comment Level 1 or Level 2. And the data elements that have been entered as Level 2 will be considered going forward for future versions of USCDI.

So, one of the tools that we have developed is called ONC on deck for the new data element and class submission system. And we expect to release that or open it up to the public on or about July 1 of this year. So, we're just waiting on PRA clearance and final design and we'll have that up and running very shortly to be able to accept new data elements for consideration. This is a summary of the previous table showing the criteria. But we will be accepting information for each of the new data elements, specifically around use case, including the benefit or value to stakeholders. We're going to be evaluating maturity on three different levels. One is the representation of standards or implementation guides, the extent that current use in systems, whether it's being exchanged or not and then, the extent of exchange in the methods and mechanisms of exchange that are already in place, all of which point to the feasibility of adoption into USCDI.

We also are interested, of course, in the challenges and burdens and barriers to implementation, including IP, intellectual property, licensing and dollar cost of development and implementation, as well as any privacy security concerns, which already pertain to some of the different data elements within USCDI but could very easily apply to new data elements. This is a high level timeline, we've all seen this before, showing the different parts of the development of USCDI. Although we would have liked to start submissions for accepting proposed new data elements for Version 2 that has not begun yet. But we will begin shortly. The submission system, actually, will be open and up and running continuously but we'll have a cut off of approximately the third quarter of each calendar year at which point we'll complete all of the evaluation of the data elements that have been submitted to date. We'll prepare a draft Version 2 based on those recommendations.

And that draft will be presented to the HITAC and to the public for comment on or about January 1 will probably be one of the things that we present at the first meeting of 2021. After a period of comment, an evaluation and recommendations by the HITAC and the public will turn internally, again, and develop our Version 2, which, once finalized, will be available for public consumption. And it may well be a new standard that is being considered for inclusion in the standards version advancement process. And we, previously, had more details on the SVAP and we're separating this out because the USCDI as a standard is one of

many that will be considered for SVAP in the future. That's it. I'm going to turn it over to Brett Andriesen who is going to talk more about the standards version advancement process.

**Brett Andriesen**
Thanks, Al. This is Brett. And I am not the parrot that Al was mentioning when he first started speaking. I'm the standards advisory lead in our office of technology. And I will just give some quick background on the SVAP. We finalized it as part of the final rule. It allows health IT developers to report newer version of standards or subjugations adopted by the secretary in the certified products following National Coordinator approval. And it's part of the real world testing conditions and maintenance of certification requirements. So, all of the eligible standards and specification for advancement under SVAP are currently listed at www.healthit.gov/svap right on the slide. And that list you can see the image to the right of the screen shot, the table, the left two columns around the standard name or the reg text citation can be sorted to view that a little bit better. And it's integrated into the larger ISA platform like the USCDI is.

Though, this doesn't include any minimum vocabulary standards or code sites so those can already be certified or upgraded to newer versions for program terms unless that's explicitly prohibited. And as noted on this slide here, public comments will be solicited to help ONC make determines as the industry readiness for advancement of specific standards or specifications. And we're looking around the next month or so. It's likely timed pretty closely with the ISA comment period. Moving on to the next slide, we'll go through some of the operational details that we're working towards. So, first and foremost, ONC will look at the standards landscape and may identify on the SVAP page standards that are under consideration already for SVAP. This wouldn't necessarily limit others for advancing but just a way to signal things that we may have our eye on or want specific feedback on. And then, we'll be establishing our regular work during comment period much like the ISA and likely aligned with that comment period.

To flip the input from industry **[inaudible] [00:23:05]** is on that eligible list of standards and will, certainly, be communicated and announced likely through typical ONC channels. So, be on the lookout in the next few weeks for more details and timeline on that. Following the comment period, ONC staff will review comments received and make recommendations to the National Coordinator for which standards to consider for advancement. ONC will publish that list of the standards and versions, specifically, that have been approved under SVAP authority. And then, finally as needed and possible, the ONC certification program may provide updated test pools or other resources to assist advancement. And then, prior to rolling out those updated versions, the clients' developers will have to take a number of steps that I have encouraged folks to take a look at the specific rule language to make sure that those updates can be rolled out to their clients.

And I think that is all we have. I think we can take a few questions, both Al and I, on this for USCDI committee members if they have them at this time.

**Carolyn Petersen**
Hey, HITAC members, please let us know just by raising your hand in the Adobe function and we'll go to callers or just on the phone also. Are there any HITAC members on the phone who have questions? Let's hear from Clem. Go ahead, please. You might be on mute, Clem. Are there any other questions from other HITAC members?

**Lauren Richie**
It looks like we don't have Clem on the phone. We can try to get him dialed in and circle back if that's okay, Carolyn.

**Carolyn Petersen**
Sure, yeah. I was looking to see – I don't see any hands raised from other HITAC members. HITAC folks, if you have a question, would you please speak up so we know you're on the line and have a question? Okay. Are you having any success getting Clem back on the line? It looks like, in the public comment chat, he says he would like to talk but we're not hearing him.

**Robert Wah**
I think he's on Adobe but he's not dialed into the voice part.

**Lauren Richie**
Yeah. Clem, if you can hear us, you just have to call the phone number in your meeting invite and you'll be connected through. Okay. So, Carolyn, I'll give you a heads up once I confirm that Clem is on the line.

**Carolyn Petersen**
Okay. I don't see any other hands or hearing from other HITAC members with questions. Do you want to give it another minute or what's your preference?

**Lauren Richie**
Is that for me, Carolyn?

**Carolyn Petersen**
Yeah. Oh, Jonathan Nebeker has a question. Go ahead, Jonathan.

**Jonathan Nebeker**
Yeah. I have a question that may betray my ignorance more than anything else. But on the maturity on Slide 5, it seemed to be the main criteria for adoption to the USCDI. At face value, they seem to make a lot of sense. I just have a concern that there seems to be a bit of a catch 22 in that use. The main requirement for adoption is use. And it seems like this creates a huge dependency on vendors implementing the use. I guess my question is how does – is this a concerning dependency? Do you have mitigation strategies? Is this not an issue? How should I think about this potential what looks like an ability for vendors to block data elements for going to USCDI?

**Al Taylor**
Well, this is Al. I'm not sure that I can comment on the latter part of your question about developers preventing use. I can't really speak to that. We're looking to adopt implement data elements that have at least demonstrated the potential for implementation use and exchange. And whether that's in a small system, a limited number of systems, a limited number of exchange settings, it would be at least the potential. In some cases, I think that the ability to exchange widespread is an indication of its value to overall national interoperability. And so, we would be looking at least for the potential for capture and exchange but it doesn't have to be by a system of a certain size. It just has to show the potential. And then, the value

of the use case is also an important criteria, although, obviously, it seems more subjective. We want to be able to demonstrate the overall value to a large group of users.

**Clem McDonald**
So, this is Clem. I think I'm live now.

**Carolyn Petersen**
Go ahead, Clem.

**Clem McDonald**
So, my question or issue was with detail to the specifics of what people are asking. So, for example, one could say we should report depressions cores. But then, which one? So, there is some tricky stuff in the hierarchy of what exactly one wanted. And we sort of face it now with some of the Emergency Room data or the admission data or vital signs data that says do this. But what about the other variation on the theme of that? So, I almost think we should be talking about classes of terms within some code system if we're going to define it well or something like that. Just saying we want to give an area doesn't mean you'll get anything that's computable.

**Al Taylor**
In some cases, Clem, there will be an almost universally accepted standard for collection, use, and exchange of the data. I think that something like the PHQ2 and 9 are good examples of that. I don't know of anybody who is advocating for something a little bit more offbeat or more niche as far as applicability.

**Clem McDonald**
And that's a good point. But somehow, it doesn't come across in the specifications that you've got to be specific at a level that you can, therefore, compute it. It's invisible, I think, and some people don't get it that that would be important.

**Al Taylor**
That's a fair point. I'd just point out, and I think everybody knows this, that in the USCDI Version 1, we have some data elements that have specific standards. And sometimes, those specific standards are simply captured within LOINC or captured within SNOMED as opposed to captured with a particular code in SNOMED or LOINC. And so, depending on the particular application there may or may not be a very specific standard of use.

**Clem McDonald**
Well, I think that's a good point. I just would like to see it elevated a little bit more so that people who are naïve about how you do this, what are their choices and to specify something.

**Al Taylor**
There are going to be submissions for recommendations for addition that are going to require further conversation. And people that submit are going to probably have a variety of levels of experience in either data element or standards work. And so, we will provide some assistance and further communication about what else is needed. And if something is determined to be of a lower level, which means not as much maturity, it may just require more information in order to complete the application.

**Clem McDonald**
Okay. Thank you.

**Al Taylor**
Sure. Thanks.

**Carolyn Petersen**
And let's go to Terry O'Malley now.

**Terrence O'Malley**
Hi. And my question is just is there an explicit roll out plan for getting the word out for On Deck, which, by the way, is a great name so congratulations?

**Al Taylor**
Congratulations on the name? Thank you very much. So, we are going to communicate it. I don't know exactly the mechanisms. But through our regular communication system, we have a list serve, which we can publicize. I would imagine the trade press might be interested in the availability of the system. We do blog about different topics that we put out as well. So, it will be in one or all of those systems.

**Terrence O'Malley**
Great. Thanks.

**Carolyn Petersen**
Let's go to Ken Kawamoto, please.

**Ken Kawamoto**
Thanks. Just a comment and follow up on what Jonathan was questioning. Isn't it a catch 22 to say widespread adoption is required, basically, to certify that it should be widespread adoption? This is something that we discussed quite at length in the USCDI task force. And I think it is a key point. So, I think the potential roles here are for the ONC to facilitate some of that piloting kind of like the SNI framework works or certain groups to get together and try to convince their vendors to show that this is doable. But I think it is quite a valid point. I'm not sure to what extent the USCDI is actually helpful if it simply acknowledges the status quo as everyone is implementing it so now it's part of USCDI.

**Al Taylor**
Thanks, Ken.

**Carolyn Petersen**
And let's go to Arien Malec.

**Arien Malec**
Good morning. So, this topic is something that has been something we've studied extensively in the past FACAs. And I'd like to point people to the standards maturity model that the somewhat strangely named NwHIN Power Team created as a set of recommendations with the National Coordinator a while back as

well as some work that we did on what was in SNI framework replacement process that I think has morphed into the SVAP. These concerns of how do we establish a floor while preserving flexibility for developers to work on a feeling is a real and valid set of issues that policy makers need to address. So, I think it would be worthwhile looking at the SVAP and ensuring that it does meet the needs for establishing flexibility in testing and using newer versions of standards or standards that address additional requirements. So, as an example, right now we have FHIR R4 and R5 that's being worked on right now. R4 is the established version and yet most EHRs are on R2.

This is, actually, a pre-SVAP issue in this case. The R2 users are there because all of the consumers are R2 and it's really hard to break that dependency. So, the situation becomes worse when we need to maintain certification on a consistent version and also need to contemplate upgrades. And I think we just need to look at the experience of ICD-10 and the upgrade there, the experience of rolling out new versions of administrative standards and how long it takes us to get to the latest versions of standards to seed the issues involved in this process. It's a tough set of issues but, again, I would encourage ONC to think heavily about how to use the SVAP to provide additional – I know the intent is to provide additional flexibility, how that works in practice, what the incentives are, and how to make sure that HIT developers get the opportunity and, potentially, grants or other kinds of pilot testing in order to develop new versions and standards while the four versions are out there. Thank you.

## HITAC Annual Report Workgroup Update (00:38:14)

**Carolyn Petersen**
Are there any other questions from HITAC members either on the Adobe or on the phone? Okay. Hearing none, I will say thank you to Al and Brett for presenting to us today. We appreciate the opportunity to hear what's going on. And I will now transition to the annual report work group update that's coming to you from myself and Aaron Miri. Can we have the next slide, please? Today, we're going to talk just briefly to let you know what the work group has been up to since you last heard from us in February. At that time, we were able to approve the annual report for fiscal year 2019. And we took a hiatus from the HITAC meetings but began working behind the scenes on the 2020 version. So, today we're going to review our membership, our meeting schedules, and our next steps and then, give you a brief presentation on the potential topic list for this year's report.

Here are our rosters. Returning to the work group are myself, Aaron Miri, Christina Caraballo, and Brett Oliver. And then, working with us from ONC are Dr. Rucker, Elise Anthony, Seth Pazinski, Lauren Richie, and Michelle Murray. So, the work group has had two meetings to date where we are discussing the various topics that came from comments from things we held over from last year's work. And as things evolve, just seeing what we're doing with the Covid work in this committee. We met in May and June and we will meet again in July and August and then, present to you in September. Today, we're just kind of giving you a sense of the topic list. And then, in September, we will be able to do more full discussion looking, again, to looking through review draft in January and getting that approved in February of 2021. What we're going to do today is present a draft list of potential topics at this meeting.

We are going to develop our draft crosswalk of topics with gaps, opportunities, and recommended activities across our target areas at our work group meetings in July and August. And then, in September, we are

going to present the draft crosswalk for discussion at the full HITAC meeting. And with that, I'll hand the mic over to Aaron to go through the list of potential topics.

**Aaron Miri**
Yes, good morning. Thank you, everybody. First of all, I just want to wish health and happiness to everybody on the call. I know that here in Austin, we are dealing with a surge of certain – you guys are seeing also affects of what's going on across the country. So, I hope all of you are being cautious and that your families are safe and sound. To that end, we did want to pick up some of the items from the annual report last year that did carry over. And you'll see a lot of applicability of these topics as we saw it all play out during the Covid situation a few months ago. So, anyway, from a topical perspective that are going to carry over from the annual report for FY '19, the ONC Cures Act, the final rule, TEFCA program updates, CMS interoperability and patient access final rule, SDOH, social determinants of health data and exchanges, use and sharing of PGHD, patient generated health data, and, of course, internet of things.

So, from some of the comments of this committee for last year's annual report, we really take a lot of time and a lot of credit to the ONC staff for making sure that all of these are captured. These are some of your explicit comments that you wanted us to talk about in this upcoming report. Around interoperability, EHR certification criteria to support patient safety. Establishment of common metadata nomenclature and use. Increasing interoperability across the care continuum being to long term post-acute care, behavioral health, home and community-based services. And then, correction of incorrect data and ramifications of exchange of incorrect data. It's amazing, again, all of these topics how we saw them and how we're seeing them play out during Covid-19. Around privacy and security, improving patient and receiver consent process for research and data sharing. And then, privacy and security concerns about the use of synthetic data. And then, patient access to information. Increased price transparency for patients. Again, all of these are very relevant and very much playing out in front of us.

So, some other potential areas here that for the next year's report. Public health. Within 21st Century Cures Act, in addition to the three priority target areas, the HITAC can make recommendations about the use of technology to support public health and data for use in quality and public reporting programs. So, some of the comments for this year around public health, specifically, support for standardized codes, data, terminology, Covid-19, patient diagnosis, treatment, and case reporting, and clinical care. I know a number of HITAC members have been very involved with the CDC and others in helping to try to overcome some of these barriers. Big hats off to Dr. Steven Lane and others for the great partnership in trying to help public health and deal with Covid-19. But this is definitely one of those areas that all of us can think about and really add to and see how we can help solve this problem.

Some other comments also around interoperability. Improving information exchange for research, information blocking, specifically, around the analysis of changing business practices and barriers to competition over time, and the impact to the proposed EHR exception and safe harbor provisions, and the definition of inducement. Privacy and security, specifically, around the safety and effectiveness of mobile health applications. I saw this play out here in Austin as we rolled out contact tracing **[audio interference]**. 2.) Organ transplant use cases for health IT for data exchange and outcome measures. And then, implications of large and private sector partnerships for third party access to health data. Again, we saw this in a major play out in the news right now with contact tracing. And patient access to information ensuring patient access and engagement and data exchange perhaps using the TEFCA.

So, some general questions. And, again, I want to go back to something Carolyn said. We're not looking for debate here. The whole point of this discussion was to get our mind wrapped around topics that were in our annual report from last year and things we're thinking about for this year. In the September committee, we do want to have a robust debate. So, I would ask each of you, if you have thoughts, marinate on it. Send it in. Let us know what you're thinking. We definitely want to have that robust discussion in September. But the degree of it, look at those topics that were sent out. Add to them. Really think through each of your locales. What have you experienced? What have your clinicians experienced and whatnot? And how can we bring that to the committee as robust stories to overcome.

And so, some specific topics here for discussion by HITAC members that we really should think through, again, improving information exchange for research, specifically, consent process certifications for received data. Think about organ transplant and use cases there. And then, ensuring patient access and engagement in data exchange, again, using the TEFCA. Those specific things, think through them. There are a lot of dimensions in all of these. And even as a committee, as an annual report work group committee, as we were talking through this, we had hours of discussion around each of these topics. We didn't begin to scratch the surface. So, with that, I think that's it. So, Carolyn, I'll turn it back over to you. But really, again, for the whole committee, I would ask you to please think about it. Email us. Let us know your thoughts and your opinions and we, absolutely, will capture those. I appreciate your time today and please be safe.

**Carolyn Petersen**
Yes. And let me add my admonitions also that we are all safe and my best wishes for good health. What we had brought forward from the last year's work was a nine page Word document with comments, some general topic areas. It's been expanded to 10 pages in light of some of the work that's going on around Covid and what we now see as public health related topics. We didn't want to bring that and present all of that to the HITAC again because much of that feedback has come from you. And we feel there is really a role for us in organizing that before we start asking for specific comments. But we really do encourage you to email us any thoughts you have. We can take that into account, at this point, and see how that fits into the overall plan and the overall report. With that, I will hand the mic back to Robert to introduce **[audio interference]**.

**Robert Wah**
Thanks, Carolyn. And thanks to you, Aaron, for your work on this important committee. To the HITAC, if there are questions or comments about the annual report, please raise your hand in the Adobe application and we'll get you recognized. Also, I want to make sure that we hear from folks who are not logged into the Adobe app. HITAC member is on the phone only. Please just announce yourself and we'll get you on the list to speak. So, anyone that has any questions or comments about the annual report, this is the time for us to hear from you. All right. I don't see any additional hands. Why don't we move on to the EHR reporting program and the draft user criteria? With that, I'll introduce Seth and Christal Ramos for that.

## EHR Reporting Program Draft User Criteria (00:48:58)

**Seth Pazinski**
Thank you, Robert. This is Seth Pazinski with office of National Coordinator for health IT. Hello, everyone and thanks for the opportunity to present. And I'm looking forward to hearing your feedback on the voluntary

draft user criteria under the EHR reporting program. So, myself and the Urban Institute team will provide an overview and get into some of the draft criteria. And then, we should have an hour or a little more than an hour for your feedback and discussion. So, hopefully, plenty of time for folks to share any thoughts or ask questions. Just a little bit of an overview before I turn it over to Christal. The EHR reporting program was created under the 21st Century Cures Act. And it's purpose is to provide publicly available comparative information about certified health IT. And there are two components to it. There is mandatory developer reporting and then, voluntary user reporting. So, today we're focused on the latter, the user reporting piece.

And the categories across both of those areas cover things like interoperability and usability and a few other required categories. So, I'm just going to give kind of a quick recap on progress to date in the EHR reporting program implementation, highlight where we are now in that process and then, touch on some next steps as well. So, first, just on the recap of progress. Our initial discussion with the HITAC came just before the Urban Institute began their work under a contract with ONC. And ONC received feedback on a request for information and discussed and obtained HITAC feedback also at that time on that request for information. And those insights and the public feedback from the request for information really left a foundation for the Urban Institute starting their work. Following that, the Urban accepted some additional background research and conducted an extensive stakeholder engagement process through various methods that you'll hear a little bit more detail on. And the results of that were, of course, published in a stakeholder input summary report.

And then, really, the first result of the work of all of that stakeholder engagement is the draft voluntary user reported criteria that are available, currently, for public comment. So, where we're at today is the draft voluntary user reported criteria were published earlier this month for a 60-day public feedback period, which ends on August 10. And so, in addition to any feedback received directly through Urban, the discussion today and resulting transcript from this meeting will serve as public feedback that Urban will consider as it works to revise a set of voluntary user reported criteria and submit that to ONC. So, one thing I just want to highlight here is kind of unlike the federal rule making process, we don't have to separately submit the comments that we hear or discuss today to Urban. We can consider any feedback we provide on this call will be considered for purposes of revising the draft criteria.

And then, as far as next steps and what to expect next, the Urban Institute, again, is ONC's contractor to implement the EHR reporting program. We'll review the feedback received and provide a revised set of voluntary user reported criteria to ONC. And then, following this step, the Urban Institute will then finalize a draft of developer reported criteria. So, again, the other half of the EHR reporting program. And that draft developer reported criteria will, similarly, be made available for public feedback and will re-engage the HITAC to get your feedback on the developer reported criteria as well. So, just a little bit of context to get us started. I'll transition it now over to Christal Ramos and the Urban Institute team to provide some additional background and take us through the draft voluntary user reported criteria. Christal.

**Christal Ramos**
All right. Great. Thank you so much, Seth. Hi, I'm Christal. And as Seth mentioned, I'll be sharing with you today about our progress to date developing the EHR reporting program. And then, we'll walk through the draft reporting criteria for the program to be voluntary reported by end users, the certified health IT products. And as these draft criteria were recently posted, we really are interested today in hearing your feedback so I hope the bulk of the time will be discussion. I just wanted to point out my colleague, Kathy, has posted the

link to the website where the user criteria are posted and they're also available in the downloads on the side, I see, if you would like to access those and reference them as I go through today. To show you the project team, as Seth mentioned, Urban has been contracted by ONC to develop this program. And we have subcontracted with HealthTech Solutions. So, a number of our team members are on the call today and will be helping for questions and discussing with us today.

The next slide is an overview, as was mentioned. The EHR reporting program was mandated by the 21st Century Cures Act to provide publicly available comparative information about certified health IT through mandatory developer reporting and voluntary user reporting. And today, we are focusing on the second one, the user reporting. The Cures Act included five domains that these criteria should cover. And that includes interoperability, usability and user centered design, security, conformance to certification testing, and other categories as appropriate. Why is this program needed? As some of the initial background work that has been built upon by this project, in 2015 ONC did a review as part of a report for congress and identified there were 18 existing health IT comparisons goals. But these tools had some major limitations, including high user fees to access information, some methodological issues, and lack of some of the specific information that would be useful as people are making decisions about purchasing or upgrading their certified health IT products.

As part of our project, we conducted additional review of these tools in 2018 and found some additional limitations. Some were no longer available. Some catered to a more narrow specialized audience. Just limits in the types of information that were available as well. During the stakeholder process, which we will talk about more shortly, stakeholders did raise concerns with existing tools that might be a need for a program such as has been mandated by the Cures Act to provide publicly available comparative information. We also did hear from stakeholders about the process. A need for this information to inform their decision making, purchase IT products, especially for a smaller or more rural practices that might not have the resources or an IT Department to help them make this purchase or may not be able to afford one of the more common products. For example, we heard from a nurse practitioner who runs her own practice who told us she thought the information on which this **[inaudible] [00:56:22]**. So, those input stuck in my mind as the reason why this is needed.

Just walking through our timeline, briefly, to develop this program, as was mentioned in the beginning, we began with a review of the RFI comments that were submitted and also reviewed existing literature and comparison tools of literature on the ways that EHR performance and health IT have been measured, how they're currently being measured in other data sources and tools. And then, from February to October in 2019, we collected stakeholder input. In November and December 2019, we developed the job criteria. And then, in the beginning of 2020, we went through a process of testing and revising the criteria. And then, we just recently posted them online for public comment, the user criteria. So, going through the stakeholder input in a little more detail, I just wanted to show you the different ways that we collected input. There were 77 comments that we analyzed from a variety of stakeholders from the RFI. We also had public forums and office hours in seven states. We went to four professional association conferences and were in the exhibit hall and had specific meetings with users and heard feedback there.

We had some topical virtual group discussions focused on the different domains like interoperability for charity. And then, there were some groups that were more defined by the types of people that joined like trading partners or ambulatory providers and a rural group as well. We had one on one discussions with

experts on safety, on measurement, on different topics like that. We also had market research calls with existing EHR comparative tools and then, a dedicated email inbox for public feedback. This next slide shows the framework summarizing what we heard from stakeholders as their priorities throughout the engagement process. And we'll go into more detail but I just wanted to start by summarizing at a high level some of the priorities we've heard, which are in the box on the left.

So, overall, we heard from stakeholders. They did see value in this program in providing comparative information to help differentiate between products. But even more than just a shopping tool to compare products, they wanted to see the program be something that really promotes transparency and accountability and safety and drive market improvements. We also wanted to make sure it filled information gaps and minimized the burden to users and said there was reporting information as well and that what we collect, ultimately, can be updated frequently. So, it will, actually, be useful. So, you can see the columns in this framework are the domains from the Cures Act. And the blue arrows running across are the types of information that they were interested in across domains. So, these included information on the functionality of certified health IT products, what capabilities does the product have on the performance, how does the product perform in the real world and then, on cost and developer practices to how is pricing structured and the contracts and user support, is it available, is it an additional fee.

And there is a link to a report summarizing our stakeholder feedback that we heard on the web page for the draft criteria that has been posted for public feedback. So, based on the stakeholder priorities, we began to drive criteria. And we envisioned the criteria coming from three different sources. From existing data sources, this would be things like CHPL, perhaps information that's been collected through other attestation processes or administrative information. CHPL was largely a source we focused on. But CHPL includes mostly binary measures on functionality. So, for information on performance but we need to collect probably more directly from developers and users. So, the other two pieces are criteria that would be directly from EHR developers and this would be mandatory and the criteria to be voluntarily collected from certified health IT users. So, it's been posted in the format of a questionnaire that would be asked of them. And next in the process, we revised the measures based on feedback that we got from subject matter experts.

We then did cognitive and feasibility testing with a small group of developers and users to see if the questions we had come up with made sense, if they were measuring what we were aiming to, if people could answer those questions. We revised the draft criteria based on the testing. And then, as we mentioned, they were posted on June 9 online. And the draft criteria for the developers are continuing to be developed and they will be posted at a later date. Here are some findings from development process to summarize for you. Not all of the stakeholder priorities were feasible to capture through the draft criteria. There are some priorities that were too burdensome to collect. And I'll probably mention some of those as we go through the individual domains more specifically. We also found that the best source for different types of stakeholder priority is varied.

So, it seems that, in terms of collecting information for users, it made the most sense to focus on usability. But then, from developers, it seemed to make more sense to focus on interoperability, privacy and security. And then, from other sources, it seemed it would be best to get information on some form of certification. We also found that end users of certified health IT products varied. There are probably a range of people we need to talk with to get the types of information that stakeholders prioritize, including clinicians, administrative staff, IT staff, and the HR specialist. And then, finally, some of the findings suggested that it

makes no sense for clinicians to be able to report on their personal experience with the products while the IT staff could report more in the aggregate for the experience of their practice. Based on the findings, user criteria we're about to go through, they cover only a small portion of the stakeholder priorities we heard given many of the priorities were determined to be a better fit collected from other sources.

In addition, given the user reporting is voluntary and knowing end users have really limited time, we aim to keep the number of questions as few as we can. So, before going into the draft user criteria, I just wanted to pause to see if anyone had a question or comment about the development process or the framework. I know there has been some chat going on but I haven't been following. But if there is anything that we need to address, I'll just pause and see. Okay. I think I will keep going.

**Robert Wah**
We have a couple of hands up. I'm not sure it's specific to these points but I'll ask Steven Lane and Terrance first to see if they have questions about your specific question.

**Steven Lane**
This is Steven Lane. I'll just offer a comment and a reminder to everyone that I was engaged as an advisor to this effort and had a chance to work closely with the teams from both Urban Institute and HealthTech as they went through this process. I just wanted to say that they did a really remarkable job reaching out across the spectrum of the user community really making an effort to reach out to small practice providers, to those working in rural areas, to clinicians and beyond, physicians looking at nurse practitioners, etc. So, I think a lot of really thoughtful effort went into gaining input to this process. So, I'm very excited to see how they put it all together here in the end.

**[Crosstalk – inaudible]**

**Terrence O'Malley**
This is Terry O'Malley. This is an impressive piece of work. And my question is more about usability across the spectrum. So, the exchange of information from hospitals, not only within their systems, but also with nursing facilities, post-acute care in particular where the interoperability sort of falls off quickly as the HITAC funds disappeared. And I'm just interested in your comments of how far out you're able to push your assessment beyond the ambulatory care setting and the hospitals themselves.

**Christal Ramos**
Great question. We grappled with this a lot. And I'll start and maybe others from my team will chime in, too. But we did really want to include long term post-acute care, behavioral health, other providers that were left out of the meaningful use incentives. So, we grappled with how to do that. Given that the requirement for this specific program focuses on certified health IT products, as we discussed, it was stakeholders, we just realized there would not really be an incentive for people to contribute information on non-certified products, which a lot of those providers use. So, in our framework and how we thought about this, we then determined they would become more thought of as trading partners. So, we thought if we could include criteria that could consider how well products trade with other systems, perhaps not within those that are certified that that might be how we could reach it. But it is limited.

I know there is an EHR compare tool that is quite widely used for long term care products. But yeah, it is a little bit of a limit to what we've done given the folks on certified products. I don't know if Gary or others want to chime in a little bit more.

**Gary Ozanich**
This is Gary Ozanich. We did solicit input from long term post-acute care stakeholders both in terms of organizations that represent those entities but also, specifically, as we had our listening sessions across the country. In some regions, we, specifically, reached out through organizations that represent those entities and also the state government to make sure that they were invited to participate in the sessions and, in particular, in some regions, we had very good turn out with long term post-acute care and behavioral health. So, we did, I believe, listen very closely and engage with the providers and other stakeholders in that space. But as Christal mentioned, the focus is on certified health IT. So, to that extent, we took a trading partner approach and suggested evaluation on how well it supports exchange and other activities with those trading partners. Christal.

**Christal Ramos**
I hope that answers the question.

**Terrence O'Malley**
Yes. One more comment though. Since interoperability is really in the eyes of the end user, it would be, I think, important to solicit feedback from, again, post-acute care behavioral health who are not traditionally engaged in the purchase and use of extensive HIT just to ask them whether or not they're getting what they need and it's complete and in a timely fashion and then, they can use what they get. That's, ultimately, the measure of interoperability.

**Christal Ramos**
True. That's a good point. Yeah. We'll, certainly, continue to think about that some more. But you're right, in terms of the trading partners reporting on their experience working with people who have specific products. Were there other hands or should I move on?

**Robert Wah**
John Kansky, you had your hand up. Did you have another comment on this specific point?

**John Kansky**
No. Sorry, I'll wait to the end. It's a general comment.

**Robert Wah**
Great. Why don't you go ahead and proceed with the presentation then?

**Christal Ramos**
Okay, great. So, I'm going to walk through draft user criteria. I'm going through each domain. And if you have the questionnaire handy, you can look at the specific questions for that section. I'm going to pause with each domain to see if you have any specific questions or comments in terms of what to prioritize to include from that domain and if you have any specific feedback on the wording of the questions, we would welcome that as well. And then, at the end, after walking through all of the domains, I'll ask some bigger

picture questions to discuss in terms of what types of end users could best report this information and how we could target and motivate this group to voluntarily contribute information. So, starting with interoperability, these are under Question 5 in the draft user criteria questionnaire. It's a very multipart question. You'll see.

And it also includes an open ended portion of the question. So, users could comment more specifically on their experience if they would like. So, for interoperability domain, the draft user criteria really focuses on the usability of various interoperability functions that emerge with priorities from a stakeholder process. So, there are other things to be considered like more reporting on specific connections that could be made or, perhaps it might seem objective, but determined through our process that it really makes the most sense for users to report on their experience and the ease of use. So, you can see the first column lists the priority topics. And then, the user criteria shows a little bit more specifically. But these criteria focus on the ease of exchange with various entities such as HIE and HIOs, the ease of connecting with the local PDMP, the ease of exchange with different types of clinicians, those who have a different product than their own, those outside of the organization, those inside of the organization, also payers.

And then, ease of exchange with public health and clinical registries. And then, the last two report the ease of producing the reports like quality measures and quality reporting requirements for specialty and the ease of attestation to providing interoperability or to mix. Given we heard a lot of these, they really reflect on the pain points we heard from stakeholders throughout the process, things that they want more information on but I think they also want a level of transparency and accountability in the field on these priorities. So, if you want to look at the questions under Question 5, I know it might not be easy to on the spot but if there are things you want to share, specifically, about the wording or about what from here you think we could prioritize, what we shouldn't prioritize, if there is something missing, we'd really love to hear that.

**Robert Wah**
Alexis, I think you have your hand up. Is it specific for this?

**Alexis Snyder**
Yeah. In terms of wording and prioritizing, I would say that prioritizing health information exchange is very important. So, nice to see it at the top of the list. At the same time, I would say two other pieces. 1.) The term ease is very subjective in what might be ease of exchange for one might be a completely different definition for another. I have to think more on what might be a good substitute. But I'm not sure that ease in each category really brings across what you're trying to convey. And then, lastly, when we talk about the ease of interoperability, I would just urge, and I had made notes as I ran through the slides that were sent out earlier so maybe it's a comment for later but just keeping in mind with interoperability also comes with opening up more problems sometimes and privacy and not losing sight of how much exchanged in an ease of exchange between systems and not losing sight of the privacy of said patient.

**Christal Ramos**
That's helpful. Thank you.

**Robert Wah**
John Kansky.

**John Kansky**
Yeah. Just a quick follow on to Alexis's line of questioning. I don't really have a solution for this but just to point out the difficulty in this overall task. The perception of, for example, the second row, ease of connecting to an PDMP from the perspective of an EHR user is going to be very dependent on what means the access to the PDMP is allowed. But what I'm, specifically, referring to or thinking of in bringing this up is that, in some states, HIEs represent a good means of getting access to the PDMP data to the EHR. But state PDMP policies prevent that. So, in one state, there might be a mechanism that the EHR can take advantage of that would make the ease of access seem much better. Whereas in other states, policies of the program would prevent that avenue from being available to the EHRs. So, in trying to characterize the ease of connectivity to a PDMP for an EHR, there are dependencies that are uncontrollable behind the scenes.

**Christal Ramos**
Very good point. Actually, we would really love everyone's feedback on this topic, too. We did try to hone in on what is best reflective of the product itself and the product's performance and functionalities that, as you're bringing out, some of these things might be also affected by policy, state level things. So, that's very helpful. Thank you.

**Robert Wah**
Carolyn Petersen, you have your hand up as well.

**Carolyn Petersen**
Thanks, Robert. Yes. I just wanted to reinforce Alexis's point about this concern with the term ease. I think we all appreciate the value of working in ways that doesn't increase the clinical burden or the burden to administrators and other people who are involved in making the interoperability a reality. At the same time, I think an emphasis on expediency can sometimes get us into real trouble. We want to find the balance between what is reasonable for reporting and measurement but also ensuring that the work is effective in the system to really give us the outcomes we're looking for.

**Christal Ramos**
So, currently, I don't know if you have the question open but I'd be interested if you have an alternative suggestion. So, the response option – so, we have a survey methodologist. We have gone through these as far as options as the way that surveys are usually structured. But they are very easy, easy, neither easy nor difficult, difficult, very difficult and then, don't know and not applicable. Is there a concept – so, I'm hearing you mention efficiency or effectiveness as other things we could focus on as an alternative to how easy it is. I don't know if you have any specific suggestions on how you would word the question instead.

**Carolyn Petersen**
I haven't looked at it in a particular degree, at this point, to be honest having just received it a few days ago. But I think it's, certainly, something that merits a broader discussion if that's something that ONC and the Urban Institute are open to.

**Christal Ramos**
Yeah. Like is it something you easy to use.

**Robert Wah**

It looks like ease has prompted a number of hands up. So, Clem, you're next.

**Clem McDonald**
Yeah. I have the same problem with the word ease. And I think it's made complex by the fact that it's usually two parties and there are two directions. And I think the first reason is the ability to – and this is from the medical records side. The ability to deliver with health information organizations and HIEs that might be the focus. I don't think I'd worry about the burden because these are usually not on the care providers. These exchange things are mostly burdens on the installation and implementation, which is a one time cost. So, I think that ease is a bad problem. And I think you've got to analyze it a little bit more about for who. You can't blame the medical record system at the other end can't do it something like with a PDMP in some cases. But I think it's important to name and push all of these issues.

**Robert Wah**
Alexis, did you want to add in addition to what you typed into the comment section?

**Alexis Snyder**
No. I also wanted to put in the comments about substituted word, perhaps seamless.

**Christal Ramos**
How seamless is it?

**Clem McDonald**
Well, the suggestion of ability or capability from Vic sounds like a better direction.

**Robert Wah**
Jonathan, you had your hand up as well. I didn't know if you wanted to speak on it or type.

**Jonathan Nebeker**
I used to do research in this area but it's been like 15 years so I'm a little rusty. But Raj, I don't know if he's on the call here, continues to do research in this area. There are standardized instruments that will provide some guidance here. And so, I just encourage referencing some of that work. There is a lot of work in social psychology that can disentangle some of the concepts others have mentioned. And so, I think this is mostly a solved problem. You just have to refer to the instruments and then, tick what you're trying to accomplish.

**Christal Ramos**
Yeah. And Raj and his team are very helpful in sharing their work with us. So, we'll continue to look at that.

**Robert Wah**
Great. Other comments on this point before we proceed with the presentation? Carolyn, you had your hand up again. Was this a second comment or was this from your first one?

**Carolyn Petersen**
I didn't intend to put it up. I'll put it down now. But just getting back to the clinical burden point, I think that it's kind of the end game issue for the patients. If the interoperability is not working and the information is not going where it needs to go, it does become a clinical burden because the only person the patient can

address to get that fixed is the provider. So, it becomes you said this was going to happen, call the office. It's a downstream effect because that's the only way the patient can engage with people. The patient can't call the IT staff and say here is what's wrong with your system and why I can't get what I need and what the law says I have to be able to access. We need to think in ways that keep the patient from needing to do things to create more problems for people who can't solve them.

**Christal Ramos**
Interesting.

**Robert Wah**
Other comments on this point before Christal proceeds?

**Raj Ratwani**
Yeah, Robert, this is Raj. Apologies, I'm not on the Acrobat. But I would like to make a comment if possible.

**Robert Wah**
Sure, absolutely. Go ahead.

**Raj Ratwani**
So, I want to come back to the point about standardized measures. Those are there and so, I think that would help a lot of the terminology here. And then, the other point I want to really stress is there was the comment around the PDMP and how state policies or even institutional policies are going to vary and, therefore, are going to impact user experience and usability. And I think that's something that we have to recognize. Nearly with every single measure that we're going to talk about is that the state of health IT is there is so much variability by implementation, by policy, and so many other factors that there is going to be this constant tension between was that actually really a product issue or is that because of a policy that's shaping the product. And we have to grow comfortable with that tension. And I would argue that we want to capture the information from a user's perspective regardless of what those policies, implementation variabilities, etc., are because there is no other mechanism to capture it.

And so, it's best to capture it through this reporting program right now and then, find a way to stratify those data by all of the other measures we can grab. So, if we start capturing this data here and we say wow, in the state of, I'm not going to name a state because this is all recorded, in the state of whatever, there is really poor experience there. But in the state of blah, blah, blah, there is really great experience there. That must be a product issue. We can say, actually, let's take a step back and let's stratify those data by policies and other things that are impacting the product. So, having gone through a lot of these discussions about I can't really capture that measure because it doesn't actually reflect the product, we can and we should because we have no other way to capture it. And it's better to capture it here and find a good way to then stratify those data by other factors than to not capture at all.

**Christal Ramos**
Thank you. That's a helpful point.

**Robert Wah**
Clem, you had your hand up.

**Clem McDonald**
Yeah. Hearing all of this, I kind of jive with the last comment. And what we might ask is the amount of what's going across these different connections because that kind of captures the net availability. And if some people are failing or if some states can't do it, hopefully, people will sort out why.

**Robert Wah**
I think I cut Emily off with that as well. Sorry about that. Emily, have you got a comment?

**Emily Johnston**
No problem. I was just going to mention that we have a slide coming up, to Raj's point, that we agree that stratification is really important. And the goal will be to collect these user criteria feedback points as well as information about the user so that analysis of these data could be stratified by state of residence, for example, or provider type or the share of uninsured patients seen at a practice. So, I think that's something that's really important and has been guiding our development in thinking about these measures as well. So, thank you for bringing that up.

**Robert Wah**
All right. Other comments on this area before we move on to the rest of the presentation? Seeing none, Christal, you can go ahead and proceed, I believe.

**Christal Ramos**
Great. Thank you. We really appreciate all of these comments. The next slide is on the usability domain. So, these are Questions 6 through 8 in the questionnaire if you're following along. And 8 is also a very multipart question. You'll see that the draft usability criteria does focus on topics of provider burden, quality and safety, and ease of use. I know we have issues with the word ease now, which we will continue to think about for various functions that should enhance usability. So, in terms of provider burden, we ask for a satisfaction rating in terms of the user satisfaction with the products, contribution to their productivity, how it all aligns with their workflow, whether it easily accesses **[inaudible] [01:26:00]** data from other products and produces clinical benefits. For quality and safety, we focus on satisfaction with the product enabling high quality care, improving patient safety, not disrupting interaction with patients, preventing errors. And it has advantages that outweigh the disadvantages.

And for both interoperability and usability, a lot of the wording we did review, as you guys have pointed us to a number of standardized questions, measures, and pulled from the language as much as we could. And then, features and functions to enhance usability. We started out with a very, very long list of features and functions. You heard from the stakeholders that we kind of narrowed it down throughout our process in terms of what people prioritize, what people seem to know, to be able to report on. And so, I won't read them all but you can see this includes a number of specific features. And it's kind of interesting. Some of the features that seemed a little bit, during the stakeholder process, like they were more important maybe for rural practices like tele medicine and mobile and remote access have become more broadly important now.

And the same way, I thought I would pause and see if you look at the usability, priorities, user criteria. If you're looking at the questionnaire, you can look at the wording, what you would prioritize. There are a lot

of functions here. So, if there are ones that would be more important or less important, I'm interested in that. And then, again, as you brought up before, is it getting at what we want and is it reflecting, as much as we can, the product itself keeping in mind that it's hard to isolate that.

**Lauren Richie**
Okay. It looks like we may have dropped Robert's audio. So, I see Denise Webb and then, Alexis Snyder for comments.

**Denise Webb**
Yes, thank you. Denise Webb. I was looking at the actual questions and the scales used. And I assume that the topic of provider burden and quality and safety, some of that was captured in Question 7, which had a satisfaction scale. And it struck me that it seemed to make more sense rather than a satisfaction scale would be to use a degree of agreement scale. So, does the user agree that the product allows users to be more productive and to what degree of agreement? Strongly agree, agree, meaning agree or disagree. It seems to be more sensible than using satisfaction. Just a suggestion.

**Christal Ramos**
Yeah. Thank you. Great suggestions.

**Robert Wah**
Alexis, you had your hand up as well.

**Alexis Snyder**
Yes, thank you. Just a couple overarching pieces. I don't have the questionnaire up in front of me but I did look at it before this call and made some notes. So, I'm sorry if I jump ahead to numbers you haven't presented. I just wanted to state, overall, I think there was a piece that said out to the clinicians for users who would be filling out this survey that it would take about 10 to 15 minutes. But reading through it and looking at all of the questions and the level of complexity of some of the ordering for the questions, particularly the ones that say to rate something with the definitions A through F, I don't see how this survey is going to take 10 to 15 minutes. And so, when you get to asking people about incentives to get people to use it, I guess that will be important because I can't see somebody taking a half an hour or more to run through this survey. It seems very complex. So, that's my overall comment.

My other specific comment is, as this is a user survey and, obviously, patients and caregivers won't be directly using the interoperability and the EHR reporting systems, etc., I wonder if there is a way to reflect in the provider burdens and quality and safety and features, etc., as we move through it asking the providers and the other users questions reflective of feedback that they have received from patients through either increased burden because of the use of this system or increased disruption to their privacy, information shared when it shouldn't be, information that didn't get shared when it should be, etc. Because I think that's an important piece as we, again like I mentioned before, open up more avenues for interoperability, we also sometimes open Pandora's box and the patients are the best to be able to – possibly, they're speaking with their healthcare systems or their clinicians about the problems that interoperability is causing for them and where in this survey can that be reflected.

**Christal Ramos**

Great point. Thank you. And the 10 to 15 minutes, it did come out of our testing. We put the questionnaire in an online platform and tested it and that was kind of the average time it took. But I could see if you needed to get information for other sources, it could take longer due to language and things like that.

**Robert Wah**
Other comments or questions on the usability draft criteria?

**Fred Balvin**
This is Fred Balvin. I was just going to comment that there is variation, potentially, on how we sent out the survey as to who fills out the information. So, sometimes, it could be a clinician or provider. Sometimes, it could be an administrative staff member of health IT specialist who might not be able to provide the best perspective on patients on the patient view of this. So, that's partially why it's a challenge that we're facing with this. And it's something that we're looking to, potentially, address.

**Robert Wah**
Other questions or comments from the HITAC? Jonathan?

**Jonathan Nebeker**
Yeah. I just wanted the team just to reference my comments in the chat about demonstrated variability by change management strategy and potential for accounting for that. And then, second, the forthcoming standards from American Association of Medical Instruments on usability. And there should be some reference to that. That's all.

**Christal Ramos**
Thank you.

**Robert Wah**
Other comments from the committee on this? All right. Seeing none, Christal, you can proceed.

**Christal Ramos**
Does anyone know if the chat get saved? Will we be able to keep it or should we copy and paste everything to make sure we have it?

**Lauren Richie**
No. We have the ability to capture the comments.

**Christal Ramos**
Okay, perfect.

**Robert Wah**
We'll capture the chat.

**Christal Ramos**
Okay. Good. I don't want to lose all of this great stuff in there. We can go to the next slide. The next slide is very short. Though I really am interested to hear more. I think you guys have raised some really good

issues related to privacy and security in terms of the trade off with interoperability and then, the patients' perspective. But, in general, we probably heard the least about this topic during our stakeholder process. What we did hear we found to be most likely better suited to be collected from other sources than these are. So, you've brought up some other points that perhaps would **[inaudible] [01:34:07]**. This is Question 13 on the questionnaire. And it's an overall satisfaction rating, security and privacy feature. And in terms of the features, we give examples of multifactor authentication, mobile based access controls, 42CFR Part 2 in HIPAA as the types of things to consider when giving the rating. And then, we also have an open ended comment box if the user wants to further explain the rating.

I think, initially, we had perhaps some separate questions for these different things. But throughout our testing process and feedback we got, it seemed to make sense to consolidate in terms of what the typical end user might be able to report on. But that was the slide but very interested if you guys have any feedback for things we could consider here.

**Robert Wah**
Questions or comments on the security draft criteria? I don't see any hands. Anybody else on the phone that's not on the Adobe app? Christal, you can go ahead and proceed.

**Christal Ramos**
Great. Thank you. As I previously mentioned, we don't have a slide for conformance to certification in terms of a domain for the user criteria given that was determined to be better suited from developers or other existing sources like CHPL or data collection during the certification process. So, the next slide focuses on the other job criteria topic, which is kind of the catch all. But the remaining priorities that didn't fit into other existing domains in the Cures Act were more general satisfaction, pricing and cost, available support from the developer, and contractual information. So, these mostly covered Questions 9 through 17. And they mostly fall within that blue horizontal arrow if you remember from **[inaudible] [01:36:07]** for cost and developer practices. You heard a lot about these topics from our stakeholders during the process.

But in terms of the satisfaction rating, we have overall product satisfaction rating and then, satisfaction with implementation process, with maintenance and upgrades, in terms of how much notice they get, what they get, how much downtime it requires. And then, the available support from the developer. For pricing and cost, there was a lot of interest here. But as you can imagine, it's pretty challenging to collect information, especially from end users who might not have all of the information. So, we had more cost measures, initially, but have narrowed down to asking about the pricing model and the approximate total implementation and maintenance costs. So, we recognize only certain types of users might be able to report this information. And then, questions on the availability of support and whether there is an additional fee required for things like desk support, dedicated client support, in person support, and other things. And then, contractual information, whether or not the contract improves the defined costs and a procedure for users to leave the product sometimes referred to as an out clause.

Interestingly, we met a lot of people along the way who were in the process of switching their EHR. So, a number of things on how challenging that is, not just for contractual reasons but other reasons. I think one of the most memorable posts is someone saying it would be easier to change my husband than to change my EHR. So, there is a lot of interest and information on this. There was some other contractual information that was of interest that is no longer relevant after the interoperability rules to gag clauses. So, we did

update our criteria to reflect in this policy landscape as much as we could. I'll just pause here. And if you have the questionnaire, you can look. I think **[audio interference]** if there are suggestions there. And then, in general, what to prioritize. I know we have a lot of questions about support or standard use but there are also a lot of priorities in that area. So, what you think is priority or if you have any questions or suggestions for us, we'd be interested to hear.

**Robert Wah**
Denise, I see your hand up.

**Denise Webb**
Yes. So, when I was with the state of Wisconsin, we had administered a similar survey where there were some questions that only one or two people in the organization could really answer. And so, I'm not sure what the plan is for disseminating the survey. But I would suggest that it might be a good idea to consolidate the questions that, generally, can only be answered by certain individuals in the organization because there is so much group practice. And in large group practice, you'll want to have those questions answered once and not slow down to each of the users within that group practice. So, I'm not exactly sure how you would do that but the point being you really do want to collect this and then, be able to tie it. So, if there are 100 clinicians that answer the survey that are in a single group practice that it would link back to the answers to the questions by the person who can answer these questions on contract and price and support and those kinds of things.

**Christal Ramos**
Yeah. Great suggestions.

**Robert Wah**
Clem, you also had your hand up.

**Clem McDonald**
Yeah. I wonder if there could be some questions asking about, and this is true because of the provider of care using the system, how much time it takes to do a given event. There are studies show that it goes up and that's the big complaint. One big complaint from providers is it takes longer than scribbling something or writing it down. So, whether there could be some question about to enter an average order – and it's a hard question to construct. But I think it would still be useful to get timing or something concrete into the questionnaire. We did a study asking how much free time they lost in one big study with the American College of Physicians. And that really didn't – that's a different issue though. It has to do with policy as well as the systems. But an awful lot of them are going to work at home now on the computer.

**Christal Ramos**
That's a great suggestion.

**Robert Wah**
Other comments or questions from the committee?

**Raj Ratwani**

Yeah. This is Raj. I have a question and a comment. The first question is there seems to be patient safety elements kind of sprinkled throughout. I heard a little bit, I think, on the interoperability side, a little on the usability side. I'm wondering if you could just recap what all of those patient safety elements are and then, maybe some discussion around is there an opportunity to introduce more patient safety focused questions given that there really are few mechanisms for our providers to report on safety issues. So, that's the question. And then, the suggestion is, on those other criteria that we just talked about, maybe something around **[audio interference]** of the vendor to respond to a reported safety issue or other high priority usability issue **[audio interference]**.

**Christal Ramos**
Great question. I'll start and my team could jump in. I think it was very helpful to hear throughout from experts in terms of whether safety should be its own column or arrow or whatever. But I think it should be baked in throughout, as you were saying. So, we did try to keep it in the front of our minds. And I think, actually, as we're talking, I'm remembering that we might have it more in terms of objective measures. It seemed that developers could more likely report on some of these things in terms of things like **[inaudible] [01:42:33]** time. I think from the user's perspective, we did try to bake it into the usability in terms of how the products more generally affect safety. In terms of things like counts or error, I think we have suggestions throughout to be able to process **[inaudible] [01:42:46]** errors or for overriding alert and things like that. But just in terms of the burden, from the user perspective, we stuck to the questionnaire format.

But we did try to keep it in mind throughout. Maybe I'll pass it to the team who worked on this a little bit more if anyone wants to jump in.

**Gary Ozanich**
This is Gary Ozanich again. Part of the challenge as we interacted with the stakeholders and capturing their knowledge and ability to I guess the way to describe it is explain or conceptualize the issue of patient safety, it came up much more in the area of clinical decision support and areas that are sort of very much product specific as opposed to certification criteria. So, the feedback we got was less concerned about – it was more about privacy likely than safety per se and, once again, more in a context of workflow. So, the ability to capture that in the questionnaires becomes a little bit more complex. I don't know, Raj, if you have thoughts on that.

**Raj Ratwani**
Well, I agree it's complex. But I would say, from every clinician that I've talked to in the previous studies that we've done, when we ask questions about can you describe a feature or element of the EHR or other health IT that prevents potential or realized patient safety risks, the answer is always yes. And the provider usually has a very concrete description, a very memorable moment where there was some interaction with the electronic health record that left them feeling really uncomfortable or where they actually committed an error. So, I think while it's difficult to capture in perhaps a structured format, I think it's important to capture. And I'll just come back to the point that I made earlier, which is there are few other ways for us to capture this information. And I think that becomes really important as we think about the different tools that we have at our disposal. And perhaps we can talk a little bit offline about maybe some specific questions that could be introduced.

And I realize that, obviously, we want to keep the queries here to a minimum given the already expressed concerns about the time to complete the survey. But I think this is a critical one and maybe other members of the committee have some ideas.

**Robert Wah**
Great. Other comments from the committee? Christal, proceed.

**Christal Ramos**
Raj, if I could just ask a follow up question. The question that you just suggested in terms of have you had a moment where you think it was a risk to safety or caused an error, do you think of that as more of an open ended question or a yes/no question?

**Raj Ratwani**
I think you could express it in a few different ways. One is to express it to say how frequently do you interact with the EHR and sort of see some of these risks so that we can determine whether their interactions are on a regular basis representing patient safety risks or really whether it's more of an anomaly. So, we could structure it that way. And I think some kind of open ended question would be really good to have as well to see what we can get back and then, to do some aggregation of those.

**Christal Ramos**
Okay. Thank you.

**Gary Ozanich**
This is Gary, again. I just wanted to comment that the feedback we got, particularly from the developers on some of these issues has to do more with the implementation of the product and the use of the product versus the product. And so, also developing our questions that may distinguish between what is the workflow and what is the implementation versus something that's, actually, associated with the product is also a complex issue. I just wanted to mention that.

**Raj Ratwani**
I would agree. I think that is a really complex issue. But I would view this as a tool where we can identify areas that need further focus. And so, if there are – it's a signal. And so, if we are getting some feedback that there is a potential safety issue in a particular implementation that doesn't mean we go throw that whole vendor company into federal prison. It means we go to that site and we begin to understand what are the specific implementation choices, workflow, training models, etc., that may be contributing to that safety issue. That's the way I would view it.

**Gary Ozanich**
Thanks.

**Christal Ramos**
Yeah. That's helpful. Kind of a bigger conversation that we can save for the end but it sounds like there are multiple purposes for this information that we collect part of it being put out there to compare products but part of it to learn other things, like you're saying. I guess we'll move on and we can maybe return to some of these bigger picture things at the end. So, the last slide related to the questions for the users are, as

Emily brought up earlier, some of the product characteristics and then, user characteristics that we heard from stakeholders that they want to be able to see what products are people using in a similar setting as me, a similar practice size as me so that they could compare results that way. So, these are Questions 1 and 2 and 18 to 24 in the questionnaire. The first question, of course, would be to identify what health IT products the respondent is responding about. And it would be a drop down for them to select.

And then, the user characteristics that we heard as important included were the type of clinical or nonclinical user, setting, practice size, type of services at the practice, what state they're in, especially if they're in an urban or rural setting, the share of patients that are uninsured or covered by Medicaid. And then, we have a question about the user proficiency with the product as well. I know someone thought that might be an issue. So, I just wanted to pause to see if there are any other suggestions for important characteristics that we might want to try to capture.

**Robert Wah**
Alexis, you had your hand up.

**Alexis Snyder**
Yes, thank you. In reference to Question 23 about the shared uninsured and/or Medicaid population, if we're talking about exchange of information between EHR and the payer, it might be good or would be good to have a question surrounding the percentage of patients that have more than one payer, more than one insurance, whether it be private and Medicaid or Medicaid/Medicare or tertiary care is important when we talk about the interoperability of the multiple players that are involved. And then, real quick, just a little wordsmithing thing perhaps. Question 24, at the bottom of the list, it talks about your expertise with the system per se and the last choice you're struggling with. And I'm not sure that people like to answer surveys and say I'm struggling with something. So, maybe I've had difficult with this or I would like more help with this. Just a small thing.

**Christal Ramos**
Good point. Thank you.

**Robert Wah**
Sasha, you had your hand up and then, it popped down so I'm not sure if you still had a comment.

**Sasha TerMaat**
Oh, I was going ask you if the product's characteristic was multi select but then, I saw my question was answered on the slide. I assume the S means it is multi select so I took my hand down. Thanks.

**Robert Wah**
Sheryl?

**Sheryl Turney**
Thank you and thank you for presenting this. I was just wondering I did review the survey but I wasn't 100% clear where a product like Availity might be captured because this is really focusing on EHR systems but we have represented payer. And we have thousands of providers who exchange data with us through a portal that's, basically, been put out by multiple payers. So, there is like a common interface that they have

to some degree. And some of the capabilities of data sharing with a payer would be taken care of by that. But I don't know if anyone filling out this form would naturally think about that because they're thinking about their EHR system and it doesn't happen through that. So, how would that be captured in this survey?

**Christal Ramos**
Great question. And we also have struggled with this. I guess part of the challenge is called the EHR reporting program but then, as we know, for certification purposes, it's not EHRs that are certified with these different functions. I think in terms of what we focus on in here, you're right. It really is – I think from a user's perspective, they would be thinking of their EHR. So, I'm not sure I currently really have a good answer. I don't know if others on the team want to chime in but it is something that we have been grappling with and we need to continue to think about.

**Sheryl Turney**
Right. It might be fair to ask just an open ended question that asks what other tools do you use for data interoperability so at least you're then now aware of what they are. Because, again, some of the interchange to the practitioner might be invisible because it's administrative staff or someone that's handling that. And I don't work in a physician's practice. I have not. But in dealing with many physicians over the years, I'm not 100% sure how much they know about what tool is used for what if they're not the ones who are actually doing it, if they have administrative staff that does it. So, again, I do think it's an important comment that other people made about who is actually completing it and then, at least gathering the knowledge so that you know hey, there are all of these other tools that people are using in order to accomplish this. And the survey is not really capturing any of that.

**Christal Ramos**
Yeah. Great point. It really points to the need for more customized questions going to different types of users, too. People just roll –

**Sheryl Turney**
Right. We have some providers that use HIEs in order to share ADTs with us. That wouldn't come out on this either. So, I kind of struggled with where to ask my question because I wasn't sure exactly where it fit in. But I do think there is a scenario for that. And from a patient's perspective, although that's been brought up a few times, I know that some systems, in terms of utilizing the data, you don't know really what's behind the curtain. And I know, personally, when my daughter who has a condition was with a system that started using Open Notes, for her, her ability to see her data increased dramatically when they implemented that. But not all of the physicians that she sees utilize it. And so, from her perspective, she's like why can I see this detail here but not over here in this system, not understanding that it really has to do with what they've implemented for their patient portal. So, just throwing that out there as well.

**Christal Ramos**
Great point.

**Robert Wah**
Other questions or comments from the committee? All right. Christal, do you have more?

**Christal Ramos**

Great, thank you. Just a thought. Such great feedback. We really appreciate it. We really do need to think more. But as we started this journey and developing the program, we were trying to think of including as many settings as far as we could to touch the care and all of this and different types of products as possible. And throughout our process, we kind of narrowed, from feedback and testing, towards doing a few focused things well if we can. But I think, in that process, we don't want to leave out important things that you guys are bringing out. So, this is really helpful. I think we can go to the last couple of slides. So, we've gone through all of the domains and categories of questions. We've addressed the first two bullets here. The last thing I wanted to discuss at a higher level. I think we've already gotten into who would be reporting this information and what types of users. Should this focus on the most recent versions of products?

I guess what that would mean for users is, in terms of a drop down, we would only include the most recent versions and then, you would, I guess, only be eligible to participate if you had a most recent version. Just thinking of the purpose being to provide transparent information on products that people would buy or upgrade to. And it's not likely they would be going to a non-most recent version. But then, I also hear the point from others that there are other uses for this information in terms of learning about products. So, I could see it going either way. Also, how should we collect this information? How do we target the different types of people who would be able to answer these questions? Some thoughts we've had range from crowd sourcing, just putting it out there and advertising it through associations and all the science media or getting some lists from FKNA or list some of the providers, lists of administrators, lists of health IT staff and blasting out an email inviting people to participate or if there are other ways that people have that you'd want to suggest.

And then, how could we motivate voluntary reporting to get people to contribute information? So, I'd be really interested in everyone's thoughts on these questions and anything else you want to comment on in terms of the bigger picture of the program or the user criteria.

**Robert Wah**
Thanks, Christal. Other comments or questions from the committee? Terry O'Malley?

**Terrence O'Malley**
Yeah. Hi, it's Terry O'Malley. Just to repeat, I think, what you already said, Christal and a couple of other people have said and that is you've got multiple questions that it can be answered best by multiple different types of roles, whether it's clinicians or administrators, etc. And so, the thought of just parsing this survey and really making it multiple surveys in one but with specific questions for each role group that they can answer easily and well. As a clinician, for example, if you ask me about what my system version was, I'd say don't ask me. But if you ask me how long it took me to order lab tests, I can tell you that. So, perhaps really parsing the survey into multiple surveys to get the information but target it, specifically, to the groups that can answer it best. And this is just a rehash of what you've already said a couple of times.

**Christal Ramos**
Yeah. I guess another part would be to send it as like a practice survey. Maybe it would go to the practice level and have them determine who could best – sometimes we do this with Medicaid surveys but send it to Medicaid and they have to collaborate among their staff to answer all of the different questions. But I don't know if that's too much of a burden, another possible approach.

**Robert Wah**
Thanks. Alexis, you had your hand up.

**Alexis Snyder**
Yeah. In addition to possibly deciding who fills it out and parsing out the surveys would be the suggestion of using branching knowledge within the survey, which might cut down on the time for some users. If the questions had nothing to do with their area of expertise, the branching logic in the survey could lead them to the next question or if it was their area of expertise, it would open up the next set of questions within that question if that makes sense. And then, my other quick piece in reference to burden, as I mentioned earlier, as far as trying to motivate people to voluntarily report, it's so difficult when we're already talking about systems that are burdensome and providers and other clinicians not having time. Where do they find the time to do this? And I don't know at all if this is an option.

But my only suggestion would be is there a way to offer some sort of one for the person who is checking off that they are having difficult or struggling with their current system to get some kind of free training going in response to their answers from vendors. And/or is there a way to have some kind of offset of cost from a vendor, which I know might be difficult because that might be choosing one or the other. But if it was some kind of generic voucher to offset the cost of any or all, it might motivate someone with not a lot of time who is interested in finding the best system to participate voluntarily.

**Christal Ramos**
Good suggestions. Something tangible, some incentive.

**Alexis Snyder**
Correct.

**Robert Wah**
Thanks. A couple of things. Lauren had put something in the public chat area. We're running a little bit ahead of schedule. For those of you that are planning a public comment, we may be able to accommodate your public comment earlier than the published schedule. The public comment period was scheduled for 12:15 but we're running a little bit ahead. So, please be prepared to make your public comment earlier than previously scheduled because it looks like we may end early. Also, Arien, you have a microphone up. I don't know if you have your hand up. I sent you a note. But if you want to speak, just put your hand up. The next person I see is Clem McDonald.

**Clem McDonald**
It seems like everybody is in agreement that there are different questions for different parties. And I didn't hear her say yeah, let's do it that way. How, actually, it's implemented isn't up to us. But it seems like there is consensus on that. But I also thought the time question, there is really compressed time. So, it might be worth going through and picking the really best questions and not doing much with any given group who would be answering it.

**Christal Ramos**
Yeah. That definitely is helpful.

**Robert Wah**
Denise, I see your hand up.

**Denise Webb**
I just wanted to add to some of the other comments regarding the actual deployment of the survey. And I think the deployment of the survey is going to need to be really well orchestrated almost to the extent where, while it's voluntary, there will have to be some sort of plan to possibly formally recruit organizations to sign up to do the survey. And then, you could have a point of contact for that organization that, actually, launches the survey. It gets everybody on board to take their part. And some well-orchestrated steps where you have a liaison at the organization that's going to get the endorsement of the leadership and to get as many of their clinicians and give them time to fill out their part. And then, if you build the branching in the survey then, it can start with that liaison answering the basic questions that apply to the whole organization. And then, pushing it on to the others where they only see the questions that they need to take. So, a little bit of technology built into this.

**Christal Ramos**
Yeah, very true. I think the buy in of the organization and that upfront work to get people to agree to participate would be really helpful.

**Denise Webb**
Yeah. And I just know from coming from a health system and hearing a lot of the concerns from providers about the EHR, while it takes some time to answer this survey, it is an opportunity for them to air their concerns and have them published so that they all can be shared amongst one another and people can make better decisions about products.

**Christal Ramos**
True. Presenting it in that way as an opportunity for them to share would be good.

**Robert Wah**
Clem, you had another question?

**Clem McDonald**
Yeah. It's really a comment. I hadn't pictured having every practitioner in a practice fill this out. That would be a huge amount of time. Probably, it should be targeted at the primary care or those – some specialty surgeons hardly touch the machine. But I just don't think you're going to get 100 or 500 practitioners filling it out. If you could ask the organization to find some volunteers who are heavy users, it might be less burden. But maybe it has to be everybody.

**Christal Ramos**
Yeah. That's a good point because what if one organization has one person fill it out and another one has 500 people fill it out. It's kind of would we want to do sampling versus just put it out there and see who answers. It sounds like people are going towards being more deliberate in targeting.

**Clem McDonald**

I think you've got to, not do sampling. You've got a whole bunch of different kinds of providers in a complex practice. And it should be the providers who are heavy users of the order entry and the note taking. And I don't know if anyone else on the call could pick out who these are. But they're not going to be the orthopedic surgeons. They have agents that do all of that work. And it probably is not going to be most any of the heavy high priced surgeons. But I think primary care and Journal of Medicine, pediatrics –

**Jim Jirjis**
Clem, it's Jim Jirjis and I can comment on this topic. I think you're right on because there are those who barely touch the machine. And you get bad answers. For me, instead of going through and picking out specialty, there are subspecialists who do use it and maybe starting with the top 50% users or something would be a better measure because though you're correct, in some specialties, they have other people interact with the computer. That's not universally true. And then, you run the risk of them missing key specialists. I think the highest 50% order users probably makes good sense. And if you're too deliberate, you get sampling error and all of that other stuff.

**Clem McDonald**
Good point.

**Christal Ramos**
Yeah, very good point.

**Robert Wah**
Clem, did you have more comment? I'm sorry.

**Clem McDonald**
No, thank you.

**Robert Wah**
Ken, I think you're next up.

**Ken Kawamoto**
Thanks. Whatever it is, I think the methodology should be, ideally, pretty standardized because, obviously, if you choose the person who you know is a clinical champion – let's say an institution has physician informaticists who are assigned to optimize the EHR and you, naturally, ask them, you're going to get very different answers than the people who have no idea how to use the system, for example. So, whatever it is, I think this needs to be systematic and, at the very least, reported how people were recruited. But it's the kind of thing you would never publish a study where you say we're comparing these 10 health systems and how they like their EHR and we're not describing how we recruited people and who actually participated. It would be meaningless.

**Clem McDonald**
Good point.

**Christal Ramos**
Yeah.

**Robert Wah**
Jim, did you have another comment?

**Jim Jirjis**
Yeah. Thank you. It is interesting because if we're trying to measure the EHR itself along these criteria, one of the interesting points I think we've all experienced is when we survey doctors. There are two types. There's the type that invests themselves in going to training and learning how the tool can be used and those are the ones that, typically, complain actual deficits in the technology. And then, there is the group that just never bothered and they give very different answers about the EHR that is inaccurate but is a reflection of how dependent that EHR may be on training. So, if you tried to assess the EHR in and of itself then, a more sophisticated user might actually give you better answers because less sophisticated users may actually give you erroneous answers because they just don't understand how their EHR works. That might be a reflection of usability but it may skew the other way.

**Christal Ramos**
Yeah, that's true because the characteristics of who fills this out is really important.

**Robert Wah**
Other comments or questions from the committee?

**Clem McDonald**
Yeah. This is Clem. Just a follow up. I put my hand back up. The idea of if it takes three days of training, that's a problem in itself. And I think if we only take the people who are trained, you're going to get a completely long answer. So, I'm for Ken's idea. In a systematic way but I think taking the frequent users would be the most useful. They would fairly care and get people who have enough experience to give a fair answer.

**Christal Ramos**
Okay.

**Robert Wah**
Other comments or questions from the committee? People on the phone, maybe not on the app, go ahead and speak up. Okay. Go ahead.

**Christal Ramos**
Oh, I'm really looking for help on **[inaudible] [02:11:28]** focused on the most recent versions only or not. If anyone has any thoughts on that, I would appreciate it.

**Jim Jirjis**
Let's think about Meditech Magic, right. So, by only focusing on expanse and you look at the financial situation many hospitals are in, if the purpose of this is only to help people as they make purchasing decisions then, you're right. You should focus on the latest release. If the purpose is to allow people to understand prior versions when they may not be yet ready to move to the new way, most people in Meditech inpatient have not moved to expanse. So, you'd be deliberately not getting feedback about platforms people

aren't about to leave. And maybe that's okay if you're only focusing on solving the problem of feature purchasing. Is that the goal?

**Christal Ramos**
I guess that's the –

**Jim Jirjis**
A lot of Meditech Magic modifications are occurring when people don't move to the new platform. There are things Meditech can still do to improve these things. And by only focusing on new versions, you're playing right into the hands of vendors who might want people to pay the money to upgrade and also may be missing things that can be done on platforms that are going to continue to be used.

**Christal Ramos**
I see. So, the feedback to the developer is on other versions that they can still make modifications to is also useful.

**Jim Jirjis**
Oh, they are, yeah. They're making lots of modifications for us, for example.

**Christal Ramos**
Okay. That's really helpful. Thank you.

**Robert Wah**
John Kansky, you had your hand up.

**John Kansky**
Thank you. So, I guess this is a comment that is best directed to the ONC. I remember when the law came out that gave this assignment to the ONC and it struck some of us, including me, as an unusual task to give the federal government. It sounded a bit like they were being asked to be consumer reports for EHR products. Now that we're much further into this and more time has passed, I guess I'm interested in any comments that the committee has or the ONC has or the contractors have about does this feel like an appropriate role for federal government. Is there precedence for this in other industries? Meaning evaluating and publishing comparative information on products. And then, finally, is there a vision for how ONC is going to be able to do this without – I guess, just respond to the potential for concern there and whether I'm worried about nothing or something. Thank you.

**Robert Wah**
Christal, do you want to respond from your standpoint and we'll have others from the ONC perhaps answer?

**Christal Ramos**
I think Seth probably would be best to respond to this.

**Seth Pazinski**
Yeah, hi. It's Seth Pazinski. So, I guess, to respond to the initial question and I'll ask, too, if others from ONC who are also engaged in this technical assistance process for the Cures Act legislation have any

additional points to weigh in. But the law as specified was clear in that the work to establish the program, at least through the OD, the research and stakeholder engagement and the development of draft criteria and going through this type of process was to be done by ONC but via a procurement. So, that was, specifically, specified in the law as a part of establishing the program. And in addition to that, the aspects of the program include both the developer piece as well as the user piece. So, I think that, too, are two distinct aspects of the program. And I feel like on the developer side, in particular, the link there is that it's a condition of certification under the ONC certification program.
So, compared to what could be done in the private sector, I think, in particular, on the developer side, that's a unique aspect that implementing the entire reporting program wouldn't be possible to be done outside of the federal government.

**Robert Wah**
Other comments or questions from the committee? Christal, did you have other questions for the committee?

**Christal Ramos**
No, I don't. The last slide just shows the feedback, email address if there is anything that people think of later that you want to share with us. We really welcome your feedback. I appreciate everyone's comments. They've been so helpful. We have all of these smart brains on this issue. We really appreciate it.

**Robert Wah**
Thank you for all of the work. And one final time, any other comments or questions from the committee? Well, thank you, again, Christal and your team, for all of the work. And I appreciate the presentation. As we noted earlier, I think we're a little bit ahead of schedule. I'm going to turn it over to Lauren to go through the process for public comment unless we have other comments from the committee.

## Public Comment (02:17:59)

**Lauren Richie**
Great, yes. If we can pull up our **[audio interference]**. And while we're pulling that up, we'll ask the operator to open the public lines.

**Operator**
Thank you. If you would like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in cue. You may press star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

**Lauren Richie**
Operator, do we have any comments in the cue?

**Operator**
Yes. We have a comment from Shelly Spiro.

**Lauren Richie**

Please proceed.

**Shelly Spiro**
Thank you. Good morning. My name is Shelly Spiro. I'm the executive director of the Pharmacy HIT Collaborative representing over 250,000 members of the Majority National Pharmacy Associations, including pharmacy education and accreditation. Our members include key pharmacy organizations involved in health IT, including the National Council for Prescription Drug Programs, NCPDP, 13 associate members representing e-prescribing, health information networks, pharmacy companies, system vendors, and other organizations that support pharmacist services. A major focus of the Pharmacy HIT Collaborative is to ensure pharmacists in all practice settings, community health system, hospital, managed care, behavioral health, long term, and post-acute care are integrated into the national health IT structure. With a wide adoption of the pharmacist e-care plan effort using CCDA and FHIR standards, we agree with Dr. O'Malley's comments to assure nontraditional EHR vendors are able to certify for interoperable exchange of clinical information. This includes pharmacy system vendors.
PHIT is the steward of over 650 SNOMED CT codes in over 100 value sets within the National Library of Medicine's value set authority center to standardize the collection of documentation and sharing of medication related pharmacist provided clinical services with standards such as the pharmacist e-care plans. The Pharmacy HIT Collaborative supports the efforts of USCDI. Thank you very much for allowing me to comment today.

**Lauren Richie**
Thank you, Shelly. Operator, do we have another comment?

**Operator**
No comments at this time.

## Wrap Up and Final Remarks (02:20:39)

**Robert Wah**
Steven, I see your hand up. I'm not sure if it's on the public comment or on the previous presentation.

**Steven Lane**
No, it's just if we have time for additional HITAC comments, I wanted to get in cue.

**Robert Wah**
Okay. Be sure to put your hand up again. Let's finish up the public comment period first and then, we'll go to the rest of the committee.

**Lauren Richie**
I don't think there are any others at this time, Robert.

**Robert Wah**
Okay. All right. Well, as we get ready to wrap up, let's hear from the committee on any other topic that we haven't had a chance to discuss during the meeting. And I think, Steven, you did have a comment about that.

**Steven Lane**
Yeah, thanks. And I just wanted to thank you for sharing information earlier about the work you're doing with Common Health. I think that's really exciting. And you two have been working with them and look forward to their progress in that context. I took the opportunity to put some comments in the chat about progress that's being made with the electronic case reporting under the auspices of care quality and also another care quality policy that was finalized and published to support greater interoperability between providers and public health. So, I put all of that in the chat with appropriate links. And I just wanted to share that with folks and thank you, Robert, for opening up that opportunity.

**Robert Wah**
Thanks. I was trying to respond to a couple of private chats and I thought it would be worth sharing with everyone about where we are with Common Health and common paths for travel and working on trying to get a standardized way to get lab information flowing through the system.

**Steven Lane**
It's all great stuff.

**Robert Wah**
Yeah. Other comments or suggestions from the committee? Anything else from the ONC that we need to talk about? Perhaps a reminder of the interoperability conference that's coming up, timing and site again.

**Lauren Richie**
Sure. **[Audio interference]** send out the reminder in the registration link to the full committee. So, if you didn't get that, just let me know and we can resend that. But that will be in August virtually, of course.

**Robert Wah**
Okay. All right. Carolyn, any other comments?

**Carolyn Petersen**
I just want to thank everyone for attending the meeting today and, particularly, for giving a very rich discussion around the EHR reporting program user criteria. From the annual report work group standpoint, we welcome you to our July and August meetings. We will be happy to see you in September. Thank you.

**Lauren Richie**
Thanks, Carolyn. And just as a reminder to the members of the public, the committee will be going on a bit of a summer break and will resume again in September. So, I hope you join us then. And I will also just turn it over to Dr. Rucker to see if there are any other closing remarks before we adjourn. Okay. It looks like he's just in – thanking everyone and I hope you all enjoy your summer in advance. Thanks, again, for the feedback today and we will adjourn. And we'll be in touch over the summer **[audio interference]**.

**Robert Wah**
Thanks, everyone.

## Adjourn (02:24:41)