Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 3: ONC HEALTH IT CERTIFICATION PROGRAM UPDATES – INSIGHTS CONDITION, STANDARDS UPDATES, AND RFIS

April 27, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Hung S. Luu	**Children's Health**	**Group Lead**
Hans Buitendijk	Oracle Health	Member
Clem McDonald	National Library of Medicine	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Dustin Charles	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Vaishali Patel	Office of the National Coordinator for Health Information Technology	Presenter

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Mike Berry with ONC, and I would like to thank you for joining us today. All of our Task Force meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled toward the end of our meeting this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate if you are here. I will start with our cochairs and our Group 3 lead. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Jim Jirjis? Elaine Johanson? Meg Marshall? Clem McDonald?

Clem McDonald
I am here.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning, I am here.

Michael Berry

Fil Southerland? All right, thank you, everyone, and now, please join me in welcoming Steven, Steve, and Hans for their opening remarks.

HTI-1 Proposed Rule Task Force Charge and Topics Worksheet (00:01:16)

Steven Lane
Thank you so much, Mike, and thank you for all of you who showed up today. This is clearly the small and mighty version of our Task Force here in our Group 3. I really appreciate those of you who have chosen to participate here. I will not be surprised if we get a couple more participants joining us here as we go forward. We also have a number of members of the public who have joined us online, and thank you all for that. I am recognizing a lot of familiar names in the public attendees, folks who have now been here with us all week, which is pretty cool.

So, we are going to leverage one of our HITAC colleagues, Dr. Hung Luu, to help to lead this group. You are really going to have three of us leading, and the hope is that that will allow us to manage the questions, the hand raising, the taking notes, etc. We did not practice this ahead of time, but basically, I would propose, Hung, that you lead the discussion, I can watch for hand raising and be sure to call on people as we can, and maybe, Ike, you can capture in the spreadsheet any items from the discussion that we want to. I know that all of us on the Task Force should have access to the spreadsheet, and I know, Hans, you are very handy with getting your ideas written down, which is great, but the goal here is very much to review the materials, to collect our thoughts, and to prepare any recommendations that we will then take back to the HITAC meeting and on to ONC. Steve, do you want to add to that?

Steven Eichner
It is hard to follow such an excellent job. I just want to welcome both the Task Force members and the public to our call this morning, and I look forward to continuing to do our good work. I will just reemphasize that the worksheets are available to Task Force members at any point. Task Force members are more than welcome to make comments, suggestions, and recommendations. Not just for any particular subgroup they are participating in, but with any of the subgroups, we do ask that you identify yourself with initials, first name, last initial, or something so that if there is a question about a comment that you enter, we have a good way of tracking down who it might be.

I request you make comments no later than a couple of hours before a meeting so that we have an opportunity to review comments before the meeting so we can address things as they might emerge, but again, that is a request, not a requirement. Please feel free to make comments at any point that it is appropriate. We will go through the worksheets in order, and then, as we get a little bit further in the process, the worksheet content will move over into a Word document kind of thing for final prep and submission to the full HITAC, and then on to ONC.

Steven Lane
Just to add some clarity for those who did not hear us discuss this earlier in the week, the worksheet itself will be displayed here as needed during the course of our meeting. It is not available to the public, but you are welcome to view it here as we are working on it. It is an internal document that the Task Force is utilizing. Hung, do you want to introduce yourself to the group, and we will just clarify your role here as best we can?

Hung S. Luu

Sure. I am an Associate Professor of Pathology at the UT Southwestern Medical Center in Dallas, and I serve as the Director of Clinical Pathology for Children's Health, a pediatric health system in northern Texas, and my focus or interests have been in laboratory data interoperability, but I also bring the perspective of a pediatric practitioner to HITAC. I am happy to help with this effort where I can. Thank you.

Steven Lane
Great. Well, why don't we go ahead in the slides, team, and we will just review our charge before we get started. Go to the next slide, there we go. So, just as a reminder, especially for those who might be new to this process, we are part of what is called as the HTI-1 Proposed Rule Task Force. We kicked off earlier this week. We are here to evaluate and provide recommendations to the HITAC on the new Health Data Technology and Interoperability Certification Program, Updates, Algorithm, Transparency, and Information Sharing Proposed Rule. That is quite a mouthful. Specifically, I am not going to read every one of these bullets, but these are the specific charges where we are focused, and we are going to be focused today on the Insights condition, which is the third bullet there, for the maintenance and certification for certified health IT, so that is going to be an interesting topic. Go to the next slide here.

All right. So, these are the more specific charges. Again, we are not going to go through this in detail, most of this does not apply to the work before us today, but we are going to be focusing today on the EHR certification requirements related to the Insights condition. Next slide. Can we just pop the worksheet up quickly so we can orient people to it? The ONC team has done a great job pulling together a multitab worksheet where we have a listing of the various topics that we are addressing with references to the portions of the proposed rule that are relevant. Our groups have started to assemble commentary on this, and I see Hans has already jumped right in and started including some member recommendations in the Group 3 tab that is available to us, so thank you for that, Hans, and we will try to get to that. Vaishali, take a look at that and we will see if we can incorporate some discussion of this into our work today.

I do not see it well, but at the bottom here, the tabs for the three groups, this is Group 3. We also have this Meeting Topic Schedule tab. If we can slide over there, what you can see is a detailed agenda for the various weeks of this effort. Today is week one of eight, the eighth week being when we deliver our information or recommendations back to the HITAC, so we really do not have a lot of time to get through this, but Group 3 will be meeting on Thursdays. I think it is every Thursday through the 1st of June. For Week 7, we have a plan to bring the whole Task Force back together again, and you can see **[inaudible] [00:10:05]**.

Steven Eichner
This is Steve Eichner. Just to add on, as we mentioned earlier, Task Force members are welcome to participate in any of the meetings, not just the subgroups you chose or were chosen for. If you want an invitation to a particular meeting, please do email ONC so that they can send you a customized Zoom link to join as a participant. If you want to join as a public audience member, you can do so using the links available on the ONC HITAC calendar, but those do not enable you to participate in the discussion. Those are listen-only positions until they come to public comment, which occurs in the last five or so minute of the meeting.

Steven Lane
Clem, you have your hand up.

Clem McDonald
It is not clear to me what an Insight condition is.

Steven Lane
Oh, are you in for a treat, Clem. That is about where we are going to go, so just hold that thought, and if that is not clear to you at the end of Vaishali's presentation, we will be sure to clarify it.

Vaishali Patel
Clem, that is one of the first things I am going to be talking about, so I am happy to address your question shortly.

Steven Lane
I keep accidentally hitting my mute button. I apologize. I invite people to look at the link that Mike put in the chat, and I think with that, we can probably return to the presentation slides and introduce Vaishali, who, I think, is going to walk us through this. There we go. Vaishali, do you want to take it away?

Insights Condition and Maintenance of Certification: Overview & Discussion (00:12:19)

Vaishali Patel
Sure, great. I am here today to talk about the Insights condition and maintenance of certification. As was done in the very brief overview of it by Mike Lipinski in the first meeting that you guys had, it was called for by the 21st Century CURES Act, and in the 21st Century CURES Act, it is called the EHR Reporting Program, and we are referring it to the Insights condition because we are having it be part of the condition for certification, and we believe that "Insights" is a better name for it than "EHR Reporting Program" because what we are hoping to get out of it is more related to gaining insights about the use of certified health IT and providing transparent reporting as opposed to comparing performance and the like, so therefore, we are referring to it as the Insights condition. Next slide, please.

So, the EHR Reporting Program in the 21st Century CURES Act called for developing transparent reporting related to a number of different domains including interoperability, usability and user-centered design, security, and also conformance to certification testing. In this first round, ONC is proposing to focus on interoperability, as that is a major priority of ONC's work and also of certified health IT, and with this direction, ONC's contractor, the Urban Institute, developed a draft set of measures that were based on research, both literature review and market research. They also obtained input from stakeholders and health IT experts as well as obtaining public feedback on a draft set of measures, including from the 2021 EHR Reporting Program Task Force of the HITAC, so, approximately a little bit less than two years ago, we brought a draft set of measures and got feedback, including from some of you, on those measures. And then, these measures were revised based on the HITAC and public feedback, along with additional research and feasibility testing, to create the current set of measures. Next slide, please.

So, the current set of measures within interoperability covers four areas. There is one measure that relates to individual access to electronic health information, which is one domain. In the next domain, clinical care information exchange, there are two measures that relate to that topic. There are four measures that relate to the topic or domain of standards conformance and adoption, and then, there are two measures that relate to public health information exchange that focus on immunizations. Each proposed measure relates to a

specific criteria or criterion that is listed in the right-hand column, and these criteria include the view/download/transmit to a third party, standardized APIs for patient and population services, clinical information reconciliation and incorporation, electronic health information export, and then, transmission to immunization registries. Next slide, please.

So, in terms of who will be reporting on these measures, we really tried to balance the need to develop measures that would maximize the number of end users of certified health IT that were covered and represented under the measures without unduly disadvantaging small startup health IT developers, and so, we developed a set of thresholds that were created based on data that we had available that estimated that about 99% of inpatient and outpatient certified health IT market share would be covered based on these thresholds, while at the same time still excluding the smallest of developers.

So, what we are proposing is that developers of certified health IT would be expected to report as required by each measure if they meet these following minimum qualifications for the measure. First, they have to have at least 50 hospital users or 500 clinician users aggregated across their certified health IT products, and their products are certified to the criterion or criteria associated with the measure, and that refers back to the last slide, where I went through the list of criteria that were associated with each measure, and then, finally, the developer has to have users of that applicable criterion. I see a question. Let me just finish this thought here.

All health IT developers will have to report either that they meet the minimum qualification and they are going to report on the measure itself, or they would report that they do not meet the minimum reporting qualification for the measure, so everyone still has to report something, it is just that those who do not meet the criteria would report that they do not meet the minimum qualifications, and those that do meet the criteria for the measure would report the measure result for that measure. Steven?

Steven Lane
Thanks, Vaishali. Since I first read this, I have been curious about these numbers. It seems to me that having 500 clinicians is a lot of clinicians. It is a number, right? But it is 10 times bigger than the 50 hospital users. It seems like a system might have 50 hospital users and have just a few clinicians, or no clinicians at all. It seems like the 50 hospital users is a much lower bar than the 500 clinician users, and I am just curious where those numbers came from and what we are trying to get at with those.

Vaishali Patel
I could spend a lot of time on this, but at a high level at this point, what I will say is this is based on the 2019 CMS Promoting Interoperability program measures, so what we did was we linked the CMS program data with the CHPL data and we analyzed the data so that there are a lot fewer hospitals than there are clinicians. To directly answer your question, the bar seems lower, but actually, it ends up being equivalent because there are a lot fewer hospitals than there are clinicians in the country that are participating in the CMS programs. And so, the thresholds are based on getting about 99% of hospitals represented and then approximately 99% of clinicians represented, and so, these thresholds were based on getting to that 99% level.

Steven Lane
That proportion, sure.

Vaishali Patel
Because there are a lot fewer hospitals, it ended up being that if you set the threshold at 50 for hospitals, you end up with 99% of the market share, whereas for clinicians, you have to set it at around 500.

Steven Lane
Got it. That makes perfect sense. When I think of a hospital, I think of it having hundreds of physicians coming and going, so the 50 hospital users seemed odd.

Vaishali Patel
Yes. The 50 "hospital users" should have been 50 hospitals and 500 clinicians. "Users" does not mean 50 hospitalists, it means 50 hospitals.

Steven Lane
Oh, okay, 50 hospitals. Now I get it.

Vaishali Patel
All right, we will have to change this slide. Fifty hospitals, 500 clinicians. Get rid of the "users." Anyway, there is a table actually in the rule… If we want to bring it up, I can pull it up and walk through it in more detail, but it might be good for me to go through the rest of this. We can come back to this, Steven, if you like, and I can pull it up off the website.

Steven Lane
That was very clear, thanks.

Vaishali Patel
All right, no problem. I think I have finished this slide. Next slide, please. So, what information will be submitted and how? So, the measure results or data would be aggregated and reported at the product level in the format that is specified by each measure. So, for example, if a certified health IT developer has three versions of a product, the measure submitted would reflect data across all three versions of the product, aggregate it together, summarize, and then report it at the product level. The reason why we went at the product level is because we believe that the product level data provides insights into the performances that vary by market, so there are inpatient products and outpatient products, so it would provide us with insights into what is going on on the outpatient side versus the inpatient side, or specialty, depending on the product, and capabilities and products vary, so we thought it was important to have it aggregated at the product level, and if we rolled it up at the developer level, those insights would be lost. Additionally, the product level is also reporting as required for real-world testing. That is also at the product level, so we thought that would be good as well, for consistency's sake.

The second piece of information besides the measure that we are proposing to require is that health IT developers should submit documentation on the data sources and the methodology that they have used to generate the data for the measures, and the documentation should really help us with correctly interpreting what measures are submitted by the developers and to ensure that we are not doing an apples-to-oranges type of thing, making sure that developers are using consistent approaches, or at least giving insights into what each developer decided to do. The documentation would include types of data sources used, how the

measures were operationalized, assumptions about the data collection that were made, information on the providers or products that were included or excluded, and the description of how the data was collected. And then, optionally, developers may also submit descriptive or qualitative information to provide additional context as applicable if they want to explain the results and give any explanation they wanted to provide related to the results or additional context that is available to provide.

And then, the submissions for the Insights condition would occur via a web-based form and method consistent with what is in the 21st Century CURES Act, and the results would be made publicly available through an ONC website to provide the greatest transparency possible. An independent entity will be involved with collecting the data, and the ACBs will continue their role in ensuring compliance. Next slide, please.

Hung S. Luu
Vaishali, I had a question about the first point, about the data being aggregated instead of broken out into two different versions. So, if there are three versions, and only one meets criteria, and the other two do not, do they all get certified, or are they able to market all three versions the same way? That might be a little confusing to consumers, who think that they would get a top-of-the-line version only to find that the functionality is just not there.

Vaishali Patel
Maybe we go back to slide with the thresholds, back one more slide. So, are you asking about the relationship between one of the products that meets this criteria versus one of them that does not across the versions?

Hung S. Luu
Yes, that is what I am saying. So, the first bullet of the next slide says that it is going to be aggregated, so if there are three different versions, the recording will be an aggregate of all three versions, and not split out to the discrete functionalities of each.

Vaishali Patel
I do not know how often this happens, but in the case where you have a product with three versions, two of the versions meet and have the associated criteria, and the other does not, I think we would only be including the ones that have the criteria associated with them, based on what is here, if that makes sense. So, products that do not have the criterion associated with the measure would not be included for the reporting for that measure. Does that make sense?

Hung S. Luu
Yes.

Vaishali Patel
So, let's just say there are three products. Two of the products have the criteria; one of the products does not have the criteria. Say they have enough users and the rest of it meets the minimum qualifications. We would roll it up for the two versions of the product that meet the criteria. Dusting, I know you are on as well. If I am getting something wrong, let me know, but I think that is how we would interpret it.

Dustin Charles
That sounds right.

Vaishali Patel
Okay. Is there another question?

Hung S. Luu
No, thank you.

Vaishali Patel
Great. So, let's jump to two slides from here. So, reporting frequency and timeline… There are two aspects to this. First, we are proposing that the reporting of the measures be phased in over two years. In the first year, we will start with measures that relate to individual access, public health exchange, and one measure that relates to applications supported through certified health IT measures. These are ONC priorities and also maybe simpler in some ways, so we are proposing to start off with that set of measures in the first year and then give additional time for developers to work on the next set of five measures that would be starting in the second year, and those are listed in the table on the right. Next slide.

So, the other aspect of the timing is how often these measures should be reported. We envision that developers of certified health IT would be collecting data for six months, and then have an additional six months to assemble the measures from the data, and then have another month to report the measure. So, there are three steps to the process: First, collecting the data, so the measures should reflect data during the six-month reporting period. In this example here, we have from April through October, the data in year one, there would be data collection during that period, and then, starting October 1st to the end of March, developers would have time to assemble the data, collate it, get it into the specifications for the measure, and then they would have a one-month window in which to report the data.

And so, that would allow for reporting every six months, and that aligns with the attestations with the conditions of certification and maintenance, and then, the submission windows would be from April 1st to the 30th and then October 1st to the 31st. Those would be the submission windows that would align with the other reporting requirements that we have.

Steven Lane
Vaishali, Hans has his hand up.

Vaishali Patel
Sure. Hi, Hans.

Hans Buitendijk
Hello, Vaishali. How are you doing?

Vaishali Patel
Good.

Hans Buitendijk

Just a couple thoughts with a caveat. As you know, Vaishali, within EHRA, there is a lot of discussion that we have had around this, and we just started diving into the details, so there are a variety of comments to go. I will give that proviso because we do not yet have all the input from everybody to provide further insight, but overall, a cadence and progression like this seems to make a lot of sense, that it helps with staging it. There are a couple of challenges that will start to come up, and we will have to figure out how to translate them into proper comments.

It is very helpful here that you are pointing to year one and year two. In the proposed rule, it uses a year of 2024, and clearly, that is going to be a challenge, given that we are already in 2023, there is no final rule yet, etc., so the start of this is going to be an important element of when it would start, and we indicate that it if it does not meet what is literally in the rule, that is going to be a major challenge based on the kinds of things that are there. I am not sure whether you are going to do this in other slides, but this is the place to bring it up. We are probably looking at some challenges where this is a requirement for EHR, so, HIT certified to certain criteria to report on as they apply, and the conditions of that. That means that needs to come from data of their clients, and there are contracts with clients as to what they can and cannot do, so I think we also need to be very considerate of how easy it is to change those contracts. It is not as easy as some may believe in the timelines and otherwise, and what it takes to adjust contracts to allow us as vendors to report on this kind of data because in the end, it is not our data. We manage as BAAs on behalf of our clients.

So, I think that is going to raise a question. With this kind of timeline and this kind of progression, what is actually the best way to obtain that data? Are there avenues that need to be explored with CMS, with their interoperability program, that some of that can be addressed more easily rather than individual vendors with their individual clients having to result, when they actually can report on this, whether they have the right to report this, since it is not their data? So, that is a challenge that we will see more about on trying to figure out what are some good suggestions to be made in that space. I wanted to raise it here because the timeline and the progression is going to indicate an expectation on when suppliers can provide what, and in this context, those two are going to be some of the challenges we will be bringing up.

Vaishali Patel
Thanks, Hans. I appreciate you raising these points, and I think it will be important in the recommendations that come from the HITAC, yourself, as well as EHRA in response to the proposed rule to outline your concerns and what you would propose as alternatives to this. What we had heard prior to developing the rule was that yes, there are contracts, some contracts allow for accessing data for the purpose of reporting requirements, whereas others may not, and that was one of the things that we actually requested comment on, so I am glad you are raising it, and we would welcome thoughts and suggestions on that front. If you all need more time because of changes that need to be required, just share those comments with us so that we can take that into consideration.

Hans Buitendijk
Steve, based on the placeholders that I have put in Column G, as those discussions get clearer, I will be looking at which ones are reasonable to raise from a HITAC perspective. There are going to be details that HITAC probably need not get into, but that will evolve over the next couple of weeks to get that clarity and suggestion.

Vaishali Patel
One other thing I will say is that this is something Congress asked ONC to do, and they do require developers to report on this, so this is coming from Congress, and we just have to figure out a way to implement it in a way that makes sense.

Hans Buitendijk
This is not a comment indicating that this cannot be done, it is just that we have some practical things to work on.

Vaishali Patel
I totally understand, and that is where we would want your input: How long would it take, what are the practical considerations, what are the alternatives? That is the purpose of getting all this public feedback.

Hans Buitendijk
Thank you.

Vaishali Patel
I believe that is the last slide. We are having an hour and a half/hourlong webinar on May 11th on this Insights condition, and will go into each of the measures in a lot more detail. I am also happy to go into more detail on the measures, but I also wanted to give you guys time to also talk amongst yourselves, be able to answer questions, and I would have just taken up the entire time by going through the measures, so I can hand it back over to Hung or Steven, and we can take it in whatever direction you all want to take it.

Steven Lane
Hung, you have the gavel.

Hung S. Luu
Okay. I guess I would like to take a measure of our membership to see if there is room for discussion. I personally would like to hear more about the measures, but I will defer to the group if there are a lot of questions.

Steven Lane
Hans?

Hans Buitendijk
From that perspective, Hung, I think it would indeed be helpful just to have a little bit more about the measures. At the same point in time, just starting to dive into the definitions of numerators and denominators, are they easy, are they difficult, are they clear enough…? We already started to find as discussion started that in examples like what an encounter is, do we have a clear definition for that? In one way, you could say that USCDI has defined it, but for the purpose of the measures, that starts to get more intriguing and precise to make sure the right data is collected. So, one of the themes that we are starting to see, similarly with immunization, is what is included, what is not, and what is a failed submission. Is it just that you have to go a little bit deeper in an HL7 message that you did not receive an AC, or is that a

success? Can you assume that? Because not everybody is sending acknowledgements back, or depending on what it is, is a warning a success or almost a failure?

I think things like that are that over the next couple of weeks, we will see quite a few discussions on each of the measures to ask if the definition is clear enough. I am not sure that is a question for HITAC. I am not sure whether that is the level of specificity of comments that, as HITAC, we want to get into, other than the more general perspective that as we discover where they are, there need to generally be more precise definitions than what is currently provided in the proposed rule, given already the kind of questions that are being raised. What do you mean with this, or how do I measure that? Do I know for sure that I got it or that I am missing a part of the population? I think that is where the measure definition is going to go for many that are going to have to provide them.

Steven Lane
Thanks, Hans. Fil, you have your hand up too.

Fillipe Southerland
Good morning. Just a couple questions. I was curious if we anticipate a progression of additional reporting guidelines over time, and is there a process around how those would be added, similar to SVAP, or would that be subject to additional rulemaking?

Vaishali Patel
I think this proposed set of measures represents measures that, as I mentioned in the beginning, focus on interoperability. Congress also asked for measures in other areas, like usability, user-centered design, security, etc. I think those would be subject to rulemaking, similar to this. We would put out a proposed set of measures, get feedback, and then implement those measures, and we also want to see how this round of measures goes and learn from our experiences from it. I do not know if that answers the question or whether you were talking about, within these measures, if there will be some additional refinements.

Fillipe Southerland
I think it does. I was just curious if we would see a continued scope expansion of additional measures and what that would look like over time.

Vaishali Patel
I think it is really going to depend on our experience with this round, and also, I think we would envision potentially addressing some of the other topic areas for further refining, maybe these measures, delving into certain areas a bit more. So, it could go in a lot of different directions, depending on the experiences with this round.

Fillipe Southerland
Okay. And then, my other question was around the definition of a clinician in the earlier criteria slide. Is that clearly defined in the rule, and is that only physicians, or does that also include nursing staff, etc.

Vaishali Patel
I do not think we have defined “clinician” in the rule, but I will say that it is not meant to only include physicians. We have not defined it in the rule.

Steven Lane
In my experience, "clinician" includes pharmacists, nurses, etc., as opposed to the term "provider," which is more restrictive and defined in federal rulemaking.

Vaishali Patel
For the purpose of the minimum qualification thresholds, we based this on CMS Promoting Interoperability program data, so maybe a way to constrain it might be referring back to how CMS defines the eligible clinicians or providers within their programs. We based the thresholds on that data, so…

Steven Lane
I am guessing that reference might be in the text of the rule itself. I do not have it in front of me.

Vaishali Patel
The reference to the Promoting Interoperability program? That is definitely in the rule, and how we develop the thresholds and all of that is described in the rule, but I do not think we specifically define "clinician" other than referring back to the CMS program.

Fillipe Southerland
Okay. I will take a look at that and leave a comment in the spreadsheet as needed. That is certainly a meaningful definition for LTPAC sector. Okay, thank you.

Steven Lane
That makes a lot of sense, Fil. Vaishali, shall we scroll back up to the "What are the measures?" slide? The slides that are showing are numbered differently than the ones that were distributed. Maybe one more. Keep going. That one, yes. Hans, you were saying that you thought that there was additional feedback or questions about the measures themselves. As Vaishali said, these have been through an entire Task Force of HITAC to get to this point. There has been a lot of public input and feedback. Again, it does not surprise me that the EHR vendors subject to this condition might continue to have input on this, but was there something in particular, Hans, that you wanted to get at here?

Hans Buitendijk
At this time, just a general awareness and perspective. EHR vendors have been part of a number of those conversations as well, providing input to date, but as you progress, the clarity that is needed to really be specific about what it intends to include, going from the conceptual understanding of these measures into precisely how they are measured are currently what you would start to get into, and there is still some work to be done to make sure that everybody is on the same page, so those are the areas where I anticipate, given discussions to date, the questions that are starting to be raised as everybody is now looking at the specific numerators and denominators being defined, that is where I do expect a number of areas, like encounters and immunizations, where there will be a question of how exactly this is really measured.

So, the intent to concept is clear, but that is typically where discussions have occurred, and some may have gone deeper. Is the clarity there to say we have a ready-to-go, implementable rule, or is there work to be done on some specifications to make that more clear? That is where the focus will be in the conversations

that at least we will have. Whether that is sufficient for HITAC to include beyond general comment, I am not convinced, but that is where the level of review is focusing right now.

Vaishali Patel
Hans, to your point, I think we do have a definition in the rule that we have proposed based actually on what the HITAC had recommended back in 2021 related to encounters, but we also requested comment on that, and if the EHRA agrees on a definition of "encounter" that you all think is better and simpler, please share that. Similarly, with the immunizations, and I am just looking at my paper copy of the rule, we had some questions also related to defining "successful" and what should be included and excluded.

We made some suggestions in there with relays and things like that, for example, but we are also open to comments and suggestions on how to define, what should be included, what should be excluded, and how to best operationalize it, and what is practical to do. And so, a lot of the recommendations we took on that were based on the discussions that we had in the HITAC. AIR was involved. I think they had done a presentation at the HITAC, so we tried to take into consideration all the nuances, but there are a lot of nuances, so if there is something that is better, simpler, or easier to operationalize, we are totally open to it, and on the immunization front as well.

Hans Buitendijk
I appreciate that. For the HITAC, and Steven, this may be where we need to understand it, I do not think the intent within the HITAC is to delve into that level of detail, other than awareness that that is there, that there are considerations, and where we have examples, I am certainly going to drop them into the spreadsheet as the conversation for the measures progresses, but I do not think the intent is to look at it at that level of detail here.

Vaishali Patel
But I am glad you guys are looking at it at that level of detail because that is what we need and want, so I am glad EHRA and the developers are looking at it under a microscope and making sure that everything under the hood will work and make sense. Steven, Hung, we have about 30-odd minutes left. I am happy to go through a few of these measures in detail. I have the slides.

Steven Lane
Before we go there, Vaishali, can we go down three slides to year one/year two? I just wanted to talk a little bit about this. Again, I think there is value in ramping this up, starting smaller and growing over time. I was curious if any of the workgroup members had any thoughts about this split, the prioritization, or why certain things were included in year one versus year two. The other thing that I would raise, and Vaishali, you have heard me say this before, is that there are other efforts out there to look at reporting and metrics around EHRs. In addition to yours, the KLAS organization does a lot of EHR evaluations, there is reporting going on within the various health information exchange networks, within Epic, Care Everywhere, and CommonWell, etc., and then, I know within Carequality, there is work going on to improve metrics, especially related to exchange. I know there has been some dialogue between this effort that you have been helping to lead and those other efforts, and I was just wondering if you could say anything about touchpoints that may exist, opportunities to align this work with other EHR reporting or metric definition efforts in the industry.

Vaishali Patel
I think both those questions are great, first, the staging of the measures, and secondly, how this aligns with all these other measurement efforts, including our own. ONC has its own separate set of measurement efforts that we have had for quite a bit of time. So, I think I will take the second one first. With regards to existing measurement efforts, KLAS does wonderful work in assessing EHR developers and vendors and providing healthcare organizations with information they need to make purchasing decisions, and the goal of the Insights condition, I would say, is not really focused on comparing EHR developers, it is really about providing national-level insights into interoperability, providing some transparent reporting on interoperability, and complementing measures that exist, and we have really sought not to duplicate measures that exist, whether that is CMS, our own measures, KLAS, or other efforts, including Carequality and others. We have really sought to make this complementary and really dig into types of information that we cannot get from other sources.

So, if we even look at a good example, Steven, in Carequality, the National Health Information Exchanges, what they are able to capture is really on volume of documents that might be exchanged, for example, but what we are hoping to capture with this is not just looking at volume of exchange by different mechanisms, but also looking at that in relation to patient encounters, because, as many have noted, just looking at volume of exchange, it is very difficult to interpret the value of that. Okay, exchange is going up, but in relation to what? What is the context around it? And so, those are the kinds of things that we have tried to address with this proposed set of measures, really to complement what is existing out there, trying not to duplicate, and focusing on areas where there is not a good set of measures that exist. We have looked at KLAS's measures, which are more about… Based on conversations with healthcare organizations, ONC's current measurement is really survey-based measurement, largely, and then, leveraging the CMS program data, which is attestation-based data.

And so, we have really tried to, again, complement and try to take it in a different direction, and not duplicate what we can get through other sources. We have really tried to hone in on things that we have tried to measure through our survey-based measures, but it is just not really feasible or does not work, and we have sought to shine a light on areas that we can through other data sources. So, that is sort of how we ended up with these topic areas. In terms of the phasing, with the 21st Century CURES Act, ONC has prioritized and is implementing a number of efforts to promote individuals' access to their electronic health information, so that is an area that is important, and that also relates to the applications supported through certified health IT, understanding better the app ecosystem and to the extent to which it supports access to electronic health information is a priority, and then, the public health space, given the pandemic, was an area that we thought would be important, and with the CDC's modernization efforts, this is an area that we thought to prioritize in the first phase and then give more time to developers to implement the rest of the measures, which primarily relate to clinical care information exchange and standards conformance and adoption.

Steven Lane
Great. I do not see any other hands up at the moment.

Hung S. Luu
Vaishali, do you want to proceed with going over briefly some of the measures?

Vaishali Patel
Yes. Maybe what I could do is just go through a couple of the measures, and I will give you a preview of the May 11th webinar, and that might stimulate conversation. I will not use that full half hour to go through the rest of the measures, but maybe I could spend another 10 minutes or so going over one or two of the measures, and that might stimulate some questions and discussion. If we could stop sharing this, I will share my screen. All right, let's see. Let me just get this into the slideshow. All right, great.

I think before getting into the measures, I will just give an orientation, which is that the format of the measures that we have proposed varies. Most do contain numerators and denominators and have several numerators and denominators because we are hoping to generate multiple metrics based on that, but other measures are just simple lists of data. We also have a measure that is a count and an attestation as well, so they do vary. A number of the measures call for stratification, and I thought it would be worth going over what we mean by stratification. Stratification involves breaking out the numerator and denominator by particular category.

So, for example, I have taken an example from our survey data, a data brief where we have looked at hospitals' capabilities to enable patient electronic access to health information, and, as you can see here, on the leftmost is the aggregated number across all hospitals by year in 2018 and 2019, and in 2021, the percentage of hospitals that had the capabilities to enable patient electronic access to health information, and then it is broken out by small versus medium to large, and that allows us to not only look at the overall trend, but also better understand and peel the onion a little bit more as to how this varies in a particular category, in this case, by small versus medium-sized hospitals. I will just go to the next slide.

Steven Lane
I will just make one observation, Vaishali. When you show the data like this, it looks a lot like things that ONC has collected data on and published metrics on in the past. I think the real difference here is rather than just reaching out and asking people, we are now making this a condition of certification and an ongoing reporting so as to really increase the transparency of this and allow us to track these standardized metrics over time in a way that we have done a decent job of, but this will allow us to go much, much deeper, which I think is part of the appeal of this.

Vaishali Patel
Yes, and also, with this first measurement area, individual access to electronic health information, we do have a survey that we partner on with the National Cancer Institute on individuals self-reporting whether they have used a portal or not, but if you try to ask folks about third-party app technology and whether their app was provided by their healthcare provider/developer versus whether it was a third party, they cannot really answer those questions. We have tried, but it is really hard for individuals to distinguish between who is giving them the app, because it is branded in a lot of different ways, and so, therefore, what we proposed is to ask it through this program because it is important for us to really understand the different mechanisms individuals are using to access their electronic health information, especially given the emphasis that ONC has put on making apps widely available to enable patients to access their health information.

And so, this measure seeks to really differentiate the different methods individuals use that relate to different criteria that are in certified health IT to access their electronic health information, including third-party app technology, apps offered by health IT developers or healthcare provides, and patient portal technology, and

ultimately, what we are hoping is that the results will help refine and assess policies that have really sought to increase individuals' access to their electronic health information. Steven, to your point, this is something that we have sought to measure, but we have not been able to get patients to self-report on this in an accurate way, and so, therefore, we are proposing to do this through the Insights condition. This is sort of where the denominator and numerator that Hans was referring to in encounters comes in.

So, for the numerator, we have two numerators, one that relates to the number of unique individuals who have had an encounter and accessed their electronic health information at least once during the reporting period using one of the three types of methods that I just mentioned, and then, the second numerator is the number of unique individuals who accessed their electronic health information regardless of whether they had an encounter during the reporting period using at least one of the three types of methods, and the reason we distinguish between "encounter" versus not having an encounter is while an encounter can trigger an individual to access their electronic health information, whether that is to look at a test result or some other information based on the encounter they had, there are also instances of needing to access one's electronic health information without having to have it be triggered by encounter, for example, filling out childhood immunization reports for summer camp. And so, we wanted to be able to include these various types of uses, one that is encounter-based and one that is not necessarily based on an encounter.

And then, we have three denominators. The first denominator is the number of unique individuals who had an encounter during the reporting period, the second is the number of unique individuals who used at least one of the three methods to access their electronic health information who had an encounter during the reporting period, and then, the third is the number of unique individuals who used at least one of the three types of methods to access their electronic health information during the reporting period regardless of whether the individual had an encounter or not. We are listing this numerous number of denominators and numerators because there is a variety of metrics that we can report that can be derived from the data, so, looking at the percentage of individuals with an encounter who access their electronic health information by at least one type of method overall, and also the percentage of individuals with an encounter who access their electronic health information by specific types of method, so, the percentage who accessed it via portal versus the percentage who accessed it via third-party app, for example.

I will not go through the entire list here, but the idea here is that we can generate a number of different metrics and then monitor it over time, and the example I have here, related to the stratification, is just, again, to explain the stratification, about looking at the overall, across all three methods, but also breaking it out by percentage of individuals or number of individuals who use third-party apps versus apps offered by their healthcare provider or developer, or portal technology separately. I will pause there to see…

Steven Lane
Vaishali, I do not see any other hands up, so I will just go ahead and jump in. I do note that there is this year one/year two, there is this sense of progression in how this is being laid out, but I anticipate that as we get this up and running, there will be learnings, observations, concerns, and challenges that come up where we may want to further evolve the methodology going forward. Will that require an additional rule to define what this looks like in year three, four, etc., or is the way this is crafted set up so that it can evolve without further rulemaking?

Vaishali Patel

I would probably defer to our regulatory affairs division. I am the PhD researcher in the room, not the lawyer to answer that question. I do not know enough about the regulatory process to get into that, but one thing I will say is that if we are proposing new measures, then I think that would probably go through future rulemaking. If it is tweaking a definition or something, gosh, I hope we do not have to go through rulemaking to do that, but I think that is a good question, and we can probably get back to you on that point, Steven. I think it is a great question, and I do not want to definitely answer that because that is not my area of expertise.

Steven Lane
Sure. Hans, your hand is up.

Hans Buitendijk
I am curious about the following. As these denominators and numerators are being further expressed, you start to look at the rules. One of the questions that goes back to a level of specification is are there any plans to define these measures using FHIR CQL? The reason why I am asking that is USCDI ties into FHIR constructs in support of that. CQL is being used in FHIR measure reports, or actually, in FHIR measure, to help specify measures, and by going into that level of formalism on defining in them beyond the English in the **[inaudible] [01:15:54]** the level of clarity on exactly what you mean, and therefore how people are mapping it to their environments, might help.

Whether we agree or disagree on some of the things, it is actually easier in some ways to identify and have the conversation around "Okay, if this is what you mean, it works or it does not," or whatever the conversation is going to be, but it might help to use a more formal language and statement that is starting to tie in with the language that is also being used to expose the data in other manners. So, that is a consideration that we might have in the HITAC, but I am curious whether that thought is already there to do that.

Vaishali Patel
No, the thought is not already there, so I am glad you are suggesting it, Hans, and we can follow up with you offline about it.

Hans Buitendijk
It seems a very natural thing to do. It does not mean that we need to automatically ingest them or not, but CMS is going on that path, using CQL for its measures and quality reporting. Is this another area where it would help? It starts to align us on what the intent is, and then we can have a much more precise discussion to make sure that everybody is understanding it, can do it, not do it, or whatever that might lead to.

Vaishali Patel
I hear the point that you are making, just going a level deeper in mapping stuff so that it is even clearer what we are asking for. So, let's follow up offline about that.

Hung S. Luu
Vaishali, we do have a comment.

Steven Lane

Sorry, you were going to do the same thing, Hung. Go ahead.

Hung S. Luu
Okay. We do have a comment in the chat from Sandeep. "Will stratification variables differ or expand for different measures, not just, say, structural or operational variables?" The example they provide is that it could be really helpful for health equity to stratify measures of individual or patient access by demographic element such as race, ethnicity, sexual orientation, gender, or disability.

Vaishali Patel
Yes. So, when we initially proposed this, we had proposed breaking it out by some demographic characteristics, including race/ethnicity. However, we got feedback from the HITAC that that level of stratification would be too difficult to implement at this stage, and so, we decided to not move forward with that based on the recommendation of the HITAC from 2021. We are definitely interested in that direction, and that is why we had originally proposed it. I think we do need to take this in steps and try to proceed in a way that would allow us to first get this program up and running and make sure the first set of measures that we have is reasonable, we can report on those, and then we peel the onion subsequently to look at those other layers. I am hopeful also with some of the work that is being done in areas to standardize the demographic data, social determinants of health, social needs, and things like that that as that work proceeds and we have more standardized data within EHRs, that will allow for reporting of these data by those types of stratifications in a way that might not be feasible right now.

Steven Lane
I remember that discussion, Vaishali.

Vaishali Patel
I wish we could go there now, but based on the recommendations that we got from the HITAC, we determined that we are not quite there yet.

Steven Lane
We do have public comment scheduled here in four more minutes. Are there other questions for Vaishali, or should we go to public comment a little early?

Vaishali Patel
I can stop sharing. Again, I have a whole bunch of other metrics, but I think you guys get the idea, and if you are interested in delving into the measures, on May 11th, we are having a webinar, so stay tuned for that if you want more of what I just went through with regards to that one measure.

Steven Lane
I know there is a link on the web to sign up for that webinar. I have not taken the time to go find it and paste it in, but maybe one of the ONC folks can pop that in so everyone has that handy. That would be nice.

Vaishali Patel
I will see if I can locate it and put it into the chat or something.

Steven Lane

I just did not want to get distracted from the hand raising. Well, Mike, do you want to go ahead and kick off the public comment a little early here?

Public Comment (01:22:07)

Michael Berry
Absolutely, thank you. There is a little bit of an echo, so hopefully you can hear me. We are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if any members of the public would like to make a comment. Okay, we will keep an eye on that. I am not seeing any hands raised at the moment, so I will turn it back to Hung and our cochairs. Thank you.

Hung S. Luu
Vaishali, I really appreciate your input today to help level-set and bring everybody up to speed on the measures and initiatives. I think that is very helpful in terms of giving everybody a good baseline to start from, and I think we will definitely be delving much deeper in the following weeks, but thank you so much for your presentation.

Vaishali Patel
You are welcome, and I also just put the link into the chat for those that want to register for the session on Thursday, May 11th, which is at 1:00 Eastern Time, on the Insights condition. Please join us.

Steven Lane
I also want to thank you, Vaishali, for coming, and Hung for helping to lead this workgroup, and the ONC team for putting together this very nice new slide that outlines precisely what this workgroup is going to be focused on for each of its subsequent meetings. As you can see, on the 11th, we will be digging into the plan to update the standard from USCDI V.1 to V.3, as well as the C-CDA companion guide updates. On the 17th, there is going to be an update from Task Force cochairs and Dr. Luu to the HITAC. Then, we will meet again on the 18th, continuing to look at standardized APIs at US CORE, the advancement to STU-5.0.1, and then we will be digging into some of the requests for information on the 25th. This workgroup, I must say, is a little lighter than the others, the Tuesday and the Wednesday workgroups, which is kind of a blessing as the week rolls on, so, again, I really want to thank, along with Hung and Ike, everyone for your participation today. Did anyone have anything they wanted to add? I still do not see any hands raised in the public comment. Anything else we need to do, or can we finish a few minutes early?

Hans Buitendijk
I do not have any further comments today, but surely a couple of comments will arrive in the spreadsheet as we dive deeper.

Vaishali Patel
I am waiting for those comments, Hans.

Steven Eichner

I was just going to add my gratitude to the presenters and everyone for participating in today's meeting, and I look forward to seeing comments in spreadsheets in future discussions.

Steven Lane
Actually, Excel team, can you pop us back over to the spreadsheet, since we do have a couple of minutes here? There we go. So, again, Hans, you are up to four recommendations here. I really appreciate that. You were characterizing these as placeholders, correct? So, do you have an intention to run this by some of your EHRA friends and come back with more specific recommendations?

Hans Buitendijk
Most definitely. These are the ones that have come up so far in discussions, and conclusions have not been reached yet. Everybody is at the start of that, but as they come about, I am going to add this up and clarify them further.

Steven Lane
So, we will put a placeholder in our workgroup planning to come back to review those once you have more specifics to share, correct?

Hans Buitendijk
Correct.

Steven Lane
Great. All right. Mark Savage did provide a suggestion in the chat that we should reconsider, the question of stratifying the variables given changes in the industry over the couple of years since this was taken up by HITAC, and it is a good point, Mark. I guess I am not quite sure whether the Task Force has much authority there. Clearly, a lot of work has gone into putting this together as it is, but certainly, that could be a suggestion. Do any workgroup members want to grab onto that and run with it? What do people think? Do I hear any enthusiasm for that suggestion? Again, I do recall the discussion we had before, and to Vaishali's point, this is a lot to get in to start with. I do not know that the technology and the burden related to stratification based on sociodemographic variables has really changed all that much, although, clearly, there is a strong interest in looking at that. Clem's hand is up. Sorry I did not see it. I am looking at the wrong part of the list. Clem, your hand is up.

Clem McDonald
I have a question about Insights condition. That is two nouns, so I just do not quite get it.

Steven Lane
It is called the Insights condition, that is to say, it is the condition of maintenance and certification related to metrics or insights on the functioning of the certified health IT.

Clem McDonald
Okay, thank you.

Steven Lane

“Insights” is being used as an adjective because it is that particular condition in this case. A formal name, perhaps. All right, well, that brings us right to the hour. Thank you, everyone. Thank you, Hung, for helping with the leadership here. We will see all of you next week.

Vaishali Patel
Thanks.

Adjourn (01:29:45)